Medicare Part B Step Therapy Policy

Policy Scope: This policy applies to Medicare Advantage product lines within Presbyterian Health Plan, Inc. and Presbyterian Insurance Company, Inc. (Presbyterian).

Policy Purpose: The purpose of this policy is to assist providers in effectively selecting medical drugs for Medicare Advantage members. This policy contains indications from the Centers for Medicare & Medicaid Services (CMS) and the Federal Drug Administration (FDA) for prescribing medications and products that help assist members in achieving cost savings.

Policy: Below are CMS indications for prescribing the following:

- Evenity (romosozumab-aqqg)
- Viscosupplementation
- Intra-Articular Steroids
- BOTOX® (onabotulinumtoxinA)
- Avastin (bevacizumab)
- Rituxan (rituximab)
- Intravenous Immune Globulin (IVIG)
- Filgrastim/Pegfilgrastim
- Vabysmo (faricimab-svoa)
- Tepezza (teprotumumab-trbw)
- Targeted Immunomodulators
    - Actemra (tocilizumab)
    - Entyvio
    - Infliximab (Avsola, Inflectra, Renflexis, unbranded infliximab)
    - Remicade
    - Orencia
    - Stelara
- Skyrizi
- Monoclonal Antibodies for Alzheimer's
    - Leqembi
    - Kisunla

Evenity (romosozumab-aqqg):

Source: FDA prescribing information, Thomson Micromedex, DrugDex Compendium

I. Evenity is considered a medically reasonable and necessary treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy
   a. Limit duration of use to 12 monthly doses
   b. **Step Therapy Requirement:**
      i. Documented trial and failure of, or contraindication to, one of the following:
         1. zoledronic acid, Prolia (denosumab) or teriparatide
      ii. OR women at high risk for fracture, which is defined as a history of osteoporotic fracture, multiple risk factors for fracture or intolerance to other available osteoporosis therapies
      iii. OR women at very high risk of fracture defined as:
         1. Recent fracture
         2. Fracture while on treatment for osteoporosis
         3. History of multiple fractures
         4. Has a very low T-score, less than -3.0
         5. Has a very high FRAX, greater than 30%

Viscosupplementation:

Source: Local coverage determinations (LCD) ID: L35427: LCD Title: Hyaluronan Acid Therapies for Osteoarthritis of the Knee

I. Viscosupplementation therapy for the knee via intra-articular injections of hyaluronic preparations are considered medically reasonable and necessary when **all** of the following conditions are met:
   a. The member is symptomatic. Such symptoms may include pain that interferes with the activities of daily living, such as ambulation and prolonged standing, or pain interrupting sleep, as well as crepitus and/or knee stiffness
   b. The clinical diagnosis is supported by radiologic evidence of osteoarthritis of the knee, such as joint space narrowing, subchondral sclerosis, osteophytes and subchondral cysts
   c. If appropriate, other diagnoses have been excluded by appropriate evaluation and management services or laboratory and imaging studies (i.e., the pain and functional disability is not considered likely to be due to a diagnosis other than osteoarthritis of the knee)
   d. The member has failed at least three months of conservative therapy. Conservative therapy is defined as:
      i. Nonpharmacologic therapy (e.g., home exercise program, education, weight loss, physical therapy if indicated)

ii. If not contraindicated, simple analgesics (e.g., acetaminophen) and/or non-steroidal anti-inflammatory drugs per hyaluronan product prescribing information

e. The member has failed to respond to aspiration of the knee when effusion is present and intra-articular corticosteroid injection therapy when inflammation is a significant component of the member's symptoms and intra-articular corticosteroids are not contraindicated

f. Step Therapy Requirement:

i. Documented trial and failure of, or contraindication to, Durolane (hyaluronate sodium) **and** Euflexxa (hyaluronate sodium)

Note: Presbyterian considers all other indications experimental and investigational because their clinical value for these indications have not been established.

Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses).

Intra-Articular Steroids

Source: FDA Prescribing Information

I. **Intra-articular steroids** are considered medically reasonable and necessary when administered for treatment of osteoarthritis and other FDA-labeled indications

a. **Step Therapy Requirement:**

i. Documented trial and failure of Kenalog or methylprednisolone acetate

Botox (onabotulinumtoxinA)

Source: LCD ID: L38809, LCD Title: Botulinum Toxins

I. Botulinum toxins (BOTOX®) are considered medically reasonable and necessary when administered for treatment of FDA-labeled indications and off-label indications (as applicable) below:

a. Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication

i. Step Therapy Requirement:

1. Documented failure/intolerance to at least two oral medications (oxybutynin, trospium, tolterodine, solifenacin, Myrbetriq)

b. Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication

i. Step Therapy Requirement:

1. Documented inadequate response or intolerant to two anticholinergic medications used for urinary incontinence, such as oxybutynin and tolterodine

c. Treatment of neurogenic detrusor overactivity (NDO) in pediatric members 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication

d. Prophylaxis of headaches in adult members with chronic migraine (i.e., a migraine that lasts at least 15 days per month with a headache lasting four hours a day or longer)
    i. **Step Therapy Requirement:**
        1. Documented trials and failures of at least two prophylactic therapies from the following classes: antihypertensives, antidepressants, anticonvulsants, for at least 60 days each
        2. Antihypertensives: beta-blockers (Propranolol, Metoprolol, Nadolol, Atenolol), calcium channel blockers (Verapamil)
        3. Antidepressants: Amitriptyline, Venlafaxine
        4. Anticonvulsants: Topiramate, Divalproex
e. Treatment of spasticity in members 2 years of age and older (1.4)
f. Treatment of cervical dystonia in adult members to reduce the severity of abnormal head position and neck pain
g. Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult members
    i. **Step Therapy Requirement:**
        1. Documented trials and failures of drying agents such as topical aluminum chloride (DrySol, Xerac AC or Hypercare)
h. Treatment of blepharospasm associated with dystonia in members 12 years of age and older
i. Treatment of strabismus in members 12 years of age and older

II. Off-label indications for onabotulinumtoxinA (BOTOX®) may be considered medically reasonable and necessary in members for the following conditions:

a. Esophageal achalasia in adults who are considered poor surgical candidates
b. Chronic anal fissure for members with inadequate response to conservative or pharmacologic treatment
c. Essential hand tremor for members with a high amplitude tremor that disrupts activities of daily living, who have had inadequate response to oral pharmacotherapy such as propranolol and primidone
d. Focal limb dystonia
e. Hemifacial spasm in adults (cranial nerve VII disorder)
f. Isolated oromandibular dystonia in adults
g. Laryngeal dystonia (spastic dysphonia) for adductor type (ADSD)
h. Bothersome simple motor tics in adolescents and adults when the benefits of treatment outweigh the risks
i. Severely disabling or aggressive vocal tics in older adolescents and adults when the benefits of treatment outweigh the risks

Limitations: Localization procedures would not be expected for easily targeted muscles and, therefore, would not be considered medically reasonable and necessary.

Cosmetic procedures are not a covered benefit under Medicare.

Treatment of wrinkles, also referred to as glabellar lines, smoker's lines, crow's feet, laugh lines and aging neck, using botulinum toxins is considered a cosmetic procedure and is not covered under Medicare.

Avastin (bevacizumab)

Source: National Comprehensive Cancer Network (NCCN), Thomson Micromedex, DrugDex Compendium

I. Presbyterian considers Avastin medically necessary based on Category 1 or 2 recommendations in the NCCN compendium or Class I or II recommendations in the Thomson Micromedex DrugDex compendium
    a. **Step Therapy Requirement:**
        i. Documented trial and failure of, or contraindication to, Zirabev

Rituxan (rituximab)

Source: NCCN, Thomson Micromedex, DrugDex Compendium

I. Presbyterian considers Rituxan medically necessary based on Category 1 or 2 recommendations in the NCCN compendium, or there must be a Class I or II recommendation in the Thomson Micromedex DrugDex compendium
    a. **Step Therapy Requirement:**
        i. Documented trial and failure of or contraindication to Ruxience
II. Rheumatoid arthritis (RA) in combination with methotrexate in adult members with moderately to severely active RA who have inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies
    a. **Step Therapy Requirement:**
        i. Documented trial and failure of, or contraindication to, Ruxience

Intravenous Immune Globulin (IVIG)

Source: LCD L35093 Intravenous Immune Globulin (IVIG)

Step Therapy Requirement for All Indications:

a. Documented trial and failure of, or contraindication to, Gamunex-C. Medicare will provide coverage for IVIG when it is used in treatment of the following conditions:
    i. Primary immunodeficiency
    ii. Immune-mediated thrombocytopenia (ITP)
    iii. Kawasaki disease
    iv. Human immunodeficiency virus (HIV) (for pediatric use only)
    v. Bone marrow transplantation
    vi. Chronic B-cell lymphocytic leukemia

vii. Primary humoral immunodeficiencies: IVIG is covered for use as replacement therapy in members with primary immunodeficiencies in whom severe impairment of antibody capacity is present in the following conditions:
    1. Congenital agammaglobulinemia
    2. Common variable immunodeficiency
    3. Wiskott-Aldrich syndrome
    4. X-linked immunodeficiency with hyper-IgM
    5. Severe combined immunodeficiencies
    6. Deficient qualitative or quantitative antibody production
    7. Have at least one bacterial infection directly attributable to this deficiency
viii. Idiopathic thrombocytopenic purpura (ITP)
    1. IVIG is covered for both acute and chronic refractory ITP
ix. Acute ITP, IVIG is covered for:
    1. Management of acute bleeding due to severe thrombocytopenia (platelet counts usually less than 30,000/µl)
    2. To increase platelet counts prior to invasive surgical procedures (e.g., splenectomy)
    3. Severe thrombocytopenia (platelet counts less than 20,000/µl) considered to be at risk for intracerebral hemorrhage
x. Chronic refractory ITP is covered for members who meet all the following conditions:
    1. Prior treatment with corticosteroids and splenectomy, except when contraindicated
    2. Duration of illness of greater than six months
    3. No concurrent illness/disease explaining thrombocytopenia
    4. Platelet counts persistently at or below 20,000/µl
xi. Chronic lymphocytic leukemia (CLL): IVIG is covered when used to prevent recurrent bacterial infections in members with B-cell chronic lymphocytic leukemia who meet all the following conditions:
    1. Must have unequivocally documented CLL
    2. An immunoglobulin G (IgG) level of less than 600 mg/dl
    3. Recent history of serious bacterial infection(s) requiring either oral or parenteral antibiotic therapy
xii. Human immunodeficiency virus (HIV) infection: IVIG is covered for members infected with HIV to reduce significant bacterial infection who meet all the following conditions:
    1. Younger than 14 years old
    2. Evidence of either qualitative or quantitative humoral immunologic defects
    3. Current bacterial infections, despite appropriate antimicrobial prophylaxis

xiii. Chronic inflammatory demyelinating polyneuritis (CIDP): The diagnosis of this condition must be documented in the medical record and must be consistent with published diagnostic criteria for this condition
    1. The member has CIDP as defined by EFNS/PNS Guidelines (J Peripheral Nervous System. 2010; 15: 1-9), Koski Guidelines (J Neuro Sci. 2009; [1-2]: 1-8), or AAN Guidelines (Neurology. 2012; 78: 1009-1015)
    2. Members responsive to an initial course of IVIG are eligible for maintenance therapy coverage only if unequivocal neurological deterioration occurs at some future point in time. It is expected an initial trial of IVIG for CIDP to last three months. If there is not any significant improvement as outlined in the above guidelines, then therapy should be discontinued. Maintenance therapy should be at the lowest dose of IVIG possible. Although members will vary in response, after a one- to two-year period of stable therapy, attempts to reduce dosing should occur. Continued dosing without attempts to reduce the dosing and check responses is considered inappropriate and subject to pre- and post-pay reviews

xiv. Multifocal motor neuropathy
    1. IVIG may be considered for first-line treatment of members who have progressive, symptomatic multifocal motor neuropathy that has been diagnosed on the basis of electrophysiology findings that rule out other possible conditions that may not respond to this treatment

xv. Dermatomyositis, polymyositis: The routine use of IVIG is not usually recommended for polymyositis or dermatomyositis. IVIG may be used in members with severe active illness for whom other interventions have been unsuccessful, have become intolerable or have been contraindicated
    1. Refractory myopathies are, by definition, diseases that are unresponsive or poorly responsive to high-dose steroids either alone or in combination with other immunosuppressive agents (azathioprine, cyclophosphamide, methotrexate). Also included in this definition are members responsive to but intolerant of continual high-dose steroids as reflected by severe adverse side effects (e.g., steroid myopathy or severe osteoporosis) in whom trials of other immunosuppressive agents, unless contraindicated, have been unsuccessful in achieving significant long-term steroid dose reductions
    2. Three other coverage conditions which must all be met, in addition to the above, are:
        a. Biopsy-proven disease (or unequivocal diagnostic features through history, exam and electromyography [EMG]/nerve conduction [NCS] studies)
        b. At least a four-month trial of prednisone or prednisone combination therapies

c. Lack of response/poor response to therapies as reflected by persistently elevated serum creatine kinase (CK) levels or lack of improvement on muscle strength improvement scales

xvi. Inclusion body myositis – Please see limitation section below:

Use of IVIG in Other Specific Situations

a. Certain unusual uses of IVIG may be covered as described below:
   i. **Autoimmune hemolytic anemia:** The routine use of IVIG is not usually recommended. IVIG may have a role in members with warm-type autoimmune hemolytic anemia that does not respond to corticosteroids or splenectomy or those for whom the latter two treatments are contraindicated
   ii. **Multiple sclerosis (MS):** The current evidence is inadequate to assess the value of IVIG in the treatment of multiple sclerosis. IVIG may be useful in members as a second-line therapy in acute relapses of relapsing-remitting MS but is generally not considered effective for maintenance therapy of MS or in slowing disease progression. LCD individual consideration may be given when IVIG is used in the treatment of an acute relapse of relapsing-remitting MS
   iii. **Systemic lupus erythematosus:** The routine use of IVIG is not usually recommended. IVIG may be used in members with severe active systemic lupus erythematosus for whom other interventions have been unsuccessful, have become intolerable or have been contraindicated
   iv. **Scleromyxedema:** Scleromyxedema is a rare illness of unknown origin that has reported case studies and series showing results with IVIG treatment. Due to the rarity of the illness, large studies are not expected. Medicare is expanding coverage for this illness on a trial basis. Review of medical records should be expected if therapy extends longer than six months to assess overall improvement and whether the provider is using the least amount of IVIG to maintain the changes. Long-term treatment is not expected to be seen for this indication
   v. **Myasthenia gravis:** Acute exacerbations of myasthenia gravis with severe muscle weakness are occasionally treated for an episode of care with a short course of IVIG (2gm/kg divided given up to five days) when other treatment modalities are not successful or available with effects lasting up to eight weeks. IVIG appears to be as good as plasma exchange in these situations. Long-term maintenance is not described, and repeated treatment regimens are not reported at this time. Should treatment be repeated within a six-month period, then providers should expect to have a documentation review to occur, either as a prepay event or in the appeals process following a denial. IVIG is not expected to be the primary/first treatment used. Documentation, if requested, would be expected to reveal other prior treatments used
   vi. **Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN):** SJS and TEN are rare, serious and potentially deadly cutaneous reactions to some drugs. Assessment tools, such as the Severity-of-Illness Score for Toxic Epidermal Necrolysis (SCORTEN), are able to predict mortality based on various factors

(e.g., age, heart rate, history of cancer or hematologic malignancy, epidermal detachment area, blood urea nitrogen (BUN), glucose and bicarbonate). Mixed reviews in the utilization of IVIG depending on the time of initiation of therapy and the dose used are noted. It appears members with a SCORTEN level of three would have significant reduction in mortality if IVIG were available. Coverage will be extended to those members with a SCORTEN level of three or greater. SJS and TEN IVIG use is expected to be a one-time treatment. Additional treatments may be denied

vii. **Systemic capillary leak syndrome (SCLS) or Clarkson's disease:** SCLS is a rare illness of unknown origin that has been reported through registries, case studies and case series. Due to the rarity of the illness, large studies are not expected to be generated. Diagnosis in the most recent review and registry review is associated with monoclonal gammopathy. Prophylaxis with IVIG given on a routine monthly basis has been associated with increased survival. This monthly prophylaxis should be tapered to the lowest effective dose. Medicare is expanding coverage for this illness on a trial basis when associated with monoclonal gammopathy and used for prophylaxis but can be withdrawn or altered based on subsequent literature. All other claims will have the appeals process for potential coverage where medical documentation and submitted literature can be reviewed for individual consideration

Filgrastim/Pegfilgrastim:

Source: Pegfilgrastim and filgrastim are covered for FDA-approved labeled indications for cancer members and severe chronic neutropenic members when they are not self-administered or administered by a caregiver, per LCD.

- Zarxio (filgrastim-sndz) is biosimilar for Neupogen (filgrastim)
- Udenyca (pegfilgrastim-cbqv), Fulphila (Pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez) are biosimilar* to Neulasta (pegfilgrastim)

Step Therapy Requirement for All Indications:

a. Neupogen and Neulasta are considered medically necessary for members who have tried and failed or have a contraindication to Udenyca, Zarxio, Fulphila, Neulasta OnPro and/or Ziextenzo

I. Presbyterian considers **granulocyte-colony stimulating factor** medically necessary for the following indications:
   a. Members with cancer who are receiving myelosuppressive therapy
   b. Members with acute myeloid leukemia who are receiving induction or consolidation chemotherapy
   c. Members with cancer who are receiving a bone marrow transplant
   d. Members who are undergoing peripheral blood progenitor cell collection and therapy

e. Members with severe chronic neutropenia (cyclic or idiopathic) who meet the following criteria:
    i. Documentation that the member is symptomatic with at least three clinically significant infections treated with antibiotics or one life-threatening infection treated with IV antibiotic therapy during the previous 12 months and one of the following:
        1. Documented diagnosis of severe chronic neutropenia (idiopathic) with an absolute neutrophil count (ANC) of less than 500/mm3 on three separate occasions over the previous six months
        or
        2. Documented diagnosis of severe chronic neutropenia (cyclic) with five consecutive days per cycle with an ANC less than 500/mm3 for each of three regularly spaced cycles over a six-month period

f. Members with severe chronic neutropenia (congenital) who have a documented diagnosis of congenital neutropenia

II. Presbyterian considers the use of granulocyte-colony stimulating factor therapy experimental and investigational for all other indications because its clinical value for these indications has not been established

*Please see the FDA drug label for the FDA-approved indications and dosages: https://labels.fda.gov/.

Vabysmo (faricimab-svoa)

I. Neovascular (Wet) Age-Related Exudative Macular Degeneration (AMD) and Diabetic Macular Edema (DME)
    a. The member has had prior therapy with bevacizumab and provider attests that the member has **not** demonstrated a positive clinical response (e.g., improvement or maintenance in best corrected visual acuity [BVCA] or visual filed, or a reduction in the rate of vision decline or the risk of more severe vision loss)
    or
    b. The member has a contraindication or intolerance to bevacizumab

Tepezza (teprotumumab-trbw)

I. Diagnosis of Graves' disease with associated thyroid eye disease (TED) (e.g., Graves' ophthalmopathy, Graves' orbitopathy)
II. One of the following:
    a. Member is euthyroid with documentation of a recent (within the last 30 days) free thyroxine (FT4) and total triiodothyronine (T3) or free T3 (FT3) level within the laboratory-defined reference range
    b. Member has a recent (within the last 30 days) free thyroxine (FT4) and total triiodothyronine (T3) or free T3 (FT3) level less than 50% above or below the laboratory-defined reference range and is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state

III. Member has not had previous surgical intervention for TED
IV. Member does not require surgical ophthalmological intervention
V. **Step Therapy Requirement**:
    a. Failure of a four-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless contraindicated or not tolerated
VI. Member with hyperglycemia or pre-existing diabetes are under appropriate glycemic control before and while receiving Tepezza

Targeted Immunomodulators

I. Actemra (tocilizmab)
    a. Rheumatoid arthritis (RA)
        i. Disease Activity Score-28 (DAS28) score greater than 3.2 or Crohn's Disease Activity Index (CDAI) score greater than 10.1
        ii. **Step Therapy Requirement:**
            1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
                a. Azathioprine
                b. Leflunomide
                c. Methotrexate
                d. Sulfasalazine
            2. Inadequate response to two of the following (unless contraindicated or not tolerated):
                a. Amjevita or Hadlima
                b. Avsola, unbranded infliximab
                c. Enbrel
                d. Xelanz
    b. Juvenile idiopathic arthritis (JIA)
        i. **Step Therapy Requirement:**
            1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
                a. Leflunomide
                b. Methotrexate
                c. Sulfasalazine
            2. Inadequate response to two of the following (unless contraindicated or not tolerated):
                a. Amjevita or Hadlima
                b. Enbrel
                c. Xeljanz
    c. Giant cell arteritis
        i. **Step Therapy Requirement:**
            1. Inadequate response to oral corticosteroids (unless contraindicated or not tolerated)

II. Entyvio (vedolizumab)
- a. Crohn's disease
  - i. To be used in the treatment of patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
    1. **Step Therapy Requirement:**
       - a. For the purpose of this policy, conventional therapy includes the use of one of the following:
         - i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
         - ii. Methotrexate
         - iii. Thiopurines (azathioprine, mercaptopurine)
       - b. Inadequate response to two of the following (unless contraindicated or not tolerated):
         - i. Amjevita or Hadlima
         - ii. Avsola, unbranded infliximab

- b. Ulcerative colitis
  - i. To be used in the treatment of moderately to severely active ulcerative colitis
  - ii. **Step Therapy Requirement:**
    1. Inadequate response to one of the following (unless contraindicated or not tolerated):
       - a. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
       - b. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
       - c. Thiopurines (azathiopurine, mercaptopurine)
       - d. Cyclosporine
    2. Inadequate response to two of the following (unless contraindicated or not tolerated):
       - a. Amjevita or Hadlima
       - b. Avsola, unbranded infliximab
       - c. Xeljanz

III. Infliximab

Source: Infliximab will be covered for FDA-approved indications. Please refer to the FDA drug label for the FDA-approved indications and dosages, and off-labeled indications per LCD L33394 and L35677.

- a. Crohn's disease:
  - i. To reduce the signs and symptoms and to induce and maintain clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
  - ii. To reduce the number of draining enterocutaneous and rectovaginal fistulas and to maintain fistula closure in adult patients with fistulizing disease
  - iii. **Step Therapy Requirement:**
    1. To be used in the treatment of moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy
    2. For the purpose of this policy, conventional therapy includes the use of one of the following (unless contraindicated or not tolerated):

a. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
b. Methotrexate
c. Thiopurines (azathioprine, mercaptopurine)

3. Inadequate response to two of the following (unless contraindicated or not tolerated):
   a. Avsola, unbranded infliximab (infliximab)
   b. Amjevita or Hadlima (adalimumab-atto)

b. Pediatric Crohn's disease:
   i. To reduce the signs and symptoms and to induce and maintain clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
   ii. **Step Therapy Requirement:**
      1. Inadequate response to corticosteroids
         and
      2. Inadequate response or intolerance to Avsola, unbranded infliximab, and Amjevita or Hadlima

c. Ulcerative colitis:
   i. To reduce signs and symptoms, induce and maintain clinical remission and mucosal healing, and eliminate corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   ii. **Step Therapy Requirement:**
      1. Inadequate response to one of the following (unless contraindicated or not tolerated):
         a. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
         b. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
         c. Thiopurines (azathiopurine, mercaptopurine)
         d. Cyclosporine
      2. Inadequate response to two of the following (unless contraindicated or not tolerated):
         a. Avsola, unbranded infliximab
         b. Amjevita or Hadlima

d. Pediatric ulcerative colitis:
   i. To reduce the signs and symptoms and to induce and maintain clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
   ii. **Step Therapy Requirement:**
      1. Inadequate response to one of the following (unless contraindicated or not tolerated):
         a. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
         b. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
         c. Thiopurines (azathiopurine, mercaptopurine)
         d. Cyclosporine
      2. Inadequate response to two of the following (unless contraindicated or not

tolerated):
    a. Avsola, unbranded infliximab
    b. Amjevita or Hadlima

e. Rheumatoid arthritis in combination with methotrexate:
    i. To reduce signs and symptoms, inhibit the progression of structural damage and improve physical function in adult patients with moderately to severely active disease
    ii. **Step Therapy Requirement:**
        1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
            a. Azathioprine
            b. Leflunomide
            c. Methotrexate
            d. Sulfasalazine
        2. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Avsola, unbranded infliximab
            b. Amjevita or Hadlima
            c. Enbrel
            d. Xeljanz

f. Ankylosing spondylitis (AS):
    i. To reduce the signs and symptoms in adult patients with active disease
    ii. **Step Therapy Requirement:**
        1. Inadequate response to at least a four-week trial of a non-steroidal anti-inflammatory drug (NSAID) (unless contraindicated or not tolerated)
        2. For peripheral AS, a documented trial and failure of both an NSAID and sulfasalazine, unless otherwise contraindicated
        3. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Avsola, unbranded infliximab
            b. Amjevita or Hadlima
            c. Enbrel
            d. Xeljanz

g. Psoriatic arthritis:
    i. To reduce signs and symptoms of active arthritis, inhibit the progression of structural damage and improve physical function in adult patients
    ii. **Step Therapy Requirement:**
        1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
            a. Cyclosporine
            b. Leflunomide
            c. Methotrexate
        2. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Avsola, unbranded infliximab
            b. Amjevita or Hadlima
            c. Enbrel
            d. Xeljanz

h. Plaque psoriasis:

i. To treat adult patient with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

ii. **Step Therapy Requirement:**

1. Inadequate response to a three-month trial of a topical agent, such as a topical corticosteroid, calcineurin inhibitor or vitamin D analog
2. Inadequate response to two of the following (unless contraindicated or not tolerated):
    a. Avsola, Unbranded infliximab
    b. Amjeita
    c. Enbrel

IV. Remicade

a. **Step Therapy Requirement:** Failure or intolerance, or clinical rationale for the avoidance of Avsola or unbranded infliximab

V. Orencia (abatacept)

a. Rheumatoid arthritis (RA)
    i. DAS28 score greater than 3.2 or CDAI score greater than 10.1
    ii. **Step Therapy Requirement:**
        1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
            a. Azathioprine
            b. Leflunomide
            c. Methotrexate
            d. Sulfasalazine
        2. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Amjevita or Hadlima
            b. Avsola, unbranded infliximab
            c. Enbrel
            d. Xeljanz

b. Juvenile idiopathic arthritis
    i. **Step Therapy Requirement:**
        1. Inadequate response to a three-month trial of one of the following (unless contraindicated or not tolerated):
            a. Leflunomide
            b. Methotrexate
            c. Sulfasalazine
        2. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Amjevita or Hadlima
            b. Enbrel
            c. Xeljanz

VI. Stelara (ustekinumab)

a. Crohn's disease
    i. To be used in the treatment of patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
        1. **Step Therapy Requirement:**

a. For the purpose of this policy, conventional therapy includes the use of one of the following:
    i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
    ii. Methotrexate
    iii. Thiopurines (azathioprine, mercaptopurine)
b. Inadequate response to two of the following (unless contraindicated or not tolerated):
    i. Amjevita or Hadlima
    ii. Avsola, unbranded infliximab

b. Ulcerative colitis
    i. To be used in the treatment of moderately to severely active ulcerative colitis
    ii. **Step Therapy Requirement:**
        1. Inadequate response to one of the following (unless contraindicated or not tolerated):
            a. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
            b. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
            c. Thiopurines (azathiopurine, mercaptopurine)
            d. Cyclosporine
        2. Inadequate response to two of the following (unless contraindicated or not tolerated):
            a. Amjevita or Hadlima
            b. Avsola, unbranded infliximab
            c. Xeljanz

VII. Skyrizi (risankizumab)

Source: Skyrizi will be covered for FDA-approved indications.

a. Crohn's disease
    i. To be used in the treatment of patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy
        1. **Step Therapy Requirement:**
            a. For the purpose of this policy, conventional therapy includes the use of one of the following:
                i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide)
                ii. Methotrexate
                iii. Thiopurines (azathioprine, mercaptopurine)
            b. Inadequate response to two of the following (unless contraindicated or not tolerated):
                i. Amjevita or Hadlima
                ii. Avsola, Unbranded infliximab

b. Ulcerative colitis
    ii. To be used in the treatment of moderately to severely active ulcerative colitis
    iii. **Step Therapy Requirement:**
        1. Inadequate response to one of the following (unless contraindicated or not tolerated):
            a. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)

b. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
c. Thiopurines (azathiopurine, mercaptopurine)
d. Cyclosporine

2. Inadequate response to two of the following (unless contraindicated or not tolerated):
   a. Amjevita or Hadlima
   b. Avsola, unbranded infliximab
   c. Xeljanz

Monoclonal Antibodies for Alzheimer's:

Leqembi, Kisunla

Source: National Coverage Determination (NCD) Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD), FDA prescribing information, Thomson Micromedex, DrugDex Compendium

I. Treatment with Leqembi or Kisunla is considered medically reasonable and necessary when all the following conditions are met:
   a. Confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease
   b. Presence of amyloid beta pathology documented by either of the following:
      i. Baseline positron emission tomography (PET) scan
      ii. Lumbar puncture results cerebrospinal fluid (CSF) Aβ42 or other CSF biomarker with evidence of high concordance with amyloid PET (e.g. Aβ42/ Aβ40, tTau/ Aβ42, pTau/ Aβ42)
   c. Brain magnetic resonance imaging (MRI) completed within the past 60 days without findings that indicate an increased risk for amyloid-related imaging abnormalities (ARIA) and/or intracerebral hemorrhage
   d. Provider attestation that monitoring for ARIA will be conducted via MRI prior to initiation and
      i. Leqembi prior to 5th, 7th and 14th infusions
      ii. Kisunla prior to the 2nd, 3rd, 4th and 7th infusions
   e. Member has not had any of the following within the past 12 months
      i. Seizure, stroke or transient ischemic attack (TIA)
   f. Member is not currently taking an anticoagulant (e.g., warfarin, apixaban)
      i. If the member is currently taking an anticoagulant, the prescriber must attest that education has been provided that the use of anti-amyloid therapy with anticoagulant therapy may increase the risk of intracerebral hemorrhage
   g. Confirmed genetic testing for ApoE ε4 (genetic testing may not be a covered benefit for all members). Testing for ApoE ε4 status to assess risk of developing ARIA should be performed prior to initiating treatment with Leqembi (incidence of ARIA was higher in ApoE ε4 homozygotes than in heterozygotes and noncarriers)

h. Provider and member participation in a CMS approved study of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease
i. Member has a Mini Mental State Exam (MMSE) score of 22-30 (inclusive) and/or a Montreal Cognitive Assessment (MoCA) score of 17-30 (inclusive) within the past 3 months
j. Baseline Alzheimer's Disease Assessment Scale – 13-item Cognitive Subscale (ADAS-Cog13)
k. Global Clinical Dementia Rating Scale – Sum of Boxes CDR score of 0.5 to 1.0 and a CDR Memory Box score of 0.5 or greater within the past 2 months

II. **Step Therapy Requirement:**
a. Inadequate response to one of the following (unless contraindicated or not tolerated):
i. donepezil, rivastigmine and galantamine.