Non-Self-Administered
Prior Authorization Approval Criteria

Effective Date: 01/01/2021

Standard Non-Self-Administered Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
NON-SELF-ADMINISTERED
PRIOR AUTHORIZATION GUIDELINES

1. **Formulary Agents**
   Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per MedImpact Pharmacy and Therapeutics Committee guidelines, when the member presents a prescription to a network pharmacy. Each request will be reviewed on individual patient need. If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
2. **Non-Formulary Agents**
   Any product not found in the Formulary listing, or any Formulary updates published by MedImpact, shall be considered a Non-Formulary drug. Coverage for non-formulary agents may be applied for in advance. When a member gives a prescription order for a non-formulary drug to a pharmacist, the pharmacist will evaluate the patient's drug history and contact the physician to determine if there is a legitimate medical need for a non-formulary drug. Each request will be reviewed on individual patient need. The following basic criteria are used:
   a. The use of Formulary Drug Products is contraindicated in the patient.
   b. The patient has failed an appropriate trial of Formulary or related agents.
   c. The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
   d. The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.

   If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
3. **Obtaining Coverage**
   Coverage may be obtained by:
   a. Faxing a completed **Prior Authorization Request** to DHMP at (303) 602-2081.
   b. Contacting DHMP Pharmacy Department at (303) 602-2070 and providing all necessary information requested.

   Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.

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ABATACEPT - IV (NSA)

Generic	Brand			
ABATACEPT/MALTOSE	ORENCIA - IV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT - IV (Orencia - IV)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz immediate/extended release

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred immunomudulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel **AND** Humira

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ABATACEPT - IV (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz immediate/extended release, Otezla

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **ABATACEPT - IV (ORENCIA - IV)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 04/01/20

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ADO-TRASTUZUMAB EMTANSINE (NSA)

Generic	Brand			
ADO-TRASTUZUMAB EMTANSINE	KADCYLA			

GUIDELINES FOR USE

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:

A. You have metastatic breast cancer (cancer has spread to other parts of body) or early breast cancer
B. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have previously received trastuzumab and a taxane (class of cancer medication), separately or in combination
   3. You have received prior therapy for metastatic disease (disease has spread) **OR** developed disease recurrence (disease returns) during or within six months of completing adjuvant (add-on) therapy
C. **If you have early breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment (disease is still present after using certain types of cancer drugs)

Commercial Effective: 05/01/20

AFAMELANOTIDE (NSA)

Generic	Brand				
AFAMELANOTIDE	SCENESSE				

GUIDELINES FOR USE

Our guideline named **AFAMELANOTIDE (Scenesse)** requires the following rule(s) be met for approval:

A. You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
B. You are 18 years of age or older
C. You have a history of phototoxic reactions (damage to the skin)
D. The requested medication will be used to increase pain free light exposure

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Commercial Effective: 07/01/20

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AFLIBERCEPT (NSA)

Generic	Brand			
AFLIBERCEPT	EYLEA			

GUIDELINES FOR USE

Our guideline named **AFLIBERCEPT (Eylea)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Neovascular (wet) age-related macular degeneration (eye disease that causes vision loss)
   2. Macular edema following retinal vein occlusion (blood vessel in the retina is blocked by blood clot)
   3. Diabetic macular edema (build up of fluid in the part of the retina)
   4. Diabetic retinopathy with diabetic macular edema (eye nerve damage due to diabetes)

B. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina (back part inside the eye) specialist

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Commercial Effective: 05/01/20

AGALSIDASE BETA (NSA)

Generic	Brand			
AGALSIDASE BETA	FABRAZYME			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:

A. You have Fabry disease (inherited disorder that causes build up of a type of fat)
B. You are 8 years of age or older
C. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist physician in genetics or inherited metabolic disorders
D. You are NOT concurrently using an alpha-galactosidase A (a-Gal A- a type of protein) pharmacological chaperone (a molecule that helps correct other bad proteins) such as migalastat
E. You are symptomatic **OR** have evidence of injury from GL-3 (Globotriaosylceramide – a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury would include decreased Glomerular filtration rate (GFR- a test to see how well kidneys function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
F. You meet ONE of the following:
    1. Female patients: Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. Male patients: Confirmation of Fabry disease via enzyme assay (type of lab test) showing you do not have enough alpha galactosidase A (a-Gal –A), OR genetic test documenting galactosidase alpha gene (GLA) mutation

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AGALSIDASE BETA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal approval:

A. You have a diagnosis of Fabry disease (inherited disorder that causes build up of a type of fat)
B. You have demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regard to at least ONE of the following:
    1. Symptoms which includes pain, hypohidrosis/anhidrosis (less sweating or no sweating), exercise intolerance, GI (gastrointestinal) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears)/hearing loss
    2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (test to measure bone density), renal (kidney) ultrasound
    3. Laboratory or histological (viewed by microscope) testing such as GL-3 (Globotriaosylceramide – a type of fat) in plasma/urine, renal biopsy

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Commercial Effective: 05/01/20

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ALEMTUZUMAB (NSA)

Generic	Brand			
ALEMTUZUMAB	LEMTRADA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried TWO drugs that have been FDA (Food and Drug Administration) approved for the treatment of relapsing forms of multiple sclerosis (MS) **(Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)

RENEWAL CRITERIA

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: an illness where immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. At least 12 months have passed since you received the most recent course of Lemtrada

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ALGLUCOSIDASE ALFA

Generic	Brand			
ALGLUCOSIDASE ALFA	LUMIZYME			

GUIDELINES FOR USE

Our guideline named **ALGLUCOSIDASE ALFA (Lumizyme)** requires that the following rules be met:

A. You have Pompe's disease (an inherited condition where complex sugar (glycogen) builds up in your body's cells because your body cannot make a type of enzyme called acid alpha-glucosidase) for approval

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Commercial Effective: 05/01/20

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ASPARAGINASE (NSA)

Generic	Brand			
ASPARAGINASE (ERWINIA CHRYSAN)	ERWINAZE			
PEGASPARGASE	ONCASPAR			

GUIDELINES FOR USE

Our guideline named **ASPARAGINASE (Erwinaze, Oncaspar)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acute lymphoblastic leukemia (ALL: type of blood and bone marrow cancer)
B. The requested medication will be used as a part of a chemotherapeutic treatment plan with multiple drugs
C. **If you are requesting Oncaspar, approval also requires ONE of the following:**
   - Oncaspar will be used as a first-line therapy
   - You have hypersensitivity to native forms of L-asparaginase (you are allergic to natural forms of a type of enzyme/protein)
D. **If you are requesting Erwinaze, approval also requires:**
   1. You have developed a hypersensitivity to a E. Coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)

Commercial Effective: 07/01/20

ATEZOLIZUMAB (NSA)

Generic	Brand			
ATEZOLIZUMAB	TECENTRIQ			

GUIDELINES FOR USE

Our guideline named **ATEZOLIZUMAB (Tecentriq)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (cancer that occurs in the urinary system)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Unresectable locally advanced/metastatic triple-negative breast cancer (breast cancer that does not have estrogen receptor, progesterone receptor, or human epidermal growth factor receptor 2 [HER-2) protein, and cannot be removed by surgery or has spread to other parts of the body)
   4. Extensive-stage small cell lung cancer (ES-SCLC: type of lung cancer)
   5. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
   6. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)

B. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You are not eligible to receive cisplatin-containing chemotherapy **AND** has a tumor that expresses PD-L1 (Programmed death-ligand 1 sustained tumor-infiltrating immune cells [IC] covering 5% or more of the tumor area), as determined by a Food and Drug Administration approved test
      b. You are not eligible to receive any platinum containing chemotherapy regardless of PD-L1 status
      c. Your disease gets worse on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
      d. Your disease gets worse within 12 months of neoadjuvant (treatment given as a first step to shrink a tumor before the main treatment) or adjuvant treatment (therapy applied after initial treatment for cancer) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic non-squamous non-small cell lung cancer (NSq NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. You do not have EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) genomic tumor abnormalities
   3. The requested medication will be given in combination with ONE of the following regimens as a first-line treatment:
      a. Bevacizumab, paclitaxel, and carboplatin, OR
      b. Paclitaxel protein-bound and carboplatin

D. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as a single-agent
   3. You meet ONE of the following:
      a. You do not have an EGFR (*epidermal growth factor receptor- a type of protein)* or ALK *(anaplastic lymphoma kinase- a type of protein)* mutation AND your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
      b. You do not have an EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) mutation, the requested medication will be used as first line treatment, AND you have tumors that have high PD-L1 (programmed death-ligand 1: type of protein) expression (PD-L1 stained 50% or more of tumor cells, or PD-L1 stained tumor infiltrating immune cells covering 10% or more of the tumor area) as determined by an Food and Drug Administration (FDA) approved test
      c. You have an ALK mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) **AND** ALK-directed therapy [such as Xalkori (crizotinib), Zykadia (ceritinib)]
      d. You have an EGFR mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) **AND** EGFR-directed therapy [such as Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

E. **If you have unresectable locally advanced or metastatic triple-negative breast cancer (TNBC), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with paclitaxel protein-bound
   3. Your tumor expresses PD-L1 (programmed death ligand 1 stained tumor-infiltrating immune cells [IC] of any intensity covering 1% or more of the tumor area), as determined by a Food and Drug Administration (FDA) approved test

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ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

F. **If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with carboplatin and etoposide as a first-line treatment

G. **If you have unresectable or metastatic hepatocellular carcinoma (HCC), approval also requires:**
   1. You have not previously been treated with systemic therapy
   2. The requested medication will be used in combination with bevacizumab

H. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. The requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
   2. You have a BRAF V600 mutation (type of gene mutation)

Commercial Effective: 09/07/20

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AVELUMAB (NSA)

Generic	Brand			
AVELUMAB	BAVENCIO			

GUIDELINES FOR USE

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
   2. Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)

B. **If you have metastatic Merkel Cell Carcinoma, approval also requires:**
   1. You are 12 years of age or older

C. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
   1. Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   3. Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxalipatin
      a. The requested medication will be used as first-line maintenance treatment

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. The requested medication will be used as first-line treatment
   2. The requested medication will be used in combination with axitinib

Commercial Effective: 10/01/20

AXICABTAGENE CILOLEUCEL (NSA)

Generic	Brand			
AXICABTAGENE CILOLEUCEL	YESCARTA			

GUIDELINES FOR USE

Our guideline named **AXICABTAGENE CILOLEUCEL (Yescarta)** requires the following rule(s) be met for approval:

A. You have a diagnosis of ANY of the following types of immune system cancers:
   1. Diffuse large B-cell lymphoma not otherwise specified
   2. Primary mediastinal large B-cell lymphoma
   3. High grade B-cell lymphoma (such as double-hit or triple-hit lymphoma)
   4. Diffuse large B-cell lymphoma arising from follicular lymphoma [such as transformed follicular lymphoma (TFL)]
B. You are 18 years of age or older
C. Therapy is prescribed by a Yescarta-certified hematologist (blood doctor) or oncologist (cancer doctor)
D. Yescarta will be administered at a treatment center that is certified to administer Yescarta
E. You have not previously tried Yescarta
F. You meet ONE of the following criteria:
   1. Your disease has worsened or relapsed (worsens after improving) after stem cell transplantation (SCT)
   2. Your disease has worsened or relapsed (worsens after improving) after two or more lines of systemic therapy (treatment that spreads through the bloodstream)

Yescarta will not be approved for ANY of the following indications:

A. Primary Central Nervous System Lymphoma (PCNSL)
B. Mantle Cell Lymphoma (MCL)
C. Burkitt's lymphoma

Commercial Effective: 07/01/20

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BELANTAMAB MAFODOTIN-BLMF (NSA)

Generic	Brand				
BELANTAMAB MAFODOTIN-BLMF	BLENREP				

GUIDELINES FOR USE

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (type of blood cancer that has returned or did not respond to previous treatment)
B. You are 18 years of age or older
C. You have received at least four prior therapies, including an anti-CD38 monoclonal antibody (such as daratumumab, isatuximab), a proteasome inhibitor (such as ixazomib, carfilzomib), and an immunomodulatory agent (such as lenalidomide, pomalidomide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

Commercial Effective: 01/01/21

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BELIMUMAB (NSA)

Generic	Brand			
BELIMUMAB	BENLYSTA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BELIMUMAB (Benlysta IV)** requires the following rule(s) be met for approval:

A. You have autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
B. You are 5 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
D. You are currently using corticosteroids, antimalarials (drug that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

RENEWAL CRITERIA

Our guideline named **BELIMUMAB (Benlysta IV)** requires the following rule(s) be met for renewal:

A. You have autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
B. You had clinical improvement while on Benlysta

Commercial Effective: 01/01/21

BELINOSTAT (NSA)

Generic	Brand			
BELINOSTAT	BELEODAQ			

GUIDELINES FOR USE

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule be met for approval:

A. You have a diagnosis of relapsed or refractory (your condition has gotten worse after improving) peripheral T-cell lymphoma (PTCL; cancer that affects a type of immune system cells)
B. You are 18 years of age or older

Commercial Effective: 07/01/20

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BENRALIZUMAB

Generic	Brand			
BENRALIZUMAB	FASENRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You are 12 years of age or older
C. Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. Fasenra will be used as add-on maintenance treatment
E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
F. You had a prior therapy with medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
G. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)
H. You are NOT receiving concurrent treatment with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Cinqair)

RENEWAL CRITERIA

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

BEVACIZUMAB (NSA)

Generic	Brand			
BEVACIZUMAB	AVASTIN			

GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Platinum-resistant recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-sensitive recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Stage III or IV epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
      b. Your disease has progressed (gotten worse) on a first-line Avastin product-containing regimen AND the requested medication is being used in combination with fluoropyrimidine- irinotecan- (for example FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CapeOx) based chemotherapy as a second-line treatment
   2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment
   2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

(Criteria continued on next page)

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BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older
   2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. The requested medication is being used in combination with interferon-alfa
   2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

F. **If you have any ophthalmic indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb, approval also requires:**
   1. The requested medication is prescribed by an ophthalmologist (eye doctor) and/or retina specialist (a special type of eye doctor)

G. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
   2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. The requested medication is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens

I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
   2. The requested medication is being used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

J. **If you have Stage III or IV epithelial ovarian/fallopian tube or primary peritoneal cancer, approval also requires:**
   1. The requested medication is being used following initial surgical resection (removal)
   2. The requested medication is being used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. The requested medication will be used in combination with atezolizumab
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

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BEVACIZUMAB-AWWB (NSA)

Generic	Brand			
BEVACIZUMAB-AWWB	MVASI			

GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/ returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   3. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   4. The requested medication is being used in combination with fluoropyrimidine-irinotecan (for example FOLFIRI) or fluoropyrimidine-oxaliplatin (for example FOLFOX, CAPeOX) based chemotherapy as a second-line treatment AND your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   3. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment

D. **If you have recurrent glioblastoma, approval also requires**
   3. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   3. The requested medication is being used in combination with interferon-alfa

F. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

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BEVACIZUMAB-BVZR (NSA)

Generic	Brand			
BEVACIZUMAB-BVZR	ZIRABEV			

GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses: metastatic colorectal cancer (mCRC: colon cancer that has spread in the body); unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned); recurrent glioblastoma (GBM: type of brain tumor); metastatic renal cell carcinoma (mRCC: type of kidney cancer); persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   2. The requested medication is being used in combination with fluoropyrimidine- irinotecan- (for example, FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example, FOLFOX, CAPeOX) based chemotherapy as a second-line treatment AND your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. The requested medication is being used in combination with interferon-alfa

F. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

Commercial Effective: 01/13/20

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BLINATUMOMAB (NSA)

Generic	Brand			
BLINATUMOMAB	BLINCYTO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
   2. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. **If you have minimal residual disease (MRD) - positive B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:**
   - You are in first or second complete remission (no symptoms or signs of *disease)*
   - You have minimal residual disease (small numbers cancer cells that remain in you after treatment) greater than or equal to 0.1%

RENEWAL CRITERIA

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   a. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
   b. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. **If you have relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
   1. You have achieved complete remission (CR) (no symptoms or signs of *disease*) or CR with partial recovery of peripheral blood counts (CPh) after two cycles of induction (starter) treatment (cycle 1 and 2) with Blincyto
   2. You have NOT received allogeneic hematopoietic stem-cell transplant (stem cells from a genetically similar, but not identical, donor)

(Renewal critera continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
   1. You have no detectable level of minimal residual disease (small numbers cancer cells that remain in you after treatment) g) within one cycle of Blincyto treatment
   2. You are relapse-free (your disease does not come back after being gone) which includes hematological (relating to blood) or extramedullary relapse, or secondary leukemia (cancer)

Commercial Effective: 07/01/20

BORTEZOMIB (NSA)

Generic	Brand			
BORTEZOMIB	VELCADE, BORTEZOMIB			

GUIDELINES FOR USE

Our guideline named **BORTEZOMIB (Velcade)** requires the following rule(s) be met for approval:

A. You have a diagnosis of multiple myeloma (plasma cell cancer) OR mantle cell lymphoma (white blood cell cancer)
B. **If you are requesting Bortezomib (manufactured by Fresenius Kabi), approval also requires:**
   1. You have previously received at least one therapy for mantle cell lymphoma (white blood cell cancer).

Commercial Effective: 07/01/20

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BOTULINUM NEUROTOXIN (NSA)

Generic	Brand			
ONABOTULINUM TOXIN A	BOTOX			
ABOBOTULINUM TOXIN A	DYSPORT			
RIMABOTULINUM TOXIN B	MYOBLOC			
INCOBOTULINUM TOXIN A	XEOMIN			

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

BOTOX

Our guideline named **BOTULINUM NEUROTOXIN (Botox)** requires the following rule(s) be met for approval:

A. You are using the requested medication for ONE of the following non-cosmetic (not for appearance) conditions:
   1. Overactive bladder (OAB)
   2. Urinary incontinence (uncontrolled leakage of urine)
   3. Prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer)
   4. Spasticity (stiffness or tightness of your muscles)
   5. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   6. Severe axillary hyperhidrosis (excessive underarm sweating)
   7. Blepharospasm (involuntary forcible closure of the eyelid); or treatment of strabismus (cross-eyed).

B. **For the treatment of overactive bladder (OAB), approval also requires:**
   1. You are 18 years of age or older.
   2. You previously tried an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot (contraindication)

(Botox criteria continued on next page)

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GUIDELINES FOR USE - BOTOX (CONTINUED)

C. **For the treatment of urinary incontinence, approval also requires:**
   1. You are 18 years of age or older.
   2. You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition such as: spinal cord injury (SCI) or multiple sclerosis (MS).
   3. You previously tried an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot

D. **For the prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer), approval also requires:**
   1. You are 18 years of age or older.
   2. You previously tried any **TWO** (2) of the following migraine prevention treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol.

E. **For the treatment of cervical dystonia and severe axillary hyperhidrosis, approval also requires:**
   1. You are 18 years of age or older.

F. **For the treatment of spasticity, approval also requires:**
   1. You are 2 years of age or older.

G. **For the treatment of blepharospasm and strabismus, approval also requires:**
   1. You are 12 years of age or older.

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

DYSPORT

Our guideline named **BOTULINUM NEUROTOXIN (Dysport)** requires you have ONE of the following non-cosmetic (not for appearance) diagnoses and meet the associated rule(s) for approval:

A. You have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) AND you are 18 years of age or older
B. You have spasticity (stiffness or tightness of your muscles) AND you are 2 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE (CONTINUED)

MYOBLOC

Our guideline named **BOTULINUM NEUROTOXIN (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   2. Chronic sialorrhea (drooling or excessive salivation)

B. You are 18 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

XEOMIN

Our guideline named **BOTULINUM NEUROTOXIN (Xeomin)** requires the following rules be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Chronic sialorrhea (drooling or excessive salivation)
   2. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   3. Blepharospasm (involuntary forcible closure of the eyelid)
   4. Upper limb spasticity (stiffness or tightness of your muscles)

B. **For the treatment of chronic sialorrhea, cervical dystonia or blepharospasm, approval also requires:**
   1. You are 18 years of age or older

C. **For the treatment of upper limb spasticity, approval also requires ONE of the following:**
   1. You are 18 years of age or older
   2. You are 2 to 17 years of age and do not have spasticity caused by cerebral palsy (an illness that affects movement, muscle tone or posture)

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

BRENTUXIMAB (NSA)

Generic	Brand			
BRENTUXIMAB VEDOTIN	ADCETRIS			

GUIDELINES FOR USE

Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Classical Hodgkin lymphoma (cancer with large, abnormal cells in immune system)
   2. Systemic anaplastic large cell lymphoma (type of non-Hodgkin lymphoma that affects immune system), or other CD30-expressing peripheral T-cell lymphomas (type of immune system cancer)
   3. Primary cutaneous anaplastic large cell lymphoma (cancer that present in the skin affecting immune system cells), or CD30-expressing mycosis fungoides (rare form of immune system cancer affecting the skin)
   4. Stage III or IV classical Hodgkin lymphoma (cHL)

B. You are 18 years of age or older

C. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
   1. You have failed autologous hematopoietic stem cell transplant (auto-HSCT; transplant cells are from your own body)
   2. You have failed at least two multi-agent chemotherapy regimens, which include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])
   3. You are considered high risk of relapse or disease progression (disease comes back or gets worse) after having auto-HSCT AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy

D. **If you have relapsed systemic anaplastic large cell lymphoma (ALCL), approval also requires:**
   1. You have failed at least one multi-agent chemotherapy regimen, which includes but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone]

E. **If you have systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, approval also requires:**
   1. You have not received previous treatment for sALCL or other CD30-expressing PTCL
   2. The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

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BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

F. **If you have primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval also requires:**
   1. You have received prior systemic therapy (therapy that spreads throughout the body in the blood)

G. **If you have Stage III or IV classical Hodgkin lymphoma (cHL), approval also requires:**
   1. The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
   2. You have not received previous treatment for Stage III or IV classical Hodgkin Lymphoma (cHL)

Commercial Effective: 07/01/20

BREXUCABTAGENE AUTOLEUCEL (NSA)

Generic	Brand				Exception/Other
BREXUCABTAGENE AUTOLEUCEL	TECARTUS				

GUIDELINES FOR USE

Our guideline named **BREXUCABTAGENE AUTOLEUCEL (Tecartus)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer that has returned or does not respond to treatment)

B. You are 18 years of age or older

Commercial Effective: 01/01/21

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BUPRENORPHINE EXTENDED-RELEASE (NSA)

Generic	Brand			
BUPRENORPHINE EXTENDED-RELEASE	SUBLOCADE			

GUIDELINES FOR USE

Our guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires the following rule(s) be met for approval:

A. You have a diagnosis of moderate to severe opioid use disorder (mis-use of a type of pain medication)
B. You previously started treatment with a transmucosal (medication that enters body through a mucous layer like those in the mouth) buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

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Commercial Effective: 07/01/20

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BROLUCIZUMAB-DBLL (NSA)

Generic	Brand			
BROLUCIZUMAB-DBLL	BEOVU			

GUIDELINES FOR USE

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:

1. You have a diagnosis of neovascular (wet) age-related macular degeneration (AMD: abnormal blood vessels grow in the eye which bleed and leak fluid, causing blurry vision)
2. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retina (area within the eye) specialist

Commercial Effective: 07/01/20

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BUPRENORPHINE IMPLANT (NSA)

Generic	Brand			
BUPRENORPHINE	PROBUPHINE			

GUIDELINES FOR USE

Our guideline named **BUPRENORPHINE IMPLANT (Probuphine)** requires the following rule(s) be met for approval:

A. You have NOT previously received ONE Probuphine treatment course in EACH arm (for a maximum of TWO 6-month treatment courses)
B. You have achieved and continued to have clinical stability on low to moderate doses of transmucosal buprenorphine (such as Subutex, Suboxone, Bunavail, or Zubsolv) defined as 8 mg per day or less of Subutex/Suboxone or a transmucosal buprenorphine equivalent for a minimum of 3 months without any need for additional dosing or adjustments
C. The requested medication is prescribed by a physician certified with the Probuphine REMS (Risk Evaluation and Mitigation Strategy) program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com

Commercial Effective: 07/01/20

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BUROSUMAB-TWZA (NSA)

Generic	Brand			
BUROSUMAB-TWZA	CRYSVITA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BUROSUMAB (Crysvita)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
   2. Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia (XLH), approval also requires:**
   1. Your diagnosis is confirmed by ONE of the following:
      a. You have XLH symptoms such as osteomalacia (bone softening), excessive fractures, bowed legs, impaired growth and ONE of the following:
         i. If you are less than 18 years of age, your serum phosphate level is less than 3.2 mg/dL with normal vitamin D levels
         ii. If you are 18 years of age or older, your serum phosphate level is less than 2.5 mg/dL with normal vitamin D levels
         iii. You have more than normal amount of FGF23 protein on assay (type of lab analysis)
         iv. You have a family history of X-linked hypophosphatemia
      b. You have a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by a genotyping (type of test)
   2. You are 6 months of age or older
   3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformities), or medical geneticist
   4. You will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
   5. You meet ONE of the following:
      a. You previously had a trial of or failure to phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
      b. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

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BUROSUMAB-TWZA (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO), approval also requires:**
   1. Your diagnosis is confirmed by the following:
      a. You have symptoms of tumor-induced osteomalacia (such as osteomalacia [softening of the bones], excessive fractures, muscle weakness, fatigue, bone pain)
   2. You are 2 years of age or older
   3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformitis), or medical geneticist
   4. Your tumors cannot be curatively resected (surgically removed) or localized
   5. You have stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
   6. You meet ONE of the following:
      - You previously had a trial of or failure to phosphate/vitamin D analog therapy
      - Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

RENEWAL CRITERIA

Our guideline named **BUROSUMAB (Crysvita)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. X-linked hypophosphatemia (XLH; inherited disorder with low phosphate blood levels)
   2. Fibroblast growth factor 23 (FGF23) -related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia (XLH), renewal also requires:**
   1. You have achieved normal blood phosphate levels as defined by the reference range for your age

C. **If you have Fibroblast growth factor 23 (FGF23) - related hypophosphatemia in tumor-induced osteomalacia, renewal also requires:**
   1. You have achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

CALASPARGASE PEGOL (NSA)

Generic	Brand			
CALASPARGASE PEGOL-MKNL	ASPARLAS			

GUIDELINES FOR USE

Our guideline named **CALASPARGASE PEGOL (Asparlas)** requires the following rule(s) be met for approval:

1. You have a diagnosis of acute lymphoblastic leukemia (type of blood and bone marrow cancer)
2. You are 1 month to 21 years of age
3. Asparlas will be used as a part of a chemotherapeutic treatment plan that contains multiple drugs

Commercial Effective: 07/01/20

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CANAKINUMAB (NSA)

Generic	Brand			
CANAKINUMAB/PF	ILARIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic *disorders* that have recurrent fever episodes and inflammation)
   4. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   5. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)

C. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You had a previous trial of the preferred immunomodulator: Actemra, unless there is a medical reason why you cannot (contraindication)

(Initial criteria continued on next page)

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CANAKINUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you have Adult-Onset Still's Disease (AOSD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) dermatologist (skin doctor), or immunologist (immune system doctor)
   2. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic *disorders* that have recurrent fever episodes and inflammation)
   4. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   5. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

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CARFILZOMIB (NSA)

Generic	Brand			
CARFILZOMIB	KYPROLIS			

GUIDELINES FOR USE

Our guideline named **CARFILZOMIB (Kyprolis)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment)
B. You are 18 years of age or older
C. You meet **ONE** of the following criteria:
    1. You have previously received one to three lines of therapy AND will use Kyprolis in combination with ONE of the following regimens:
        a. lenalidomide and dexamethasone; OR
        b. dexamethasone; OR
        c. daratumumab and dexamethasone
    2. You have previously received one or more lines of multiple myeloma therapy and will be using Kyprolis alone

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Commercial Effective: 09/14/20

CEMIPLIMAB-RWLC (NSA)

Generic	Brand			
CEMIPLIMAB-RWLC	LIBTAYO			

GUIDELINES FOR USE

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:

A. You have a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (type of skin cancer that has spread or has highly developed)
B. You are not a candidate for curative surgery or curative radiation.

Commercial Effective: 07/01/20

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CERLIPONASE ALFA (NSA)

Generic	Brand			
CERLIPONASE ALFA	BRINEURA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for approval:

A. You have a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2; group of severe diseases that affect the nervous system, including mental and movement skills), also known as tripeptidyl peptidase 1 (TPP1) deficiency
B. Your diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
C. You are ambulatory (able to walk) and experiencing symptoms such as instability, intermittent falls, requires assistance to walk, or can crawl only
D. You have a documented CLN2 Clinical Rating Scale Score (test to measure the severity of ceroid lipofuscinosis type 2) of 3 to 5, with a minimum score of 1 in each of the motor and language category
E. You are 3 years of age or older
F. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or pediatric ceroid lipofuscinosis type 2 specialist

RENEWAL CRITERIA

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for renewal:

A. You have improved or maintained baseline motor function (such as ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (such as ambulation, walking or crawling) from baseline
B. You have a ceroid lipofuscinosis type 2 (CLN2) motor score of at least 1 (such as you are not bedridden or immobile)

Commercial Effective: 07/01/20

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CETUXIMAB (NSA)

Generic	Brand			
CETUXIMAB	ERBITUX			

GUIDELINES FOR USE

Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon/rectum cancer that has spread)
   2. Locally or regionally advanced squamous cell carcinoma (type of skin cancer) of the head and neck
   3. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck
   4. Recurrent or metastatic squamous cell carcinoma of the head and neck.

B. **If you have metastatic colorectal cancer (mCRC), approval also requires:**
   1. Your cancer is KRAS wild-type (a type of gene with no mutation) as determined by an FDA (Food and Drug Administration)-approved test
   2. Your cancer is epidermal growth factor receptor (EGFR)-expressing as determined by an FDA-approved test
   3. You meet also ONE of the following:
      i. The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
      ii. The requested medication is being used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy
      iii. The requested medication is being used as a single agent AND you have failed oxaliplatin-based and irinotecan-based chemotherapy unless you are intolerant to irinotecan

C. **If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used in combination with radiation therapy

D. **If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

(Criteria continued on next page)

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CETUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

E. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used as a single agent
   2. You have previously failed platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

Commercial Effective: 07/01/20

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COPANLISIB (NSA)

Generic	Brand			
COPANLISIB	ALIQOPA			

GUIDELINES FOR USE

Our guideline named **COPANLISIB (Aliqopa)** requires the following rule(s) be met for approval:

A. You have relapsed follicular lymphoma (FL: a type of blood cancer)
B. You are 18 years of age or older
C. You have received at least two prior systemic therapies (therapy that travels through the blood) for follicular lymphoma

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Commercial Effective: 07/01/20

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CRIZANLIZUMAB-TMCA (NSA)

Generic	Brand			
CRIZANLIZUMAB-TMCA	ADAKVEO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (type of red blood cell disorder)
B. You are at least 16 years old
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. You have previously tried hydroxyurea, unless there is a medical reason why you cannot (contraindication)
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year. (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
    2. You are having sickle cell associated symptoms (such as pain or anemia) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels)

RENEWAL CRITERIA

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute (sudden and severe) complications of sickle cell disease (SCD) (such as a reduction in number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever and low oxygen levels]).

Commercial Effective: 04/01/20

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DARATUMUMAB (NSA)

Generic	Brand			
DARATUMUMAB	DARZALEX			

GUIDELINES FOR USE

Our guideline named **DARATUMUMAB (Darzalex)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet **ONE** of the following criteria:
   1. You have newly diagnosed multiple myeloma and are not eligible for autologous stem cell transplant (cells from your own body) and will receive daratumumab in combination with lenalidomide and dexamethasone
   2. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
   3. You are newly diagnosed with multiple myeloma, not eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone
   4. You are newly diagnosed with multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, thalidomide and prednisone
   5. You have received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
   6. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received one to three prior lines of therapy **AND** will receive daratumumab in combination with carfilzomib and dexamethasone
   7. You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI: class of drug for myeloma cancer) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
   8. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for myeloma) and an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) **AND** you will receive daratumumab as monotherapy (single drug to treat condition)
   9. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent **AND** will receive daratumumab as monotherapy

Note: Proteasome inhibitors examples include: bortezomib, carfilzomib, or ixazomib and Immunomodulatory agent examples include: lenalidomide, pomalidomide, or thalidomide.

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DARATUMUMAB-HYALURONIDASE-FIHJ (NSA)

Generic	Brand				
DARATUMUMAB-HYALURONIDASE-FIHJ	DARZALEX FASPRO				

GUIDELINES FOR USE

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet ONE of the following criteria:
    1. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with bortezomib, melphalan and prednisone
    2. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with lenalidomide and dexamethasone
    3. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment), received at least one prior therapy AND will receive daratumumab in combination with lenalidomide and dexamethasone
    4. You have received at least one prior therapy AND will receive daratumumab in combination with bortezomib and dexamethasone
    5. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for multiple myeloma) AND an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) AND you will receive daratumumab as monotherapy (will not be used in combination with another drug)
    6. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent AND will receive daratumumab as monotherapy (will not be used in combination with another drug)

Note: Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib; immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

Commercial Effective: 10/01/20

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DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

Generic	Brand			
DAUNORUBICIN/ CYTARABINE LIPOSOME	VYXEOS			

GUIDELINES FOR USE

Our guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires the following rule(s) be met for approval:

A. You have a new diagnosis of therapy-related acute myeloid leukemia (type of white blood cell cancer) OR acute myeloid leukemia with myelodysplasia-related changes (type of blood and bone marrow cancer that affects production of blood cells)
B. You are 18 years of age or older

Commercial Effective: 07/01/20

DENOSUMAB-PROLIA (NSA)

Generic	Brand			
DENOSUMAB	PROLIA			

GUIDELINES FOR USE

Our guideline named **DENOSUMAB (Prolia)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones after menopause), osteoporosis in a male patient, glucocorticoid-induced osteoporosis (weak and brittle bones caused by steroids), bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer (using the medication to lower hormone levels for prostate cancer that has not spread to other parts of the body), or bone loss in women receiving adjuvant aromatase inhibitor therapy (type of breast cancer drug) for breast cancer.

B. **If you have postmenopausal osteoporosis, approval also requires ONE of the following:**
   1. You are at high risk for fracture defined as ONE of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
      c. No prior treatment for osteoporosis AND FRAX score (tool to measure your fracture risk) greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)
   3. You are unable to use oral therapy (for example, due to upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or your daily routine)

C. **If you have glucocorticoid-induced osteoporosis OR are a male with osteoporosis, approval also requires:**
   1. You are at high risk for fractures defined as ONE of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. Two or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

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DENOSUMAB-PROLIA (NSA)

GUIDELINES FOR USE (CONTINUED)

D. **If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer, OR you are a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:**
   1. You are at high risk for fracture. Some risk factors include history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of gonadotropin releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

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DENOSUMAB-XGEVA (NSA)

Generic	Brand			
DENOSUMAB	XGEVA			

GUIDELINES FOR USE

Our guideline named **DENOSUMAB (Xgeva)** requires you meet ONE of the following criteria:

A. You have multiple myeloma (plasma cell cancer) OR bone metastases from solid tumors (cancer has spread to bones from solid tumors) AND the requested medication is being used to prevent skeletal-related events (such as bone fractures or bone pain requiring radiation)
B. You have giant cell tumor of bone that is unresectable (tumor cannot be removed completely through surgery) or where surgical resection is likely to result in severe morbidity (illness)
C. You have hypercalcemia (higher than normal levels of calcium in blood) of malignancy that does not respond to bisphosphonate therapy (such as Fosamax, Actonel, or Boniva)

Commercial Effective: 07/01/20

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DINUTUXIMAB (NSA)

Generic	Brand			
DINUTUXIMAB	UNITUXIN			

GUIDELINES FOR USE

Our guideline named **DINUTUXIMAB (Unituxin)** requires the following rule(s) be met for approval:

A. You have high-risk neuroblastoma (a type of cancer that usually affects glands above the kidneys)
B. You are 17 years of age or younger
C. You have received an autologous (cells are from your own body) stem cell transplant
D. You had a partial response to chemotherapy given before you had an autologous stem cell transplant
E. You have not undergone 5 cycles of dinutuximab in the past
F. Dinutuximab will be used concurrently (at the same time) with isotretinoin and either Leukine or Proleukin

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Commercial Effective: 07/01/20

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DURVALUMAB (NSA)

Generic	Brand			
DURVALUMAB	IMFINZI			

GUIDELINES FOR USE

Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic urothelial carcinoma (urinary system cancer), unresectable (cannot be completely removed with surgery) Stage III non-small cell lung cancer (NSCLC), or extensive-stage small cell lung cancer (ES-SCLC)
B. You are 18 years of age or older
C. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
   1. Your disease has worsened on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. Your disease has worsened within 12 months of neoadjuvant or adjuvant treatment (additional treatment given before or during the main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
D. **If you have unresectable Stage III non-small cell lung cancer (NSCLC), approval also requires:**
   1. Your disease has not worsened after using concurrent platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (you used chemotherapy and radiation therapy at the same time)
E. **If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:**
   1. The requested medication is being used as first line of therapy
   2. The requested medication will be used in combination with etoposide and either carboplatin or cisplatin

Commercial Effective: 05/01/20

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ECALLANTIDE (NSA)

Generic	Brand			
ECALLANTIDE	KALBITOR			

GUIDELINES FOR USE

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (a type of genetic disorder where you have extreme swelling in various parts of the body)
B. You are 12 years of age or older
C. Your diagnosis is confirmed by complement testing (measures the amount of certain types of proteins in the blood)
D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
E. The medication is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor) or hematologist (blood specialty doctor)
F. The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe, possible life-threatening allergic reaction) and/or angioedema (extreme swelling/allergic reaction)

Commercial Effective: 07/01/20

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ECULIZUMAB (NSA)

Generic	Brand			
ECULIZUMAB	SOLIRIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
   2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
   3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)

B. Eculizumab (Soliris) is NOT being used for hemolytic uremic syndrome related to Shiga toxin E. coli (small blood vessels in your kidneys become damaged and inflamed caused by a type of bacteria)

C. **If you have generalized myasthenia gravis (gMG), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive anti-acetylcholine receptor antibody test
   4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
   5. You had a trial of corticosteroids, unless there is a medical reason why you cannot (contraindication)
   6. You meet ONE of the following:
      a. Failure of treatment with at least 2 immunosuppressive therapies (drugs that weaken
      b. your immune system such as azathioprine, cyclophosphamide, methotrexate)
      c. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (types of blood therapy)

(Initial criteria continued on the next page)

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ECULIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   3. You have confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
      a. At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
      b. PNH granulocyte clone size greater than or equal to10%
   4. You meet **ONE** of the following:
      a. Transitioning from alternative complement inhibitor therapy (such as Ultomiris)
      b. Documentation of evidence of intravascular hemolysis (blood cells being destroyed) such as lactate dehydrogenase [LDH] level greater than or equal to 1.5 times the upper limit of normal, hemoglobinuria (type of blood protein is in urine) OR you have a history of major adverse vascular event from thromboembolism (blood clot)

E. **If you have neuromyelitis optica spectrum disorder (NMOSD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
   4. You have at least ONE of the following core clinical characteristics:
      a. Optic neuritis (inflammation that damages eye nerve)
      b. Acute myelitis (sudden and severe inflammation of the spinal cord)
      c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
      d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
      e. Symptomatic narcolepsy (sudden sleepiness) or acute diencephalic clinical syndrome (tumor in a part of brain) with NMOSD-typical diencephalic MRI lesions (affected areas)
      f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
   5. You will NOT use rituximab, inebilizumab, or satralizumab together with Soliris

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ECULIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
   2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
   3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)

B. **If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:**
   1. You have had clinical benefit compared to baseline such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (type of enzyme) and hemoglobin levels

C. **If you have generalized myasthenia gravis, renewal also requires:**
   1. You have had clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

D. **If you have neuromyelitis optica spectrum disorder, renewal also requires:**
   1. You have had a reduction in relapse frequency compared to baseline

Commercial Effective: 10/01/20

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EDARAVONE (NSA)

Generic	Brand			
EDARAVONE	RADICAVA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You are currently taking or have previously tried riluzole (Rilutek)
C. The medication is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system) or ALS specialist at an ALS Specialty Center or Care Clinic
D. You have the disease (from onset of symptoms) for less than 2 years
E. Your Normal Respiratory Function defined as a Forced Vital Capacity (FVC) is greater than 80%
F. You have mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (Amyotrophic Lateral Sclerosis Functional Rating Scale; for example, speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

RENEWAL CRITERIA

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You have improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (such as Amyotrophic Lateral Sclerosis Functional Rating Scale)
C. You do not require invasive ventilation (such as inserting a breathing tube into your throat)
D. Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R (Amyotrophic Lateral Sclerosis Functional Rating Scale Revised)

Commercial Effective: 07/01/20

ELOSULFASE ALFA (NSA)

Generic	Brand			
ELOSULFASE ALFA	VIMIZIM			

GUIDELINES FOR USE

Our guideline named **ELOSULFASE ALFA (Vimizim)** requires you have Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome - rare metabolic condition that mainly affects the skeleton).

Commercial Effective: 07/01/20

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ELOTUZUMAB (NSA)

Generic	Brand			
ELOTUZUMAB	EMPLICITI			

GUIDELINES FOR USE

Our guideline named **ELOTUZUMAB (Empliciti)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet ONE of the following criteria:
    1. Empliciti is used in combination with lenalidomide and dexamethasone if you have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
    2. Empliciti is used in combination with pomalidomide and dexamethasone if you have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib)

Commercial Effective: 07/01/20

EMAPALUMAB-LZSG (NSA)

Generic	Brand			
EMAPALUMAB-LZSG	GAMIFANT			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for approval:

A. You have primary hemophagocytic lymphohistiocytosis (HLH; inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. Your diagnosis is confirmed by ONE of the following:
   1. You have undergone a genetic test identifying HLH-associated gene mutation such as PRF1 (type of gene), UNC13D (type of gene)
   2. You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (type of high cholesterol) and/or hypofibrinogenemia (type of genetic disorder); hemophagocytosis (destruction of certain types of cells) in bone marrow or spleen or lymph nodes, and no evidence of malignancy; low or absent natural killer-cell activity; ferritin level of at least 500 mcg/L; soluble CD25 level of at least 2,400 U/mL
C. You have refractory, recurrent, or progressive disease (disease returns or does not respond to treatment and gets worse); **OR** you had a trial or intolerance to conventional hemophagocytic lymphohistiocytosis therapy (such as chemotherapy, steroids, immunotherapy)
D. The requested medication will be used at the same time with dexamethasone
E. Therapy is prescribed by or given in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (blood doctor), or oncologist (cancer doctor)

RENEWAL CRITERIA

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for renewal:

A. You have hemophagocytic lymphohistiocytosis (inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. You have not received successful hematopoietic stem cell transplantation
C. You have demonstrated improved immune system response from baseline as shown by any of the following: your fever has gone away, decreased splenomegaly (spleen size has gotten smaller), improvement in central nervous system symptoms such as altered mental status, improved complete blood count, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 (type of protein) levels

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ENFORTUMAB (NSA)

Generic	Brand				
ENFORTUMAB VEDOTIN-EJFV	PADCEV				

GUIDELINES FOR USE

Our guideline named **ENFORTUMAB (Padcev)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic urothelial cancer (type of urinary system cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor
D. You have previously received a platinum-containing chemotherapy (type of cancer medication) in the neoadjuvant/adjuvant (given before surgery or as an add-on), locally advanced or metastatic setting (cancer has spread to other parts of the body)

Commercial Effective: 04/01/20

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ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (NSA)

Generic	Brand			
IMIGLUCERASE	CEREZYME			
TALIGLUCERASE ALFA	ELELYSO			
VELAGLUCERASE ALFA	VPRIV			

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

ELELYSO

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Elelyso)** requires the following rule(s) be met for approval:

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 4 years of age or older

VPRIV

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Vpriv)** requires the following rule(s) be met for approval:

- You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
- You are 4 years of age or older
- You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

CEREZYME

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Cerezyme)** requires the following rule(s) be met for approval:

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 18 years of age or older
C. You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

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EPOPROSTENOL IV (NSA)

Generic	Brand			
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN			
EPOPROSTENOL SODIUM (ARGININE)	VELETRI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOPROSTENOL (Flolan, Veletri)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

RENEWAL CRITERIA

Our guideline named **EPOPROSTENOL (Flolan, Veletri)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable in the 6-minute walk distance test AND your World Health Organization functional class has remained stable or improved (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

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EPTINEZUMAB-JJMR (NSA)

Generic	Brand				
EPTINEZUMAB-JJMR	VYEPTI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
   4. You had a previous trial of Aimovig AND Emgality
C. **If you have chronic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
   4. You had a previous trial of Aimovig AND Emgality

RENEWAL CRITERIA

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

A. Vyepti is being prescribed for preventive treatment of migraines
B. You also meet **ONE** of the following:
   1. You have experienced a reduction in migraine or headache frequency by at least 2 days per month with Vyepti therapy
   2. You have experienced a reduction in migraine severity with Vyepti therapy
   3. You have experienced a reduction in migraine duration (length of time) with Vyepti therapy

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ERIBULIN (NSA)

Generic	Brand			
ERIBULIN MESYLATE	HALAVEN			

GUIDELINES FOR USE

Our guideline named **ERIBULIN (Halaven)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic (cancer has spread) breast cancer
   2. Unresectable or metastatic liposarcoma (cancer that starts in fat cells that has spread or cannot be completely removed by surgery)

B. **If you have metastatic breast cancer, approval also requires:**
   A. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)
   B. You had previous treatment with a taxane (such as paclitaxel and docetaxel)

C. **If you have unresectable or metastatic liposarcoma, approval also requires:**
   1. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)

Commercial Effective: 07/01/20

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ESKETAMINE (NSA)

Generic	Brand			
ESKETAMINE	SPRAVATO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time)
   2. Major depressive disorder (MDD: clinical depression or low mood)

B. **If you have treatment-resistant depression (TRD), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with an oral antidepressant
   3. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
   4. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
   5. You do NOT have active substance abuse
   6. You had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression. Classes of anti-depressants include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), bupropion, mirtazapine, serotonin modulator, tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs) are optional. You must have used the drugs for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

C. **If you have major depressive disorder (MDD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
   3. You have acute suicidal ideation or behavior (thoughts of killing yourself)
   4. The requested medication will be used in combination with an oral antidepressant
   5. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
   6. You do NOT have active substance abuse

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ESKETAMINE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:

A. You have treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time) OR major depressive disorder (MDD: clinical depression or low mood)
B. You have demonstrated clinical benefit (improvement in depression) compared to baseline

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Commercial Effective: 01/01/21

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ETELCALCETIDE (NSA)

Generic	Brand			
ETELCALCETIDE	PARSABIV			

GUIDELINES FOR USE

Our guideline named **ETELCALCETIDE (Parsabiv)** requires the following rule(s) be met for approval:

A. You have secondary hyperparathyroidism (too much parathyroid hormone due to low blood calcium levels)
B. You are 18 years of age or older
C. You have chronic kidney disease
D. You are on hemodialysis (a way of removing toxins from your blood)
E. You are NOT taking another calcimimetic agent (a drug that acts like calcium in the body
F. such as cinacalcet)

Commercial Effective: 07/01/20

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ETEPLIRSEN (NSA)

Generic	Brand			
ETEPLIRSEN	EXONDYS 51			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETEPLIRSEN (Exondys-51)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 51 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **ETEPLIRSEN (Exondys-51)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

Commercial Effective: 01/01/21

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FAM-TRASTUZUMAB (NSA)

Generic	Brand				
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU				

GUIDELINES FOR USE

Our guideline named **FAM-TRASTUZUMAB (Enhertu)** requires the following rule(s) be met for approval:

A. You have unresectable (cannot be surgically removed) or metastatic (cancer has spread to other parts of the body) HER2-positive (type of protein that causes breast cancer cells to grow) breast cancer
B. You are 18 years of age or older
C. You have received two or more prior anti-HER2-based regimens (drug that works against a protein called human epidermal growth factor receptor 2) in the metastatic setting (cancer has spread to other parts of the body)

Commercial Effective: 04/01/20

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FULVESTRANT (NSA)

Generic	Brand			
FULVESTRANT	FASLODEX			

GUIDELINES FOR USE

Our guideline named **FULVESTRANT (Faslodex)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer
   2. HR-positive advanced breast cancer
   3. HR-positive, HER2-negative advanced or metastatic breast cancer (cancer that has spread)

B. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have not previously been treated with endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (using a single drug to treat a condition)

C. **If you have hormone receptor (HR)-positive advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have experienced disease progression (it has gotten worse) following endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (used alone)

D. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used concurrently (at the same time) with Ibrance (palbociclib) or Verzenio (abemaciclib) and you are a female that has experienced disease progression (it has gotten worse) after endocrine (hormone) therapy
   2. The requested medication will be used in combination with Kisqali (ribociclib) and you meet ALL of the following:
      a. You are a female and postmenopausal
      b. You have not received prior endocrine based therapy for metastatic breast cancer (such as letrozole, anastrozole, tamoxifen, exemestane) OR you have experienced disease progression on endocrine therapy

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GEMTUZUMAB OZOGAMICIN (NSA)

Generic	Brand			
GEMTUZUMAB OZOGAMICIN	MYLOTARG			

GUIDELINES FOR USE

Our guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires that ONE of the following rule(s) be met for approval:

1. You have newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML) –positive acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many immature white blood cells) AND you are 1 month of age or older
2. You have relapsed (returning) or refractory (resistant) CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML) AND you are 2 years of age or older

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Commercial Effective: 07/01/20

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GIVOSIRAN (NSA)

Generic	Brand				
GIVOSIRAN	GIVLAARI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for approval:

A. You have acute hepatic porphyria (enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
B. You are 18 years of age or older
C. You have genetic confirmation of AHP mutation (a change in your DNA that make up your gene), OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA) (PBG and ALA: urine or blood tests that measure the level of porphyrins – a chemical that helps make hemoglobin in your body)
D. You have experienced two or more acute (sudden and severe) hepatic porphyria attacks in the past 12 months
E. The medication is prescribed by or given in consultation with a geneticist (doctor who specializes in conditions of gene disorders), hepatologist (doctor who specializes in treating the liver), hematologist (doctor who specializes in the study of blood, blood-forming organs and blood diseases), gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), neurologist (doctor who specializes in disorders of the nervous system), dermatologist (doctor who treats conditions of the skin, hair and nails), or a healthcare provider experienced in managing acute hepatic porphyria
F. Your doctor provided documentation of your weight

RENEWAL CRITERIA

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for renewal:

A. You have acute hepatic porphyria (AHP: enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
B. You have achieved or maintained clinical (medical) benefit compared to baseline (such as less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
C. You have not received a liver transplant (replaced your bad liver with a healthy liver from another person)
D. Your doctor provided documentation of your weight

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GOLIMUMAB - IV (NSA)

Generic	Brand			
GOLIMUMAB - IV	SIMPONI ARIA - IV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried any **TWO** of the following preferred agents, unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   2. You meet ONE of the following criteria:
      a. You are 2 to 17 years old
      b. You are 18 years of age or older and have previously tried any TWO of the following preferred agents, unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Cosentyx, Enbrel, Xeljanz (IR or XR, immediate-release or extended-release)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

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GOLIMUMAB - IV (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any **TWO** of the following preferred agents, unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred agents, unless there is a medical reason why you cannot (contraindication): Enbrel and Humira

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GOLIMUMAB - IV (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 01/01/21

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GOLODIRSEN (NSA)

Generic	Brand				
GOLODIRSEN	VYONDYS-53				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLODIRSEN (Vyondys-53)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **GOLODIRSEN (Vyondys-53)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

Commercial Effective: 01/01/21

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

Generic	Brand			
TRIPTORELIN PAMOATE	TRIPTODUR, TRELSTAR			
HISTRELIN ACETATE	SUPPRELIN LA, VANTAS			
LEUPROLIDE ACETATE	LUPRON DEPOT–PED, LUPRON DEPOT, LUPANETA, FENSOLVI			
GOSERELIN ACETATE	ZOLADEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar, Fensolvi)** requires the following rule(s) be met for approval:

A. You have or are using the requested drug for ONE of the following:
   1. Advanced prostate cancer
   2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
   3. Central precocious puberty (CPP; early sexual development in girls and boys)
   4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)
   5. As an endometrial-thinning agent prior to endometrial ablation (surgical removal of body tissue) for dysfunctional uterine bleeding
   6. Palliative treatment (treatment for pain or discomfort) of advanced breast cancer
   7. Management of locally confined carcinoma (cancer) of the prostate
   8. Anemia caused by uterine leiomyomata (fibroids; small muscle tumor)

B. **If you have advanced prostate cancer, approval also requires:**
   1. The request is for Lupron Depot, Zoladex, Vantas, or Trelstar

(Initial criteria continued on next page)

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe pain from endometriosis, approval also requires:**
   1. The request is for Lupron Depot, Lupaneta, or Zoladex
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
   4. You had a previous trial of a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)

D. **If you are female and have central precocious puberty, approval also requires:**
   1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
   2. You are 2 years of age or older
   3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 8 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

E. **If you are male and have central precocious puberty, approval also requires:**
   1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
   2. You are 2 years of age or older
   3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 9 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

F. **If you are using the requested medication as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, approval also requires:**
   1. The request is for Zoladex

(Initial criteria continued on next page)

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

G. **If you are using the requested medication for palliative treatment of advanced breast cancer, approval also requires:**
   1. The request is for Zoladex
   2. You are a premenopausal or perimenopausal female

H. **If you are using the requested medication for the management of locally confined carcinoma of the prostate, approval also requires:**
   1. The request is for Zoladex
   2. The requested medication will be used in combination with flutamide

I. **If you have anemia caused by uterine leiomyomata, approval also requires:**
   1. The request is for Lupron Depot
   2. You are using the requested medication for preoperative hematologic (blood) improvement
   3. The requested medication will be used with iron therapy

RENEWAL CRITERIA

NOTE: For palliative treatment of advanced breast cancer, management of locally confined prostate carcinoma, preoperative hematologic improvement of anemia caused by uterine leiomyomata, or use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, please refer to the Initial Criteria section.

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar, Fensolvi)** requires the following rule(s) be met for renewal:

A. You have or are using the requested drug for ONE of the following:
   1. Advanced prostate cancer
   2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
   3. Central precocious puberty (CPP; early sexual development in girls and boys)
   4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)

B. **If you have moderate to severe pain associated with endometriosis, renewal also requires:**
   1. The request is for Lupron Depot, Lupaneta, or Zoladex
   2. You experienced improvement of pain related to endometriosis while on therapy
   3. You are receiving add-back therapy at the same time (combination estrogen-progestin or progestin-only contraceptive preparation)
   4. You have NOT received a total course of therapy exceeding 12 months

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have central precocious puberty (CPP), renewal also requires:**
   1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
   2. Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   3. You have not reached actual age which corresponds to current pubertal age

D. **If you have advanced prostate cancer, renewal also requires:**
   1. The request is for Lupron Depot, Zoladex, Vantas, or Trelstar

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Commercial Effective: 05/25/20

HYALURONATE (NSA)

Generic	Brand				
HYALURONATE SODIUM	EUFLEXXA, HYALGAN, GEL-ONE, GELSYN-3, ORTHOVISC, SUPARTZ FX, GENVISC 850, VISCO-3, TRIVISC, TRILURON, SODIUM HYALURONATE				
HYALURONATE SODIUM, STABILIZED	MONOVISC, DUROLANE				
HYALURONATE, MODIFIED, NON-CROSSLINK	HYMOVIS				
HYLAN G-F 20	SYNVISC, SYNVISC-ONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for approval:

A. You have osteoarthritis (cartilage between joints breaks down leading to pain, stiffness and swelling) of the knee
B. You are 21 years of age or older
C. You have failed a minimum of a 6-week trial of non-pharmacologic (non-drug) therapy such as education, exercise, use of insoles or braces, weight loss and physical therapy
D. You had a previous trial of intra-articular (injected within the joints) steroids

RENEWAL CRITERIA

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for renewal:

A. It has been at least 6 months since your last treatment on the same knee

Commercial Effective: 07/01/20

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HYDROXYPROGESTERONE CAPROATE (NSA)

Generic	Brand			
HYDROXYPROGES-TERONE CAPROATE	MAKENA			
HYDROXYPROGES-TERONE CAPROATE	HYDROXY-PROGESTERONE CAPROATE (GENERIC FOR DELALUTIN)			

GUIDELINES FOR USE

Our guideline named **HYDROXYPROGESTERONE CAPROATE (Makena)** requires the following rule(s) be met for approval:

A. The medication will be used to lower the risk of preterm (early than normal 37 weeks) birth in a woman with a history of singleton spontaneous preterm birth
B. You do **NOT** have multiple gestations (twins, triplets, etc.)
C. You are at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation (embryo/fetus)
D. You have a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes

Our guideline named **HYDROXYPROGESTERONE CAPROATE (Generic Delalutin)** requires you are a non-pregnant female and are using the medication for **ONE** of the following:

A. For treatment of advanced adenocarcinoma of the uterine corpus (uterine cancer/tumor Stage III or IV)
B. For the management of primary/secondary amenorrhea (lack of normal menstruation) and abnormal uterine bleeding caused by hormonal imbalance with no organic pathology (no disease from body/organs), such as submucous fibroids or uterine cancer
C. As a test for endogenous (within the body) estrogen production
D. For the production of secretory endometrium and desquamation (shedding of the tissue lining of the uterus)

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IBALIZUMAB-UIYK (NSA)

Generic	Brand				
IBALIZUMAB-UIYK	TROGARZO				

GUIDELINES FOR USE

Our guideline named **IBALIZUMAB-UIYK (Trogarzo)** requires the following rule(s) be met for approval:

A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
B. You are 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
D. You are treatment experienced (previously treated)
E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
F. You are failing your current antiretroviral regimen

Commercial Effective: 10/01/20

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IMMUNE GLOBULIN

Generic	Brand			
IMMUNE GLOBULIN	BIVIGAM, CARIMUNE NF NANOFILTERED, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA			
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED			
IMMUNE GLOBULIN / MALTOSE	OCTAGAM			
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA			
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU			
IMMUN GLOB G(IGG)-IFAS/GLYCINE	PANZYGA			
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG			
IMMUNE GLOBULIN (HUMAN)-KLHW	XEMBIFY			
IMMUNE GLOBULIN (HUMAN)-SLRA	ASCENIV			

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN** requires the following rule(s) be met for approval:

A. **For Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Carimune NF Nanofiltered, Flebogamma DIF, Gammagard S-D, Gammaplex, Privigen, Octagam, or Panzyga for intravenous (IV) injection**, approval requires you to have ONE of the following diagnoses:
   1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
   2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
   3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

4. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
5. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
6. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
7. Guillain-Barre Syndrome (immune system attacks the nerves)
8. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
9. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
10. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
11. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
12. Reduction of secondary infections in pediatric HIV infections
13. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
14. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
15. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
16. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
17. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
18. Neonatal sepsis (blood infection in infants)
19. Rotaviral enterocolitis (severe diarrhea among infants and young children)
20. Toxic shock syndrome (life-threatening complication of certain bacterial infections)
21. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
22. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
23. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

(Criteria continued on next page)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

B. **For Asceniv, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)
   2. You are 12 years of age or older
   3. You have tried any other TWO immunoglobulin products

C. **For Gamastan S-D, approval requires:**
   1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella

D. **For Hizentra, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

E. **For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

F. **For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

Commercial Effective: 04/01/20

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INEBILIZUMAB-CDON (NSA)

Generic	Brand				
INEBILIZUMAB-CDON	UPLIZNA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, satrilizumab, or eculizumab together with Uplizna

RENEWAL CRITERIA

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for renewal:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You have shown clinical benefit (such as reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations) on therapy with Uplizna

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INFLIXIMAB (NSA)

Generic	Brand			
INFLIXIMAB	REMICADE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

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INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as, methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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INFLIXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulatory (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira
      b. You are 18 years of age or older AND have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age
      b. You are 18 years of age or older AND have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira,Stelara, Xeljanz (immediate release unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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INFLIXIMAB-ABDA (NSA)

Generic	Brand			
INFLIXIMAB-ABDA	RENFLEXIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/ extended release)

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INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   5. You are 18 years of age or older
   6. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   7. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   8. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more form of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   4. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   5. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   6. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulatory (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira
      b. You are 18 years of age or older AND have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age
      b. You are 18 years of age or older AND have previously tried any TWO of the following preferred immunomodulators (class of drugs): Humira, Stelara, Xeljanz immediate release/extended release

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-ABDA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease **OR** you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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INFLIXIMAB-AXXQ (NSA)

Generic	Brand				
INFLIXIMAB-AXXQ	AVSOLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz immediate release/extended release

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INFLIXIMAB-AXXQ (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of the following standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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INFLIXIMAB-AXXQ (NSA)

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]
      b. You are 18 years of age or older AND have previously tried BOTH of the following, preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless there is a medical reason why you cannot (contraindication)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age
      b. You are 18 years of age or older AND have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Xeljanz (immediate release/extended release

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INFLIXIMAB-AXXQ (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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INFLIXIMAB-DYYB (NSA)

Generic	Brand			
INFLIXIMAB-DYYB	INFLECTRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **INFLIXIMAB- DYYB (Inflectra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   6. You are 18 years of age or older
   7. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   8. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   9. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   10. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz immediate release/extended release

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INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   5. You are 18 years of age or older
   6. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   7. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   8. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   5. You are 18 years of age or older
   6. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   7. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   8. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   6. You are 18 years of age or older
   7. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   8. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   9. You have previously tried at least ONE or more form of conventional therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   10. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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INFLIXIMAB-DYYB (NSA)

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   4. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   5. You have previously tried at least ONE conventional therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   6. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulatory (class of drug), unless there is a medical reason why you cannot (contraindication): Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]
      b. You are 18 years of age or older AND have previously tried BOTH of the following, preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   4. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   5. You have previously tried at least ONE conventional therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   6. You meet ONE of the following:
      c. You are 6 to 17 years of age
      d. You are 18 years of age or older AND have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Xeljanz (immediate release/extended release

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB- DYYB (Inflectra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   3. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   4. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   2. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   2. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   2. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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Commercial Effective: 04/01/20

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INOTUZUMAB OZOGAMICIN (NSA)

Generic	Brand			
INOTUZUMAB OZOGAMICIN	BESPONSA			

GUIDELINES FOR USE

Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory B-cell pre-cursor acute lymphoblastic leukemia (ALL- type of blood and bone marrow cancer that affects white blood cells.)
B. You are 18 years of age or older
C. You have **NOT** received 6 cycles of Besponsa previously

Commercial Effective: 07/01/20

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IOBENGUANE IODINE 131 (NSA)

Generic	Brand			
IOBENGUANE I 131	AZEDRA			

GUIDELINES FOR USE

Our guideline named **IOBENGUANE IODINE 131 (Azedra)** requires the following rule(s) be met for approval:

A. You have unresectable (cannot be removed completely through surgery), locally advanced or metastatic pheochromocytoma (type of tumor that releases hormones) or paraganglioma (type of tumors)
B. You are 12 years of age or older
C. You require systemic anticancer therapy (cancer treatment that travels in the blood throughout the entire body)
D. The tumors are iobenguane scan positive (type of test that detects a tumor)
E. You have **NOT** previously received 1 dosimetric dose (measurement of how much radiation dose is absorbed by the body) and 2 therapeutic doses of Azedra

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Commercial Effective: 07/01/20

IPILIMUMAB (NSA)

Generic	Brand			
IPILIMUMAB	YERVOY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed with surgery or has spread)
   2. Cutaneous melanoma (type of skin cancer)
   3. Advanced renal cell carcinoma (type of kidney cancer)
   4. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (types of colon cancer)
   5. Hepatocellular carcinoma (liver cancer)
   6. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)
   7. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 12 years of age or older

C. **If you have cutaneous melanoma, approval also requires:**
   1. The requested medication will be used for adjuvant (add-on) treatment
   2. There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
   3. You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. The requested medication will be used in combination with Opdivo (nivolumab)
   2. You have intermediate or poor risk disease
   3. You have not received prior treatment for advanced renal cell carcinoma

E. **If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:**
   1. You are 12 years of age or older
   2. The requested medication will be used in combination with Opdivo (nivolumab)
   3. You have disease progression (disease gets worse) following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

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IPILIMUMAB (NSA)

INITIAL CRITEIRA (CONTINUED)

F. **If you have hepatocellular carcinoma, approval also requires:**
   1. The requested medication will be used in combination with Opdivo (nivolumab)
   2. You have previously been treated with Nexavar (sorafenib)

G. **If you have metastatic or recurrent non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
   3. The requested medication is used as first-line treatment
   4. You have NOT received Yervoy for more than 2 years
   5. You meet ONE of the following:
      a. **For metastatic NSCLC,** the requested medication will be used in combination with Opdivo (nivolumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
      b. **For metastatic or recurrent NSCLC,** the requested medication will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

H. **If you have malignant pleural mesothelioma, approval also requires:**
   1. You are 18 years of age or older
   2. Yervoy will be used as first line treatment in combination with Opdivo (nivolumab)

RENEWAL CRITERIA

Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for renewal:

A. The request is for adjuvant (add-on) treatment of cutaneous melanoma (type of skin cancer)
B. You do not have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant)
C. You have not been treated with Yervoy for more than 3 years

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Commercial Effective: 10/19/20

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IRINOTECAN LIPOSOMAL (NSA)

Generic	Brand			
IRINOTECAN LIPOSOMAL	ONIVYDE			

GUIDELINES FOR USE

Our guideline named **IRINOTECAN LIPOSOMAL (Onivyde)** requires the following rule(s) be met for approval:

A. You have metastatic adenocarcinoma of the pancreas (type of pancreas cancer that has spread)
B. You have experienced disease progression (disease has worsened) despite a trial of gemcitabine-based therapy (type of cancer drug)
C. Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin

Commercial Effective: 07/01/20

ISATUXIMAB-IRFC (NSA)

Generic	Brand				
ISATUXIMAB-IRFC	SARCLISA				

GUIDELINES FOR USE

Our guideline named **ISATUXIMAB-IRFC (Sarclisa)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. The requested medication will be used in combination with pomalidomide and dexamethasone
D. You have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as ixazomib, carfilzomib)

Commercial Effective: 07/01/20

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IXABEPILONE (NSA)

Generic	Brand			
IXABEPILONE	IXEMPRA			

GUIDELINES FOR USE

Our guideline named **IXABEPILONE** requires the following rule(s) be met for approval:

A. You have metastatic (cancer that has spread to other parts of body) or locally advanced breast cancer
B. You meet **ONE** of the following:
1. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) **OR**
2. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), and a taxane (paclitaxel or docetaxel) **AND** the requested medication is being used in combination with Xeloda (capecitabine)

Commercial Effective: 07/01/20

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LETERMOVIR IV (NSA)

Generic	Brand			
LETERMOVIR	PREVYMIS			

GUIDELINES FOR USE

Our guideline named **LETERMOVIR IV (Prevymis)** requires the following rule(s) be met for approval:

A. You are undergoing an allogeneic hematopoietic stem cell transplant (you have cells transplanted from a matching donor)
B. You are 18 years of age or older
C. You are CMV (Cytomegalovirus)-seropositive [R+]
D. Prevymis will be used for prophylaxis (prevention) of cytomegalovirus infection and disease
E. Prevymis will be started between Day 0 and Day 28 post-transplantation (before or after engraftment)
F. You are not receiving the medication beyond 100 days post-transplantation

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Commercial Effective: 07/01/20

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LURBINECTEDIN (NSA)

Generic	Brand				
LURBINECTEDIN	ZEPZELCA				

GUIDELINES FOR USE

Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:

A. You have metastatic small cell lung cancer (SCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You had disease progression (worsening) on or after platinum-based chemotherapy (such as carboplatin or cisplatin)

Commercial Effective: 10/01/20

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LUSPATERCEPT-AAMT (NSA)

Generic	Brand				
LUSPATERCEPT-AAMT	REBLOZYL				

GUIDELINES FOR USE

Our guideline named **LUSPATERCEPT-AAMT (Reblozyl)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells)
B. You are 18 years of age or older
C. You have ONE of the following conditions:
   1. Beta thalassemia (blood disorder that reduces the production of hemoglobin) and you require regular red blood cell (RBC) transfusions
   2. Myelodysplastic syndromes (group of blood disorders caused when production of blood cells is disrupted) with ring sideroblasts (cells that contain rings of iron deposits) (MDS-RS)
   3. Myelodysplastic/myeloproliferative neoplasm (group of disorders in which the bone marrow makes too many white blood cells) with ring sideroblasts and thrombocytosis (excess of blood clotting cells (platelets)) (MDS/MPN-RS-T)
D. **If you have myelodysplastic syndromes with ring sideroblasts (MDS-RS) OR myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T), approval also requires:**
   1. You are failing an erythropoiesis (red blood cell production) stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks

Commercial Effective: 05/01/20

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LUTETIUM LU 177 DOTATATE (NSA)

Generic	Brand			
LUTETIUM LU 177 DOTATATE	LUTATHERA			

GUIDELINES FOR USE

Our guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires the following rule(s) be met for approval:

A. You have somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs: type of hormone cancer in digestive tract)
B. You are 18 years of age or older
C. You will be treated with a long-acting octreotide (type of hormone) as maintenance therapy together with the requested medication
D. You have been previously treated with a long acting somatostatin analog (such as octreotide or lanreotide) before the request of this medication
E. You have **NOT** previously received 4 doses of Lutathera

Commercial Effective: 07/01/20

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MEPOLIZUMAB

Generic	Brand			
MEPOLIZUMAB	NUCALA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Severe asthma with an eosinophilic phenotype (inflammatory type)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
   3. Hypereosinophilic syndrome (HES) (a rare blood disorder)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
   3. Nucala will be used as add-on maintenance treatment
   4. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
   5. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   6. You have experienced at least ONE asthma exacerbation (worsening of symptoms) within the past 12 months. Exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days
   7. You are not being treated on the requested medication concurrently (at the same time) with Xolair, Dupixent, or another anti-IL-5 asthma biologic (such as Cinqair, Fasenra)

C. **If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have hypereosinophilic syndrome (HES), approval also requires:**
   1. You are 12 years of age or older
   2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

Commercial Effective: 10/12/20

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MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand			
MINOCYCLINE HCL MICROSPHERES	ARESTIN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have documentation of confirmed periodontitis (inflammation and infection of the gums)
B. You are age 18 years or older
C. The medication is prescribed by or given in consultation with an oral health care professional
D. You do not have a history of minocycline or tetracycline sensitivity or allergy
E. You do not have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. The requested medication will be administered by an oral health professional
G. The requested medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. The requested medication is not being used for acutely abscessed periodontal pocket (not used for short-term and sudden infection with pus-filled pocket)
I. The medication is not being used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus
    2. Chemotherapy
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. The medication is not being used in the regeneration of alveolar bone (bone that has tooth sockets), either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

RENEWAL CRITERIA

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have documentation of periodontitis (inflammation and infection of the gums)
B. The medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

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MITOMYCIN (NSA)

Generic	Brand				
MITOMYCIN	JELMYTO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for approval:
A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an oncologist (doctor who specializes in cancer) or urologist (doctor who specializes in the urinary tract and male reproductive organs)

RENEWAL CRITERIA

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for renewal:
A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You were reassessed at no sooner than 3 months after initiation of Jelmyto
C. You showed complete response at the time of assessment

Commercial Effective:10/01/20

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MITOXANTRONE (NSA)

Generic	Brand			
MITOXANTRONE HCL	NOVANTRONE			

GUIDELINES FOR USE

Our guideline named **MITOXANTRONE** requires ONE of following rules be met for approval:

A. The medication is prescribed by or given in consultation with an oncologist (tumor/cancer doctor)
B. You have ONE of the following:
   1. Pain related to advanced refractory prostate cancer
   2. Acute nonlymphocytic leukemia (type of white blood cell cancer)
   3. Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis (disease where immune system attacks nerves)

Commercial Effective: 07/01/20

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MOGAMULIZUMAB-KPKC (NSA)

Generic	Brand			
MOGAMULIZUMAB-KPKC	POTELIGEO			

GUIDELINES FOR USE

Our guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires the following rule(s) be met for approval:

A. You have Mycosis Fungoides or Sezary syndrome (types of blood cancers that affect the skin)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or not responsive to therapy)
D. You have tried and failed at least one prior systemic therapy (treatment that travels in the blood throughout the body)

Commercial Effective: 07/01/20

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MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand			
MOMETASONE FUROATE	SINUVA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

RENEWAL CRITERIA

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Commercial Effective: 10/01/20

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MOXETUMOMAB PASUDOTOX (NSA)

Generic	Brand			
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI			

GUIDELINES FOR USE

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) be met for approval:

A. You have hairy cell leukemia (HCL: type of blood and bone marrow cancer)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or is not responsive to therapy)
D. You have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (type of drug that treats certain blood cancers)
E. You have NOT previously received 6 cycles of Lumoxiti

Commercial Effective: 07/01/20

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NATALIZUMAB (NSA)

Generic	Brand			
NATALIZUMAB	TYSABRI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried or have a contraindication to (a medical reason why you cannot use) ONE conventional agent, such as corticosteroids (for example, budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried or have a contraindication to (a medical reason why you cannot use) BOTH of the following preferred immunomodulators (class of drugs): Humira AND Stelara (**NOTE:** Pharmaceutical samples from the prescriber or manufacturer assistance programs do not qualify.)

C. **If you have a relapsing form of multiple sclerosis (MS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is being used as monotherapy (used by itself)
   3. You have previously tried TWO medications indicated for the treatment of multiple sclerosis (MS) (**NOTE**: The following medications are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)

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NATALIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms goes away and returns), and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, renewal also requires ONE of the following:**
   1. **If you have received at least 12 months of Tysabri therapy, renewal also requires** that you have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tysabri
   2. **If you have only received 6 months of Tysabri therapy, renewal also requires** that you are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

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NECITUMUMAB (NSA)

Generic	Brand			
NECITUMUMAB	PORTRAZZA			

GUIDELINES FOR USE

Our guideline named **NECITUMUMAB (Portrazza)** requires the following rule(s) be met for approval:

A. The medication will be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body) in combination with gemcitabine and cisplatin

Commercial Effective: 07/01/20

NIVOLUMAB (NSA)

Generic	Brand			
NIVOLUMAB	OPDIVO			

GUIDELINES FOR USE

Our guideline named **NIVOLUMAB (Opdivo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (type of skin cancer that has spread or cannot be completely removed with surgery)
   2. Melanoma with lymph node involvement or metastatic (cancer that has spread to other parts of the body) disease
   3. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)
   4. Metastatic small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   5. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)
   6. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   7. Classical Hodgkin lymphoma (cHL: a type of immune system cancer)
   8. Recurrent (returning) or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has spread to other parts of the body)
   9. Locally advanced, or metastatic urothelial carcinoma (urinary system cancer)
   10. Microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer
   11. Hepatocellular carcinoma (HCC: liver cancer)
   12. Unresectable (cannot be removed by surgery) advanced, recurrent (returning) or metastatic esophageal squamous cell carcinoma (ESCC: type of cancer that affects the esophagus [tube that runs from the throat to the stomach] and has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
   2. You will not be using the requested medication with Tafinlar (dabrafenib), Mekinist (trametinib), Zelboraf (vemurafenib) or Cotellic (cobimetinib)

C. **If you have melanoma with lymph node involvement or metastatic disease, approval also requires:**
   1. You have undergone complete resection (completely removed by surgery)
   2. The requested medication will be used as an adjuvant (add-on) treatment

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NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

D. **If you have metastatic or recurrent non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
   3. The requested medication is used as first-line treatment
   4. You have NOT received Opdivo for more than 2 years
   5. You meet ONE of the following:
      a. **For metastatic NSCLC:** the requested medication will be used in combination with Yervoy (ipilimumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
      b. **For metastatic or recurrent NSCLC:** the requested medication will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

E. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your disease has worsened while on or after platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. If you have ALK mutations (type of gene mutation), your disease must have worsened after using an FDA-approved ALK-directed therapy (such as crizotinib, ceritinib)
   3. If you have EGFR mutations (type of gene mutation), your disease must have worsened after using an FDA-approved EGFR-directed therapy (such as erlotinib, gefitinib, afatinib)

F. **If you have metastatic small cell lung cancer (SCLC), approval also requires:**
   1. Your disease has gotten worse after platinum-based chemotherapy (such as cisplatin, carboplatin) and at least one other line of therapy

G. **If you have malignant pleural mesothelioma, approval also requires:**
   3. You are 18 years of age or older
   4. Opdivo will be used as first line treatment in combination with Yervoy (ipilimumab)

H. **If you have advanced renal cell carcinoma (RCC), approval also requires ONE of the following:**
   1. Opdivo will be used alone and you have previously received one prior anti-angiogenic therapy (drugs that stop tumors from growing their own blood vessels such as Sutent (sunitinib), Votrient (pazopanib), Cabometyx (cabozantinib), Inlyta (axitinib), Nexavar (sorafenib)
   2. Opdivo will be used in combination with Yervoy (ipilimumab) AND meet the following:
      a. You have intermediate or poor risk disease
      b. You have not received prior treatment for advanced renal cell carcinoma

(Criteria continued on next page)

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NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

I. **If you have classical Hodgkin lymphoma (cHL), approval also requires:**
   1. You are 18 years of age or older
   2. Your disease has relapsed or worsened after ONE of the following:
      a. Autologous hematopoietic stem cell transplantation (cells from your own body are used) and Adcetris (brentuximab vedotin)
      b. Three or more lines of systemic therapy that includes autologous hematopoietic stem cell transplantation

J. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC), approval also requires:**
   1. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

K. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
   1. Your disease has worsened during or following platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. Your disease has worsened within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

L. **If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
   3. Your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

M. **If you have hepatocellular carcinoma (HCC), approval also requires:**
   1. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
   2. You have been previously treated with Nexavar (sorafenib)

N. **If you have esophageal squamous cell carcinoma (ESCC), approval also requires:**
   1. You have previously received treatment with fluoropyrimidine and platinum-based chemotherapy (type of cancer medications)

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NUSINERSEN (NSA)

Generic	Brand			
NUSINERSEN	SPINRAZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for approval:

A. You have Spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. If you are **presymptomatic (symptoms have not yet appeared), approval also requires:**
    1. There is documentation showing you have up to three copies of survival motor neuron 2 (*SMN2: type of protein in spinal cord*) based on screening done when you were a newborn)
E. **If you are symptomatic (symptoms have appeared), approval also requires:**
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
    3. If you previously had gene therapy, you had less than expected clinical benefit with gene therapy

RENEWAL CRITERIA

Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for renewal:

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

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OBINUTUZUMAB (NSA)

Generic	Brand			
OBINUTUZUMAB	GAZYVA			

GUIDELINES FOR USE

Our guideline named **OBINUTUZUMAB (Gazyva)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
   2. Follicular lymphoma (FL: type of cancer with abnormal immune cells)
   3. Stage II bulky, III or IV follicular lymphoma

B. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. The requested medication will be used in combination with chlorambucil

C. **If you have follicular lymphoma, approval also requires:**
   1. You have relapsed after or are refractory to (your disease has returned or is resistant to) a regimen containing Rituxan (rituximab)
   2. The requested medication will be used in combination with bendamustine for the initial six cycles OR as monotherapy (the only drug used in treatment) thereafter

D. **If you have stage II bulky, III or IV follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received previous treatment for stage II bulky, III or IV follicular lymphoma
   3. The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] OR as monotherapy (the only drug used in treatment) thereafter

Commercial Effective: 07/01/20

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OCRELIZUMAB (NSA)

Generic	Brand			
OCRELIZUMAB	OCREVUS			

GUIDELINES FOR USE

Our guideline named **OCRELIZUMAB (Ocrevus)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary progressive multiple sclerosis (type of disease where body attacks its own nerves and it slowly gets worse)
   2. Relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)

B. **If you have primary progressive multiple sclerosis (PPMS), approval also requires:**
   1. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have previously tried any TWO agents indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)
      b. You show signs of severe disease requiring high-efficacy disease modifying therapy (DMT) such as high lesion (affected areas) volume and/or count, walking disability, or rapid decline

Commercial Effective: 01/01/21

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OFATUMUMAB (NSA)

Generic	Brand			
OFATUMUMAB	ARZERRA			

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB (Arzerra)** requires the following rule(s) be met for approval:

A. You have chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
B. **If you have previously untreated chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. Fludara (fludarabine)-based therapy is considered inappropriate for you
   3. The requested medication will be used in combination with chlorambucil
C. **If you have relapsed chronic lymphocytic leukemia (type of blood and bone marrow cancer that has returned), approval also requires:**
   1. The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide
D. **If you are requesting extended treatment of chronic lymphocytic leukemia, approval also requires:**
   1. You are in complete or partial response
   2. You have received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia
E. **If you have refractory chronic lymphocytic leukemia, approval also requires:**
   1. You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

Commercial Effective: 09/14/20

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OLARATUMAB (NSA)

Generic	Brand			
OLARATUMAB	LARTRUVO			

GUIDELINES FOR USE

Our guideline named **OLARATUMAB (Lartruvo)** requires the following rule(s) be met for approval:

A. You have soft tissue sarcoma (STS: type of cancer that starts in soft tissues like muscles/tendons)
B. The request is for continuation of Lartruvo therapy (you are currently on Lartruvo)
C. The requested medication will be used in combination with doxorubicin for the first 8 cycles
D. The histologic subtype of sarcoma (the type of tissue cancer such as undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen (a treatment plan that contains a specific type of cancer drug)
E. You are not responsive to curative treatment with radiotherapy or surgery

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Commercial Effective: 07/01/20

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OMALIZUMAB (NSA)

Generic	Brand			
OMALIZUMAB	XOLAIR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe persistent asthma
   2. Nasal polyps (small growths in the nose)
   3. Chronic idiopathic urticaria (severe itching with unknown cause)

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You have a positive skin prick or RAST test (type of blood test to identify what you're allergic to) to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a documented baseline IgE (type of antibody that is produced by your immune system if you have an allergy) serum level greater than or equal to 30 IU/mL
   5. You previously had treatment with medium, high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol or formoterol), long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   6. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
   7. Xolair will be used as add-on maintenance treatment
   8. You are not using the requested medication at the same time with Dupixent or anti-IL5 (interleukin-5) asthma biologic such as Nucala, Cinqair, Fasenra

C. **If you have nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response to nasal corticosteroids
   3. Xolair will be used as add-on maintenance treatment

D. **If you have chronic idiopathic urticaria, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You still experience hives on most days of the week for at least 6 weeks
   9. You have tried a high dose H1 antihistamine (type of allergy medication such as four-fold dosing of Clarinex or Xyzal) AND leukotriene antagonist (type of allergy medication such as montelukast) for at least 2 weeks

OMALIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe persistent asthma
   2. Chronic idiopathic urticaria (severe itching with unknown cause)

B. **If you have moderate to severe persistent asthma, renewal also requires:**
   1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   2. You have shown a clinical response with ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from baseline before treatment
      d. Reduction in severity or frequency of asthma-related symptoms which may include wheezing, shortness of breath, or coughing

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Commercial Effective: 01/01/21

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ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

Generic	Brand			
ONASEMNOGENE ABEPARVOVEC-XIOI	ZOLGENSMA			

GUIDELINES FOR USE

Our guideline named **ONASEMNOGENE ABEPARVOVEC-XIOI (Zolgensma)** requires the following rule(s) be met for approval:

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You are less than 2 years of age
C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. You have documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (SMN1: type of protein in spinal cord) mutations such as deletions and/or point mutations
E. You do NOT have anti-adeno-associated virus vector (anti-AAV9) antibody titers (amount of a type of immune system cells in blood) greater than 1:50 as determined by an enzyme linked immunosorbent assay (ELISA: type of lab test)
F. You do NOT have advanced spinal muscular atrophy (SMA) such as complete paralysis of the limbs or permanent ventilator dependence

Commercial Effective: 07/01/20

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PACLITAXEL PROTEIN-BOUND (NSA)

Generic	Brand			
PACLITAXEL PROTEIN-BOUND	ABRAXANE			

GUIDELINES FOR USE

Our guideline named **PACLITAXEL (Abraxane)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC: cancer that is in the advanced stage or that has spread to other parts of the body)
   3. Small Cell Lung Cancer (SCLC)
   4. Metastatic adenocarcinoma of the pancreas (pancreas cancer that has spread to other parts of the body)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have tried a chemotherapy regimen (cancer-treating medications) containing an anthracycline (cancer drug such as doxorubicin or epirubicin) or paclitaxel

C. **If you have metastatic adenocarcinoma of the pancreas, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine

Commercial Effective: 07/01/20

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PALIVIZUMAB (NSA)

Generic	Brand			
PALIVIZUMAB	SYNAGIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You are less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)

B. **If you are less than 12 months old, you must meet ONE of the following**:
   1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
   2. You are profoundly immunocompromised during RSV season (your body cannot fight off infections)
   3. You have received a solid-organ transplant during RSV season
   4. You have congenital (starting from birth) heart disease conditions at birth such as: acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
   5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
   6. You were born premature at less than 29 weeks (gestational age)
   7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely

C. **If you are less than 24 months old, you must meet ONE of the following:**
   1. You are profoundly immunocompromised during RSV season (a condition where your body cannot fight off infections)
   2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy
   3. You have received a solid-organ transplant during RSV season

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PALIVIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You are under 24 months old
B. You meet **ONE** of the following:
   1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during respiratory syncytial virus (RSV: type of lung and respiratory tract infection) prevention season (mid-September to mid-May)
   2. This request is for a second year of coverage and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy

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Commercial Effective: 07/01/20

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PANITUMUMAB (NSA)

Generic	Brand			
PANITUMUMAB	VECTIBIX			

GUIDELINES FOR USE

Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body) with wild-type RAS gene (a gene called RAS when it is found in its natural, unchanged form). Wild-type RAS is defined as wild-type in both the KRAS gene and NRAS gene, as determined by a Food and Drug Administration (FDA)-approved test for this use
B. You must meet ONE of the following:
    1. Vectibix will be used as monotherapy (the only drug used to treat your cancer) AND you have been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing cancer treatment (chemotherapy)
    2. Vectibix will be used in combination with FOLFOX (regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

Commercial Effective: 07/01/20

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PATISIRAN (NSA)

Generic	Brand			
PATISIRAN	ONPATTRO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You are 18 years of age or older
C. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
    1. Biopsy (surgical removal of a sample) of tissue/organ to confirm amyloid (abnormal protein that can build up in any tissue or organ) presence AND chemical typing to confirm the presence of TTR protein
    2. DNA genetic sequencing (lab test for genes) to confirm hereditary transthyretin-mediated amyloidosis (hATTR)
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), or a physician at an amyloidosis treatment center (center that treats a certain type of genetic disease), or medical geneticist
E. You have Stage 1 or 2 polyneuropathy (nerve damage/pain all over your body)

RENEWAL CRITERIA

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You have not progressed to stage 3 polyneuropathy as evidenced by functional decline such as being wheelchair-bound or bedridden

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Commercial Effective: 07/01/20

PEGAPTANIB (NSA)

Generic	Brand			
PEGAPTANIB SODIUM	MACUGEN			

GUIDELINES FOR USE

Our guideline named **PEGAPTANIB (Macugen)** requires the following rule(s) be met for approval:

1. You have neovascular (wet) age-related macular degeneration (a chronic eye disorder that causes blurred vision or a blind spot in your visual field)
2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina specialist

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Commercial Effective: 07/01/20

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PEGLOTICASE (NSA)

Generic	Brand			
PEGLOTICASE	KRYSTEXXA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGLOTICASE (Krystexxa)** requires the following rules be met for approval:

A. You have chronic gout that is refractory to conventional therapy (resistant to standard treatments)
B. You are 18 years of age or older
C. You have symptomatic gout as shown by **ONE** of the following:
   1. At least 3 or more gout flares in the previous 18 months
   2. History of at least 1 gout tophus (uric acid crystallizes in joints like hands/feet)
   3. Gouty arthritis (severe pain and inflammation in joints due to gout)
D. You had a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications such as allopurinol, lesinurad
E. You do not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (you are missing an enzyme that helps red blood cells work properly)
F. You will not be on urate-lowering therapy (such as xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) at the same time as using pegloticase
G. You have experienced failure, contraindication (medical reason why you cannot use), intolerance or inadequate response to previous therapy with a maximum tolerated dose for TWO conventional gout medications for at least 3 months (such as allopurinol, probenecid, lesinurad)

RENEWAL CRITERIA

Our guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level below 6 mg/dL for renewal.

Commercial Effective: 07/01/20

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PEMBROLIZUMAB (NSA)

Generic	Brand			
PEMBROLIZUMAB	KEYTRUDA			

GUIDELINES FOR USE

Our guideline named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that has spread to other parts of the body or cannot be completely removed with surgery)
   2. Melanoma with involvement of lymph node(s) following complete resection (you have a type of skin cancer that involves the immune system after surgical removal)
   3. Non-small cell lung cancer
   4. Metastatic small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   5. Head and neck squamous cell carcinoma (type of neck cancer)
   6. Classical Hodgkin lymphoma (type of immune system cancer)
   7. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
   8. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (type of urinary system cancer)
   9. Unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (type of cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)
   10. Recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (type of cancer in the stomach/lower part of throat)
   11. Recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus (type of throat/esophagus cancer)
   12. Recurrent or metastatic cervical cancer
   13. Hepatocellular carcinoma (liver cancer)
   14. Recurrent locally advanced or metastatic Merkel cell carcinoma (type of skin cancer)
   15. Advanced renal cell carcinoma (kidney cancer)
   16. Advanced endometrial carcinoma (type of cancer that starts in the uterus)
   17. Bladder cancer
   18. Unresectable or metastatic solid tumors (type of cancer that cannot be removed with surgery or has spread to other parts of the body)
   19. Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned or has spread to other parts of the body)
   20. Unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC: type of colon or rectal cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)

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PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

21. Locally recurrent unresectable or metastatic Triple-Negative Breast Cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)

B. **If you have melanoma (skin cancer) with involvement of lymph node(s) after complete surgical removal, approval also requires:**
   1. The requested drug will be used as add-on (adjuvant) treatment

C. **If you have metastatic nonsquamous non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
   2. The medication is used in combination with pemetrexed and platinum chemotherapy
   3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

D. **If you have metastatic squamous non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
   2. The medication is used in combination with carboplatin and either paclitaxel or nab-paclitaxel

E. **If you have non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for NSCLC (it is being used as first-line treatment)
   2. The medication will be given as a single agent (not given in combination with chemotherapy)
   3. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
   4. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   5. You meet **ONE** of the following:
      a. You have stage III non-small cell lung cancer AND are not a candidate for surgical resection (removal) or definitive chemoradiation
      b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

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PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

F. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. The medication will be given as a single agent (it is not given in combination with chemotherapy)
   2. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
   3. You experienced disease progression (disease has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
   4. You meet **ONE** of the following:
      a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (gene mutations)
      b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after ALK-directed therapy such as Xalkori (crizotinib) or Zykadia (ceritinib)
      c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after EGFR-directed therapy such as Tarceva (erlotinib), Iressa (gefitinib) or Gilotrif (afatinib)

G. **If you have metastatic small cell lung cancer (SCLC), approval also requires:**
   1. You experienced disease progression (has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin
   2. You have received at least one other prior line of therapy

H. **If you have metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC), approval also requires:**
   1. The medication is used as a first line treatment
   2. You meet **ONE** of the following:
      a. The medication will be given in combination with platinum and fluorouracil (FU)
      b. The medication will be given as a single agent AND the tumors have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test

I. **If you have recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), approval also requires:**
   1. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
   2. The medication will be given as a single agent

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PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

J. **If you have classical Hodgkin lymphoma (cHL), approval also requires ONE of the following:**
   1. You have refractory classical Hodgkin lymphoma (disease is resistant to treatment)
   2. You have relapsed (disease has returned) after 2 or more prior lines of therapy

K. **If you have primary mediastinal large B-cell lymphoma (PMBCL), approval also requires ONE of the following:**
   1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
   2. You have relapsed (disease has returned) after 2 or more prior lines of therapy

L. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
   1. You are not eligible to receive cisplatin-containing chemotherapy and your tumors have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
   2. You are not eligible for any platinum-containing chemotherapy regardless of PD-L1 (type of protein) status
   3. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
   4. You experienced disease progression (has gotten worse) within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin

M. **If you have bladder cancer, approval also requires:**
   1. You have Bacillus Calmette-Guerin (BCG; a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a group of abnormal cells that have not spread) with or without papillary tumors
   2. You are ineligible for or have chosen not to undergo cystectomy (surgery to remove part of or all of the urinary bladder)

N. **If you have unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient, approval also requires ONE of the following:**
   1. You have a solid tumor that has progressed (gotten worse) after using prior treatment and have no satisfactory alternative treatment options
   2. You have colorectal cancer that has progressed (gotten worse) following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

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PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

O. **If you have recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have tumors that have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test
   2. You experienced disease progression (has gotten worse) on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy (treatment for a type of protein present in the cancer)

P. **If you have recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus, approval also requires:**
   1. You have tumors that have PD-L1 (programmed death-ligand 1; a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
   2. You experienced disease progression (has gotten worse) after one or more prior lines of systemic therapy (treatment that spreads throughout the bloodstream)

Q. **If you have recurrent or metastatic cervical cancer, approval also requires:**
   1. You experienced disease progression (has gotten worse) on or after chemotherapy
   2. You have tumors that have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test

R. **If you have hepatocellular carcinoma, approval also requires:**
   1. You have previously been treated with sorafenib

S. **If you have advanced renal cell carcinoma (RCC), approval also requires:**
   1. You have not received prior systemic chemotherapy treatment (therapy that travels throughout the bloodstream) for renal cell carcinoma (it is used as first line treatment)
   2. The medication is used in combination with axitinib

T. **If you have advanced endometrial carcinoma, approval also requires:**
   1. The medication is used in combination with lenvatinib (Lenvima)
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You experienced disease progression following prior systemic therapy (disease has gotten worse after previous treatment)
   4. You are not a candidate for curative surgery or radiation

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PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

U. **If you have unresectable or metastatic solid tumors, approval also requires:**
   1. Your solid tumors are tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food Drug Administration (FDA)-approved test
   2. Your disease has worsened following prior treatment and you have no alternative treatment options

V. **If you have recurrent or metastatic cutaneous squamous cell carcinoma, approval also requires:**
   1. Your disease is not curable by surgery or radiation

W. **If you have unresectable or metastatic MSI-H or dMMR colorectal cancer, approval also requires:**
   1. Keytruda is being used as first-line treatment

X. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), approval also requires:**
   1. The medication is used in combination with chemotherapy
   2. You have tumors that have PD-L1 (programmed death-ligand 1; a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test

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Commercial Effective: 01/01/21

PEMETREXED (NSA)

Generic	Brand			
PEMETREXED DISODIUM	ALIMTA			

GUIDELINES FOR USE

Our guideline named **PEMETREXED (Alimta)** the following rules be met for approval:

A. You have one of the following diagnoses:
   1. Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   2. Metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   3. Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC)
   4. Malignant pleural mesothelioma (cancer of the protective lining of the lung)

B. **If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with cisplatin for initial treatment
   2. The requested medication is being used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy

C. **If you have metastatic, non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used for initial (starting) treatment
   2. The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
   3. You do NOT have EGFR (Epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations (types of gene mutations)

D. **If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used as a single agent
   2. You have received prior chemotherapy

E. **If you have malignant pleural mesothelioma (cancer of the protective lining of the lung), approval also requires:**
   1. The requested medication is being used in combination with cisplatin for initial (starting) treatment
   2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

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PERTUZUMAB (NSA)

Generic	Brand			
PERTUZUMAB	PERJETA			

GUIDELINES FOR USE

Our guideline named **PERTUZUMAB (Perjeta)** requires the following rule(s) be met for approval:

A. You have a diagnosis of HER2- positive metastatic breast cancer (breast cancer that has spread to other body parts and that tests positive for a protein called human epidermal growth factor receptor 2), OR HER2- positive locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR HER2- positive early breast cancer

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have not received prior therapy with an anti-HER2 agent (drug that works against a protein called human epidermal growth factor receptor 2) or chemotherapy for metastatic disease (cancer treatment for disease that has spread to other parts of the body)
   2. The requested medication will be used in combination with trastuzumab and docetaxel

C. **If you have locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), you must also meet ALL of the below:**
   1. The requested drug will be used in the neoadjuvant setting (given before surgery); and
   2. The requested drug will be used in combination with trastuzumab and chemotherapy (cancer drug treatment) as part of a complete drug regimen for early breast cancer

D. **If you have early breast cancer, approval also requires:**
   1. You are at a high risk of recurrence (cancer returning)
   2. The requested drug will be used in the adjuvant setting (as an add-on)
   3. The requested drug will be used in combination with trastuzumab and chemotherapy (cancer drug treatment)

Commercial Effective: 07/01/20

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA)

Generic	Brand				
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	PHESGO				

GUIDELINES FOR USE

Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Locally advanced, inflammatory, or early breast cancer (tumor is greater than 2 cm in diameter or node positive)
   2. Early breast cancer at high risk of recurrence (returning)
   3. Metastatic breast cancer (breast cancer has spread to other parts of the body)

B. **If you have locally advanced, inflammatory or early breast cancer (tumor is greater than 2 cm in diameter or node positive), approval also requires:**
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)

C. **If you have early breast cancer at high risk of recurrence, approval also requires:**
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)

D. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive
   2. You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
   3. The requested medication is being used in combination with docetaxel

Commercial Effective: 01/01/21

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PLERIXAFOR (NSA)

Generic	Brand			
PLERIXAFOR	MOZOBIL			

GUIDELINES FOR USE

Our guideline named **PLERIXAFOR (Mozobil)** requires you meet the following rule(s) for approval:

A. You have Non-Hodgkin's lymphoma (cancer of a part of the immune system called the lymph system) or multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell)
B. The medication is prescribed by or given in consultation with a hematologist or oncologist (blood or cancer doctor)

Commercial Effective: 07/01/20

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POLATUZUMAB VEDOTIN (NSA)

Generic	Brand			
POLATUZUMAB VEDOTIN-PIIQ	POLIVY			

GUIDELINES FOR USE

Our guideline named **POLATUZUMAB VEDOTIN (Polivy)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (a type of cancer that affects your white blood cells and returns or resistant to treatment)
B. You are at least 18 years old
C. The requested drug will be used in combination with bendamustine and a rituximab product (type of cancer drug)
D. You have had at least two prior therapies.
E. You are not a candidate for autologous hematopoietic stem cell transplant (cells transferred from your own body)

Commercial Effective: 07/01/20

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PORFIMER (NSA)

Generic	Brand			
PORFIMER SODIUM	PHOTOFRIN			

GUIDELINES FOR USE

Our guideline named **PORFIMER (Photofrin)** requires that the drug is being used for one of the following conditions:

A. The reduction of blockage and palliation of symptoms (treatment focused on relief from the symptoms and stress of a serious illness) in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or,
B. Treatment of microinvasive endobronchial non-small cell lung cancer (a type of lung cancer that involves airway blockage) where surgery and radiation therapy cannot be used; or
C. Helping to lessen your symptoms with completely obstructing or partially obstructing esophageal cancer, where in the opinion of your physician, you cannot be treated with Nd:YAG laser therapy (a high intensity laser that can be used to remove cancer) or,
D. The ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy (removal of precancerous cells of the esophagus and you did not have surgical treatment for esophageal cancer)

Commercial Effective: 07/01/20

PRALATREXATE (NSA)

Generic	Brand			
PRALATREXATE	FOLOTYN			

GUIDELINES FOR USE

Our guideline named **PRALATREXATE (Folotyn)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (a type of white blood cell cancer that returns or does not fully respond to treatment).

Commercial Effective: 07/01/20

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RAMUCIRUMAB (NSA)

Generic	Brand			
RAMUCIRUMAB	CYRAMZA			

GUIDELINES FOR USE

Our guideline named **RAMUCIRUMAB (Cyramza)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced or metastatic (cancer that has spread to other parts of the body), gastric cancer or gastro-esophageal junction adenocarcinoma (cancer of the stomach or caner of the esophagus [tube that connects mouth and stomach])
   2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of your body)
   3. Metastatic colorectal cancer (type of rcolon or rectum cancer that has spread to other parts of the body)
   4. Hepatocellular carcinoma (type of liver cancer)

B. **If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:**
   1. The requested medication will be used as a single agent or in combination with paclitaxel
   2. You have experienced disease progression (disease has worsened) on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires ONE of the following:**
   1. The requested medication will be used in combination with docetaxel and you meet ONE of the following:
      a. You have experienced disease progression (disease has worsened) on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin)
      b. You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK : type of enzyme) genomic tumor abnormality AND your disease has gotten worse on an Food and Drug Administration (FDA)-approved therapy (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza
   2. The requested medication will be used in combination with erlotinib as first-line treatment AND your tumors have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 (L858R) substitution mutations

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RAMUCIRUMAB (NSA)

GUIDELINE FOR USE (CONTINUED)

D. **If you have metastatic colorectal cancer, approval also requires:**
   1. The requested medication will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
   2. You have experienced disease progression (disease has worsened) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

E. **If you have hepatocellular carcinoma, approval also requires:**
   1. The requested medication will be used as a single agent
   2. You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
   3. You have been treated with sorafenib (Nexavar)

Commercial Effective: 07/01/20

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RANIBIZUMAB (NSA)

Generic	Brand			
RANIBIZUMAB	LUCENTIS			

GUIDELINES FOR USE

Our guideline named **RANIBIZUMAB (Lucentis)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neovascular (wet) age-related macular degeneration (abnormal blood vessels form in your eye causing vision loss), diabetic macular edema (buildup of fluid in the eye affecting vision), diabetic retinopathy (damage to blood vessels in the eye due to high blood sugar), macular edema following retinal vein occlusion (buildup of fluid in eye due to vein blockage), or myopic choroidal neovascularization (abnormal blood vessels grow in the back of the eye).
B. The medication is prescribed by an ophthalmologist (doctor who specializes in medical and surgical eye disease) or retina specialist.

Commercial Effective: 07/01/20

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RAVULIZUMAB-CWVZ (NSA)

Generic	Brand			
RAVULIZUMAB-CWVZ	ULTOMIRIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare disorder that causes abnormal blood clots to form in small vessels in the kidneys)

B. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. You are 18 years of age or older
   2. There is documentation of your current weight
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   4. You have confirmed paroxysmal nocturnal hemoglobinuria as supported by **ALL** of the following via flow cytometry (type of measurement of physical and chemical qualities of cells):
      a. At least 2 different GPI-protein deficiencies (you're missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
      b. Paroxysmal nocturnal hemoglobinuria granulocyte clone size of 10% or greater
   5. You meet **ONE** of the following:
      a. You are transitioning from alternative complement inhibitor therapy (such as Soliris)
      b. You have evidence of intravascular hemolysis (blood cells break down within your blood stream) such as lactate dehydrogenase level of at least 1.5 times the upper limit of normal or hemoglobinuria (urine has substance called hemoglobin)
      c. You have history of major adverse vascular event from thromboembolism (blood clot)

C. **If you have atypical hemolytic uremic syndrome, approval also requires:**
   1. You are one month of age or older

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RAVULIZUMAB-CWVZ (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely)
B. You have shown clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (an enzyme) and hemoglobin levels) compared to baseline (before you started treatment)

Commercial Effective: 11/09/20

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RESLIZUMAB (NSA)

Generic	Brand			
RESLIZUMAB	CINQAIR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You are 18 years of age or older
C. Cinqair is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. Cinqair will be used as add-on maintenance treatment
E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
F. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
G. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
H. You are not being treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Fasenra) at the same time with requested medication

RENEWAL CRITERIA

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (type of lung test) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

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RITUXIMAB (NSA)

Generic	Brand			
RITUXIMAB	RITUXAN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Non Hodgkin's Lymphoma (NHL: type of blood cancer)
   3. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   4. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)
   6. Moderate to severe Pemphigus Vulgaris (PV: immune disease with blisters that break out on the skin and on the lining of the mouth)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried at least ONE DMARD (disease modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (Immediate Release/Extended Release)

C. **If you have Non Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)

D. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
   3. You are currently using chemotherapy at the same time with the requested medication

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RITUXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

E. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 2 years of age or older
   2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) along with the requested medication

F. **If you have moderate to severe Pemphigus Vulgaris (PV), approval also requires:**
   1. You are 18 years of age or older

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal

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Commercial Effective: 04/01/20

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RITUXIMAB-ABBS (NSA)

Generic	Brand			
RITUXIMAB-ABBS	TRUXIMA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   3. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   4. Wegener's Granulomatosis (WG: condition that causes inflammation of the blood vessels)
   5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

B. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

C. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

D. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   4. You had a previous trial of at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had a previous trial of any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (Immediate release/extended release)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ABBS (NSA)

INITIAL CRITERIA (CONTINUED)

E. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 18 years of age or older
   2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) with requested medication

RENEWAL CRITERIA

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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Commercial Effective: 04/01/20

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

Generic	Brand			
RITUXIMAB/ HYALURONIDASE, HUMAN - SQ	RITUXAN HYCELA			

GUIDELINES FOR USE

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnosis:
   1. Follicular Lymphoma (FL: type of cancer that affects a type of white blood cells)
   2. Diffuse Large B-cell Lymphoma (DLBCL: cancer that affects specific immune system cells)
   3. Chronic Lymphocytic Leukemia (blood and bone marrow cancer) in adult patients who have received or will receive at least one full dose of a rituximab product by intravenous infusion (given into the veins) before starting requested medication

B. **If you have Follicular Lymphoma (FL), approval also requires ONE of the following:**
   1. The medication will be used as a single agent if you have relapsed or refractory Follicular Lymphoma (cancer that has returned or does not fully respond to treatment)
   2. The medication will be used in combination with first line chemotherapy if you have previously untreated Follicular Lymphoma
   3. The medication will be used as a single-agent for maintenance therapy if you have achieved a complete or partial response to rituximab in combination with chemotherapy
   4. The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy if you have non-progressing (does not get worse, including stable disease) Follicular Lymphoma

C. **If you have Diffuse Large B-cell Lymphoma (DLBCL) approval also requires ONE of the following:**
   1. The medication will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or other anthracycline-based chemotherapy regimens for previously untreated Diffuse Large B-cell Lymphoma (DLBCL)

D. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires ONE of the following:**
   1. The medication will be used in combination with fludarabine and cyclophosphamide (FC)

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RITUXIMAB-PVVR (NSA)

Generic	Brand			
RITUXIMAB-PVVR	RUXIENCE			

GUIDELINES FOR USE

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
   3. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   4. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

B. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)

C. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
   3. You are using chemotherapy at the same time with requested medication

D. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 18 years of age or older
   2. You are using glucocorticoids (steroids such as methylprednisolone or prednisone) at the same time with the requested medication

Commercial Effective: 07/01/20

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ROMIDEPSIN (NSA)

Generic	Brand			
ROMIDEPSIN	ISTODAX			

GUIDELINES FOR USE

Our guideline named **ROMIDEPSIN (Istodax)** requires the following rule(s) be met for approval:

A. You have a diagnosis of cutaneous T-cell lymphoma or peripheral T-cell lymphoma (type of cancer that affects a certain type of immune system cells).
B. **If you have cutaneous T-cell lymphoma, approval also requires the following:**
   1. You had a trial of Zolinza (vorinostat), unless there is a medical reason why you cannot (contraindication) AND you are not able to tolerate oral medications.
   2. You have tried at least one form of systemic therapy (such as retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND you are able to tolerate oral medications.
C. **If you have peripheral T-cell lymphoma, approval also requires the following:**
   1. You have received at least one prior treatment.

Commercial Effective: 07/01/20

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ROMIPLOSTIM (NSA)

Generic	Brand			
ROMIPLOSTIM	NPLATE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for approval:

A. You have chronic immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
B. You are 1 year of age or older
C. You had a trial of, unless there is a medical reason why you cannot (contraindication) use, corticosteroids or immunoglobulins, or you had an insufficient response to a splenectomy (surgical removal of spleen)
D. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
E. **If you are between 1 and 17 years old, approval also requires:**
    1. You had chronic immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding) for at least 6 months

RENEWAL CRITERIA

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for renewal:

A. You have chronic immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
B. You had a clinical response, as defined by an increase in platelet count to at least 50 X 10(9)/L (at least 50,000 per microliter)

Commercial Effective: 07/01/20

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ROMOSOZUMAB (NSA)

Generic	Brand			
ROMOSOZUMAB-AQQG	EVENITY			

GUIDELINES FOR USE

Our guideline named **ROMOSOZUMAB (Evenity)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones)
B. You have not received a total of 12 months or more of Evenity therapy.
C. You meet **ONE** of the following criteria:
   1. You are at high risk for fractures defined as **ONE** of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density [BMD] T-score (measurement of how high your risk for osteoporosis is) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.
      c. No prior treatment for osteoporosis **AND** FRAX score (test for your risk of fractures) greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
   2. You are unable to use oral therapy. Reasons include upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
   3. You had an adequate trial of, intolerance to, or a contraindication to (medical reason why you cannot use) bisphosphonates such as Fosamax, Actonel, Boniva

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Commercial Effective: 07/01/20

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SACITUZUMAB (NSA)

Generic	Brand				
SACITUZUMAB GOVITECAN-HZIY	TRODELVY				

GUIDELINES FOR USE

Our guideline named **SACITUZUMAB (Trodelvy)** requires the following rule(s) be met for approval:

A. You have metastatic triple negative breast cancer (mTNBC: breast cancer that has spread to other parts of the body and does not have estrogen receptors, progesterone receptors, and human epidermal growth factor receptor 2 [HER2: type of protein])
B. You are 18 years of age or older
C. You have tried at least two previous therapies for metastatic disease (disease that has spread to other parts of the body)

Commercial Effective: 05/11/20

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SEBELIPASE ALFA (NSA)

Generic	Brand			
SEBELIPASE ALFA	KANUMA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for approval:

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol), as confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarge spleen)
B. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor), hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)
C. You meet ONE of the following:
    1. A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
    2. A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
    3. A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

RENEWAL CRITERIA

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for renewal:

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol) presenting after the first 6 months of life and not considered rapidly progressive (getting worse)
B. You have documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
    1. A relative reduction from baseline in any one of the following lipid levels (fat lab measurements such as LDL-c, Non-HDL-c, or triglycerides)
    2. Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
    3. A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

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SILTUXIMAB (NSA)

Generic	Brand			
SILTUXIMAB	SYLVANT			

GUIDELINES FOR USE

Our guideline named **SILTUXIMAB (Sylvant)** requires the following rule(s) be met for approval:

A. You have multi-centric Castleman's disease (MCD: disease that affects the lymph nodes and related tissues)
B. You are negative for both human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8)

Commercial Effective: 07/01/20

SUFENTANIL (NSA)

Generic	Brand			
SUFENTANIL CITRATE	DSUVIA			

GUIDELINES FOR USE

Our guideline named **SUFENTANIL (Dsuvia)** requires the following rule(s) be met for approval:

A. You have acute pain (sudden and severe pain)
B. You are 18 years of age or older
C. Your pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products
D. Your treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

Commercial Effective: 07/01/20

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TAFASITAMAB-CXIX (NSA)

Generic	Brand				
TAFASITAMAB-CXIX	MONJUVI				

GUIDELINES FOR USE

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of white blood cancer that has returned or did not respond to previous treatment)
B. You are 18 years of age or older
C. The requested medication will be used in combination with lenalidomide
D. You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)

Commercial Effective: 01/01/21

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TAGRAXOFUSP-ERZS (NSA)

Generic	Brand			
TAGRAXOFUSP-ERZS	ELZONRIS			

GUIDELINES FOR USE

Our guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires the following rule(s) be met for approval:

A. You have blastic plasmacytoid dendritic cell neoplasm (BPDCN: aggressive and rare disease of the bone marrow and blood that can affect multiple organs)
B. You are 2 years of age or older

Commercial Effective: 07/01/20

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TALIMOGENE LAHERPAREPVEC (NSA)

Generic	Brand			
TALIMOGENE LAHERPAREPVEC	IMLYGIC			

GUIDELINES FOR USE

Our guideline for **TALIMOGENE LAHERPAREPVEC (Imlygic)** requires the following rule(s) be met for approval:

A. You have unresectable melanoma (type of skin cancer that cannot be removed with surgery)
B. Your melanoma lesions are recurrent after initial surgery (cancer returns after surgery)
C. You do not have a history of primary or acquired immunodeficient states (conditions that weaken your immune system), leukemia (type of white blood cell cancer), lymphoma (type of cancer affecting immune system), or Acquired Immunodeficiency Syndrome (AIDS)
D. You are not currently receiving immunosuppressive therapy (treatment that weakens your immune system)
E. You are not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy
F. The request is for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions (injected into the skin layers) that are visible, palpable (can be felt), or detectable by ultrasound guidance

Commercial Effective: 07/01/20

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TEMOZOLOMIDE – IV (NSA)

Generic	Brand			
TEMOZOLOMIDE - IV	TEMODAR - IV			

GUIDELINES FOR USE

Our guideline named **TEMOZOLOMIDE (Temodar) - IV** requires you have one of the following diagnoses for approval:

A. Metastatic melanoma (type of skin cancer)
B. Anaplastic astrocytoma (type of brain tumor)
C. Glioblastoma multiforme (type of tumor affecting brain or spine)
D. Small cell lung cancer (SCLC)

Commercial Effective: 07/01/20

TEMSIROLIMUS (NSA)

Generic	Brand			
TEMSIROLIMUS	TORISEL			

GUIDELINES FOR USE

Our guideline named **TEMSIROLIMUS (Torisel)** requires the following rule(s) be met for approval:
A. You have advanced renal cell carcinoma (RCC: type of kidney cancer).

Commercial Effective: 07/01/20

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TEPROTUMUMAB-TRBW (NSA)

Generic	Brand				
TEPROTUMUMAB-TRBW	TEPEZZA				

GUIDELINES FOR USE

Our guideline named **TEPROTUMUMAB-TRBW (Tepezza)** requires the following rule(s) be met for approval:

A. You have thyroid eye disease (a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards)

Commercial Effective: 07/01/20

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THYROTROPIN ALFA FOR INJECTION (NSA)

Generic	Brand			
THYROTROPIN ALFA FOR INJECTION	THYROGEN			

GUIDELINES FOR USE

Our guideline named **THYROTROPIN ALFA FOR INJECTION (Thyrogen)** requires that the requested product is being used as adjunctive (add-on) treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease (used to destroy thyroid tissue that is left over after using another treatment and you have no signs of the disease spreading in body)

Commercial Effective: 07/01/20

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TILDRAKIZUMAB-ASMN (NSA)

Generic	Brand			
TILDRAKIZUMAB-ASMN	ILUMYA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

Commercial Effective: 04/01/20

TISAGENLECLEUCEL (NSA)

Generic	Brand			
TISAGENLECLEUCEL	KYMRIAH			

GUIDELINES FOR USE

Our guideline named **TISAGENLECLEUCEL (Kymriah)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. B-cell precursor acute lymphoblastic leukemia (ALL: type of immune system cancer)
   2. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of immune system cancer that has returned or did not fully respond to previous treatment) not otherwise specified, high grade B-cell lymphoma (type of white blood cell cancer), or DLBCL arising from follicular lymphoma (FL: type of white blood cell cancer) such as transformed follicular lymphoma

B. Treatment is prescribed by a Kymriah-certified hematologist (blood specialist) or oncologist (tumor/ cancer doctor)

C. Kymriah will be administered at a treatment center that is certified to administer Kymriah

D. You have not had a previous trial of Kymriah

E. **If you have B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:**
   1. You are 25 years of age or younger
   2. You have **ONE** of the following criteria:
      a. You are in second or greater bone marrow relapse (disease returns)
      b. You are currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT: donor cells are from another person)
      c. You have not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (you have primary refractory disease)
      d. You have not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
      e. You have Philadelphia chromosome positive (Ph+; type of gene mutation) acute lymphoblastic leukemia and meets at least **ONE** of the following:
         i. You had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
         ii. You are unable to tolerate TKI therapy
         iii. You have a medical reason why you cannot take TKI therapy (contraindication)
      f. You are not eligible for allogeneic stem cell transplantation (SCT)

F. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e., transformed follicular lymphoma (TFL)], approval also requires:**
   1. You are 18 years of age or older
   2. You meet **ALL** of the following criteria:

a. You are refractory (disease does not fully respond to treatment) or have had disease progression (gotten worse) after two or more lines of systemic therapy including rituximab and an anthracycline
b. You had disease progression or relapsed (disease worsens or returns) after autologous hematopoietic stem cell transplantation (ASCT) **OR** you are not eligible for ASCT

Commercial Effective: 07/01/20

TOCILIZUMAB – IV (NSA)

Generic	Brand			
TOCILIZUMAB - IV	ACTEMRA - IV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   4. Schimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS: inflammatory response that can be triggered by a variety of factors such as infections and certain drugs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

C. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel AND Humira

(Initial criteria continued on next page)

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TOCILIZUMAB – IV (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval also requires:**
   1. You are 2 years of age or older

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

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TRABECTEDIN (NSA)

Generic	Brand			
TRABECTEDIN	YONDELIS			

GUIDELINES FOR USE

Our guideline named **TRABECTEDIN (Yondelis)** requires the following rule(s) be met for approval:

A. You have unresectable or metastatic liposarcoma or leiomyosarcoma (cancer of the fat cells or muscles that cannot be removed with surgery or has spread to other parts of body).
B. You have previously received therapy with an anthracycline-containing regimen such as doxorubicin.

Commercial Effective: 07/01/20

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TRASTUZUMAB-ANNS

Generic	Brand			
TRASTUZUMAB-ANNS	KANJINTI			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-ANNS (Kanjinti)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The request is for adjuvant (add-on) therapy
   3. You meet **ONE** of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet **ONE** of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body), approval also requires:**
   1. You have HER2-positive tumor (you have a type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil

3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20

TRASTUZUMAB-DKST (NSA)

Generic	Brand			
TRASTUZUMAB-DKST	OGIVRI			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-DKST (Ogivri)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (cancer has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (type of cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The request is for adjuvant (add-on) therapy
   3. You meet **ONE** of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive metastatic breast cancer (you have a type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet **ONE** of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive metastatic cancer (you have a type of protein and the cancer has spread to other parts of the body) as detected by a Food and Drug Administration-(FDA)-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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Commercial Effective: 07/01/20

TRASTUZUMAB-DTTB (NSA)

Generic	Brand				
TRASTUZUMAB-DTTB	ONTRUZANT				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB- DTTB (Ontruzant)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. The request is for adjuvant (add-on) therapy
   2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
   4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

C. **If you have metastatic breast cancer, approval also requires:**
   3. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   4. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
   5. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-DTTB (NSA)

GUIDELINES FOR USE (CONTINUED)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

Generic	Brand			
TRASTUZUMAB	HERCEPTIN			
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Breast cancer
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously tried chemotherapy for metastatic disease (disease has spread to other areas of body)
   3. If you are requesting Herceptin Hylecta, you must be 18 years of age or older
   4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

C. **If you have breast cancer, approval also requires:**
   1. The request is for adjuvant therapy (add-on therapy to main treatment)
   2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) tumor as detected by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

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GUIDELINES FOR USE (CONTINUED)

4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri
5. If you are requesting Herceptin Hylecta, you must be 18 years of age or older

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma (stomach-throat cancer that has spread), approval also requires:**
1. The request is for Herceptin (not Herceptin Hylecta)
2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) metastatic breast cancer as detected by a Food and Drug Administration (FDA)-approved test
3. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
4. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20

TRASTUZUMAB-PKRB (NSA)

Generic	Brand				
TRASTUZUMAB-PKRB	HERZUMA				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-PKRB (Herzuma)** requires the following rule(s) be met for approval:

E. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

F. **If you have breast cancer, approval also requires:**
   4. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   5. The request is for adjuvant (add-on) treatment
   6. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
   7. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

G. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
   3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

(Criteria continued on next page)

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TRASTUZUMAB-PKRB (NSA)

GUIDELINES FOR USE (CONTINUED)

H. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive tumor (type of protein found in stomach cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20

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TRASTUZUMAB-QYYP (NSA)

Generic	Brand			
TRASTUZUMAB-QYYP	TRAZIMERA			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB- QYYP (Trazimera)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. etastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. The request is for adjuvant (add-on) therapy
   2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

(Criteria continued on next page)

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TRASTUZUMAB-QYYP (NSA)

GUIDELINES FOR USE (CONTINUED)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20

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USTEKINUMAB

Generic	Brand			
USTEKINUMAB	STELARA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe active Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. Your current weight has been documented

C. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) OR dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

E. **If you have moderate to severe active Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. Your current weight has been documented

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract

B. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), renewal also requires:**
   5. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis (PsA), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
   2. Your current weight has been documented

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VEDOLIZUMAB (NSA)

Generic	Brand			
VEDOLIZUMAB	ENTYVIO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract) OR moderate to severe Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe Crohn's Disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

C. **If you have moderate to severe Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Xeljanz (Immediate Release/Extended Release)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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VEDOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   2. Moderate to severe Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

Commercial Effective: 04/01/20

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VESTRONIDASE ALFA-VJBK (NSA)

Generic	Brand			
VESTRONIDASE ALFA-VJBK	MEPSEVII			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for approval:

A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
B. The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
C. You have a documented urinary GAG (glycosaminoglycan: type of chemical that builds up when your body cannot break it down) level of greater than three times the upper level of normal based on the laboratory test
D. Your diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of beta-glucuronidase enzyme activity deficiency (you don't have a protein that breaks down a chemical) or genetic testing
E. You have at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
   1. Enlarged liver and spleen
   2. Joint limitations
   3. Airway obstructions or pulmonary (lung/breathing) dysfunction
F. You have not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII
G. You have limitation in mobility, but you still have ambulatory (walking) capacity for the six-minute walk test (6MWT) to be measured and evaluated

RENEWAL CRITERIA

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for renewal:

A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
B. You have improved, maintained, or demonstrated less than expected decline in ambulatory (walking) ability based on a six-minute walk test compared to baseline

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VILTOLARSEN (NSA)

Generic	Brand				
VILTOLARSEN	VILTEPSO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VILTOLARSEN (Viltepso)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **VILTOLARSEN (Viltepso)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

Commercial Effective: 01/01/21

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VINCRISTINE LIPOSOMAL (NSA)

Generic	Brand			
VINCRISTINE SULFATE LIPOSOMAL	MARQIBO			

GUIDELINES FOR USE

Our guideline named **VINCRISTINE SULFATE LIPOSOMAL (Marqibo)** requires the following rule(s) be met for approval:

A. You have Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (a type of cancer that does not have a certain gene mutation)
B. You meet ONE of the following criteria:
   1. You have experienced a relapse (disease returns) two or more times
   2. You have experienced disease progression after treatment with two or more anti-leukemia therapies

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Commercial Effective: 07/01/20

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VORETIGENE NEPARVOVEC-RZYL (NSA)

Generic	Brand			
VORETIGENE NEPARVOVEC-RZYL	LUXTURNA			

GUIDELINES FOR USE

Our guideline named **VORETIGENE NEPARVOVEC-RZYL (Luxturna)** requires the following rule(s) be met for approval:

A. You have confirmed biallelic RPE65 mutation-associated retinal dystrophy (loss of vision in one or both eyes due to a gene mutation)
B. You are 3 years of age or older
C. Your diagnosis of biallelic RPE65 (type of gene) mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
D. The requested medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retinal specialist
E. You have a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
F. You have enough retinal cells as demonstrated by sufficient retinal thickness
G. You do **NOT** have pre-existing eye conditions that may lead to blindness independently of RPE65 (type of gene) -mutation associated retinal dystrophy. Pre-existing eye conditions may include leukemia (type of cancer) with Central Nervous System/optic nerve involvement, macular edema (fluid buildup in the eye) or cytomegalovirus retinitis (inflammation of the retina of the eye that can lead to blindness)
H. You have **NOT** previously received gene therapy (including Luxturna) for the treatment of vision loss
I. The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

Commercial Effective: 07/01/20

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ZIV-AFLIBERCEPT (NSA)

Generic	Brand			
ZIV-AFLIBERCEPT	ZALTRAP			

GUIDELINES FOR USE

Our guideline named **ZIV-AFLIBERCEPT** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (cancer has spread in body)
B. You previously had a trial of an oxaliplatin-containing regimen (such as FOLFOX)
C. You will be using the requested medication with fluorouracil, leucovorin, irinotecan (FOLFIRI) at the same time

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Commercial Effective: 07/01/20

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