Medicare Part B Step Therapy Policy

Policy Scope: This policy applies to Medicare Advantage product lines within Presbyterian Health Plan, 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
- Prolia, Xgeva
- Viscosupplementation
- Intra-Articular Steroids
- Botox
- Avastin
- Cinvanti
- Rituxan
- Hemophilia
- Intravenous Immune Globulin (IVIG)
- Filgrastim/Pegfilgrastim
- Krystexxa
- Leqvio
- Nucala
- Ohtuvayre
- Yupelri
- Qutenza
- Tepezza
- Vyepti
- Saphnelo
- Spravato
- Amvuttra
- Ultomiris
- Vyvgart
- Monoclonal Antibodies for Multiple Sclerosis

- Ocrevus
- Tysabri

- Briumvi
- Targeted Immunomodulators
  - Actemra
  - Entyvio
  - Infliximab (Avsola, Inflectra, Renflexis)
  - Remicade
  - Orencia
  - Stelara
  - Tremfya
- Simponi
- Skyrizi
- Monoclonal Antibodies for Alzheimer's
  - Leqembi
  - Kisunla
- Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ocular Indications
  - Eylea
  - Beovu
  - Vabysmo
- Leucovorin and Levo leucovorin
- Antineoplastics
  - Irinotecan
  - Trastuzumab
- Programmed Cell Death Ligand 1 Inhibitors (PD-L1)
  - Keytruda, Opdivo, Tecentriq, Imfinzi, Imjudo or Yervoy

Evenity

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. 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

II. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to, one of the following:
      i. Zoledronic acid
      ii. Jubbonti or Prolia

iii. Wyost or Xgeva

III. **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

IV. **Or** women at very high risk of fracture defined as:
   a. Recent fracture
   b. Fracture while on treatment for osteoporosis
   c. History of multiple fractures
   d. Has a very low T-score, less than -3.0
   e. Has a very high Fracture Risk Assessment Tool (FRAX) score, greater than 30%

Prolia

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Considered medically reasonable and necessary for the treatment of:
   a. Treatment of postmenopausal women with osteoporosis at high risk for fracture
   b. Treatment to increase bone mass in men with osteoporosis at high risk for fracture
   c. Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
   d. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
   e. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

II. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to, the following:
      i. Jubbonti (denosumab-bbdz)

Xgeva

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Considered medically reasonable and necessary for the treatment of:
   a. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
   b. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
   c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

II. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to, the following:
      i. Wyost (denosumab-bbdz)

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

II. Step Therapy Requirement:
   a. Adequate 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

II. **Step Therapy Requirement:**
    a. Adequate documented trial and failure of Kenalog or methylprednisolone acetate

Botox

Source: LCD ID: L38809, L35170, A58423, A57185

I. Botulinum toxins (Botox) are considered medically reasonable and necessary when administered for treatment of FDA-labeled indications and off-label indications as outlined in CMS Local Coverage Determinations (LCD) and billing and coding articles.

II. The following diagnoses have an applicable step therapy:
    a. Treatment of overactive bladder 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, 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 severe axillary hyperhidrosis that is inadequately managed by topical agents in adult members
        i. Step Therapy Requirement:
            1. Adequate documented trials and failures of drying agents such as topical aluminum chloride (DrySol, Xerac AC or Hypercare these are nonformulary)

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

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

II. **Step Therapy Requirement:**
    a. Adequate documented trial and failure of, or contraindication to, Zirabev

Cinvanti

Source: NCCN, Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Cinvanti is considered medically reasonable and necessary when administered for the treatment of:
    a. Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin as a single-dose regimen.
    b. Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen.
    c. Nausea and vomiting associated with initial and repeat courses of MEC as a three-day regimen

II. **Step Therapy Requirement for All Indications:**
    a. Adequate documented trial and failure of, or contraindication to, Emend (fosaprepitant)

Rituxan

Source: NCCN, Thomson Micromedex, DrugDex Compendium, LCD L39297 Off-Label Use of Rituximab and Rituximab Biosimiliars

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

II. Rheumatoid arthritis in combination with methotrexate in adult members with moderately to severely active rheumatoid arthritis who have inadequate response to one or more tumor necrosis factor antagonist therapies

III. Off-label indications as per LCD L39297

IV. **Step Therapy Requirement:**
    i. Adequate documented trial and failure of, or contraindication to, Ruxience or Truxima

Hemophilia

Source: NCCN, Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. **Step Therapy Requirement:**
    a. Adequate documented trial and failure of, or contraindication to the following
        i. Desmopressin if appropriate for indication
        ii. One of the following:
            1. Corifact, Humate-P, Feiba, Nuwig, Wilate, Afstyla

Intravenous Immune Globulin (IVIG)

Source: LCD L35093 IVIG and LCD L39314 Off-Label IVIG

I. **Step Therapy Requirement for All Indications:**
    a. Adequate documented trial and failure of, or contraindication to, Gammagard. Medicare will provide coverage for IVIG when it is used in treatment of the following conditions:
        i. Off label indications as per LCD L39314

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/.

Krystexxa

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Krystexxa is medically necessary for the treatment of chronic gout in adult patients who do not respond to conventional therapy

II. **Step Therapy Requirement**
   a. Adequate documented trial and failure of, or contraindication to, both of the following:
      i. Allopurinol
      ii. Febuxostat

Leqvio

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Leqvio is medically necessary as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

II. **Step Therapy Requirement for All Indications:**
   a. Adequate documented trial and failure of, or contraindication to:
      i. High-intensity statin
      ii. Repatha

Nucala

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Nucala is medically necessary for the following treatments:

a. Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients aged 18 years and older with inadequate response to nasal corticosteroids
b. Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
c. For adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
d. For adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause

II. Not indicated for the relief of acute bronchospasm

III. **Step Therapy Requirement:**
a. Adequate documented trial and failure of, or contraindication to:
i. Xolair

Ohtuvayre

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Ohtuvayre is medically necessary for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

II. Step therapy requirement:

a) Trial and failure of, or contraindication to all of the following:
i. Long-acting beta agonists **(**LABA)
ii. Long-acting muscarinic antagonists **(**LAMA)
iii. Stiolto or Anoro Ellipta
iv. Steroid and LABA combination
v. Trelegy Ellipta

Yupelri

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Yupelri is medically necessary for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)

II. Step therapy requirement:

b. Trial and failure of, or contraindication to all of the following:
i. Long-acting beta agonists **(**LABA)
ii. Steroid and LABA combination
iii. Stiolto or Anoro Ellipta
iv. Trelegy Ellipta

Qutenza

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Qutenza is medically necessary for the following treatments:
   a. Neuropathic pain associated with postherpetic neuralgia (PHN)
   b. Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

II. Step therapy requirement:
   a. Adequate documented trial and failure of, or contraindication to all of the following:
      i. Gabapentin
      ii. Pregabalin
      iii. Duloxetine

Tepezza

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. Members with hyperglycemia or pre-existing diabetes are under appropriate glycemic control before and while receiving Tepezza

Vyepti

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Is medically necessary for the preventive treatment of migraine in adults

II. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to:

i. Aimovig

Saphnelo

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Saphnelo is medically necessary in the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy

II. Will not be used for severe active lupus nephritis or severe active central nervous system lupus

III. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to, all of the following:
      i. Hydroxychloroquine
      ii. Methotrexate, azathioprine, mycophenolate or cyclophosphamide

Spravato

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Spravato is medically necessary in the treatment of:

   a. Treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant.

   b. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

II. Step therapy

   a. Trial and failure of at least 2 formulary antidepressants

Amvuttra

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Amvuttra is medically necessary in the treatment of:

   a. The polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
      i. Baseline Neuropathy Impairment Score +7 (mNIS+7) is required
   b. The cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits

II. **Step Therapy Requirement:**
   a. Adequate documented trial and failure of, or contraindication to:
      a. For cardiomyopathy diagnosis only: Vyndamax

Ultomiris

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. This step therapy policy only applies to the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive (1.3)

II. **Step Therapy Requirement:**
    a. Adequate documented trial and failure of, or contraindication to:
        i. Pyridostigmine
        ii. Two immunosuppressants from the following list:
            1. azathioprine
            2. cyclosporine
            3. mycophenolate
            4. tacrolimus

Vyvgart

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Medically necessary for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

II. **Step Therapy Requirement:**
    a. Adequate documented trial and failure of, or contraindication to:
        i. Ultomiris

Monoclonal Antibodies for Multiple Sclerosis

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Medically necessary for the treatment of patients with relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in adults

II. Treatment of primary progressive MS in adults

III. **Step Therapy Requirement:**
    a. Ocrevus and Tysabri
        i. Inadequate response to unless contraindicated or not tolerated
            1. Briumvi
    b. Briumvi
        i. Inadequate response to unless contraindicated or not tolerated
            1. Fingolimod or teriflunomide

Targeted Immunomodulators

I. Actemra
    a. Rheumatoid arthritis
        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
    c. Enbrel
    d. Xelanz

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

c. Giant cell arteritis
    i. **Step Therapy Requirement:**
        1. Inadequate response to oral corticosteroids (unless contraindicated or not tolerated)

II. Entyvio
a. Crohn's disease
    i. To be used in the treatment of patients with moderately to severely active Crohn's disease
        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

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,
    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
            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 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
    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
    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
    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, an adequate 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,
         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
         b. Amjevita or Hadlima
         c. Enbrel
         d. Xeljanz

h. Plaque psoriasis:
   i. To treat adult patients 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
         b. Amjeita
         c. Enbrel

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

V. Orencia
   a. Rheumatoid arthritis

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,
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
a. Crohn's disease
i. To be used in the treatment of patients with moderately to severely active Crohn's disease
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. Adequate documented trial and failure of, or contraindication to, to Amjevita or Hadlima
i. Avsola
and
c. Adequate documented trial and failure of, or contraindication to, the following:
i. Yesintek, Steqeyma and Imuldosa

b. Ulcerative colitis
i. To be used in the treatment of moderately to severely active ulcerative colitis
1. **Step Therapy Requirement:**

a. Adequate documented trial and failure of, or contraindication to the following:
    i. Aminosalicylates (balsalazide, mesalamine, sulfasalazine)
    ii. Corticosteroids (e.g, prednisone, prednisolone, dexamethasone, budesonide)
    iii. Thiopurines (azathiopurine, mercaptopurine)
    iv. Cyclosporine
b. Adequate documented trial and failure of, or contraindication to the following:
    i. Amjevita or Hadlima
    ii. Avsola,
    iii. Xeljanz

    and
c. Adequate documented trial and failure of, or contraindication to the following:
    i. Yesintek, Steqeyma and Imuldosa

Skyrizi

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

Skyrizi will be covered for FDA-approved indications.

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

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

ii. Inadequate response to two of the following (unless contraindicated or not tolerated):
    1. Amjevita or Hadlima
    2. Avsola
    3. Xeljanz

Tremfya

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

Tremfya will be covered for FDA-approved indications.

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

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

Simponi

Source: Thomson Micromedex, DrugDex Compendium, FDA Prescribing Information

I. Simponi will be covered for all FDA approved indications

II. Step Therapy Requirement: Adequate documented trial and failure of, or contraindication to all of the following:

i. One of the following DMARDs:

a. Leflunomide

b. Methotrexate

c. Sulfasalazine

ii. Amjevita or Hadlima

iii. 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, 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. Member has a Mini-Mental State Examination (MMSE) score of 22-30 (inclusive) and/or a Montreal Cognitive Assessment (MoCA) score of 17-30 (inclusive) within the past three months
i. Baseline Alzheimer's Disease Assessment Scale – 13-item Cognitive Subscale (ADAS-Cog13)
j. Global Clinical Dementia Rating Scale – Sum of Boxes Clinical Dementia Rating (CDR) score of 0.5 to 1.0 and a CDR Memory Box score of 0.5 or greater within the past two months

k. Provider must enroll member in a CMS National Patient Registry, or the provider and member must participate in a CMS-approved study, FDA approved randomized controlled trial, or studies supported by the NIH of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

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

Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ocular Indications

Eylea

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Eylea is medically necessary for treatment of patients with neovascular (wet) age-related macular degeneration (AMD)

II. **Step Therapy Requirement**:
a. Adequate documented trial and failure of, or contraindication to, the following:
i. Pavblu

Beovu

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Neovascular (wet) AMD and diabetic macular edema

II. **Step Therapy Requirement**
a. Adequate documented trial and failure of, or contraindication to:
i. Pavblu or Eylea

Vabysmo

Source: FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Neovascular (wet) AMD and diabetic macular edema
   a. The member has had prior therapy with bevacizumab or Pavblu and provider attests that the member has **not** demonstrated a positive clinical response (e.g., improvement or maintenance in best corrected visual acuity or visual field, or a reduction in the rate of vision decline or a reduction in the risk of more severe vision loss)
   or
   b. The member has a contraindication or intolerance to Avastin

Leucovorin and Levo leucovorin

Fusilev, Khapzory, Vykoura

Source: National Comprehensive Cancer Network **(**NCCN), FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. **Step Therapy Requirement**
   a. Adequate documented trial and failure of, or contraindication to leucovorin

Antineoplastics

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

Irinotecan

Onivyde

I. Treatment of metastatic pancreatic adenocarcinoma

II. **Step Therapy Requirement**
   a. Adequate documented trial and failure of, or contraindication to,
      i. Generic irinotecan
      ii. Camptosar

*Step therapy does not apply if NCCN prefers Onivyde

Trastuzumab

Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Ontruzant Kanjinti

I. **Step Therapy Requirement**
   a. Adequate documented trial and failure of, or contraindication to,
      i. Ogivri

ii. Trazimera

Programmed Cell Death Ligand 1 Inhibitors (PD-L1)

Source: National Comprehensive Cancer Network **(**NCCN), FDA Prescribing Information, Thomson Micromedex, DrugDex Compendium

I. Treatment of non-small cell lung cancer (NSCLC)
   a. Applies to Keytruda and Keytruda QLEX, Opdivo and Opdivo Qvantig, Tecentriq, Imfinzi, Imjudo or Yervoy
   b. Adequate documented trial and failure of, or contraindication to, Libtayo

II. Treatment of metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (CSCC) in patients who are not candidates for curative surgery or curative radiation
   a. Applies to Keytruda and Keytruda QLEX

III. **Step Therapy Requirement**
   a. Adequate documented trial and failure of, or contraindication to, Libtayo