PROVIDENCE
Medicare Advantage Plans

A division of Providence Health Assurance

PROVIDENCE MEDICARE ADVANTAGE PLANS

2022 STEP THERAPY CRITERIA FOR PART B DRUGS

This list pertains to the following Providence Medicare Advantage Plans:

BRIDGE 1 + Rx (HMO-POS), BRIDGE 2 + Rx (HMO-POS), CHOICE + Rx 001 (HMO-POS), CHOICE + Rx 002 (HMO-POS), COMPASS + Rx (HMO-POS), COTTONWOOD + Rx (HMO-POS), DUAL PLUS (HMO D-SNP), ENRICH + Rx (HMO), EXTRA PART B ONLY + Rx (HMO), EXTRA + Rx 001 (HMO), EXTRA + Rx 002 (HMO), FOCUS MEDICAL (HMO), HARBOR + Rx (HMO), LATITUDE +Rx (HMO-POS), PINE + Rx (HMO), PRIME + Rx (HMO), SELECT MEDICAL (HMO-POS), SUMMIT + Rx (HMO-POS), TIMBER + Rx (HMO), ALIGN GROUP PLANS + RX (HMO), DISCOVER GROUP PLAN + RX (HMO-POS), EXPLORE GROUP PLAN + RX (HMO-POS)

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For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 (TTY users should call 711), seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit ProvidenceHealthAssurance.com.

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Medicare Part B Step Therapy

- Some medically administered Part B medications, like injectable drugs or biologics, may have special requirements or coverage limits, such as step therapy.
- Step therapy requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug.
- The step therapy requirement does not apply to members who have already received treatment with the non-preferred drug within the past 365 days.
- Both preferred and non-preferred drugs may still be subject to prior authorization or quantity limits.
- The step therapy criteria outlined in this document may also involve a combination of Part B and Part D drugs. For example, we may not cover a Part B drug unless you try a Part D drug first. Or, we may not cover a Part D drug unless you try a Part B drug first. This is dependent on the therapy described to treat your medical condition. This document contains the Step Therapy protocols for Medicare Part B drugs that are associated with your plan.

How Step Therapy Works

In the list below, you'll see drugs labeled as either Step 1 (Preferred drug), Step 2 (Non-Preferred drug) or Step 3 (Non-Preferred drug). Step 2 and Step 3 drugs require step therapy.
For example: Before you can get a Step 3 drug, you have to first try a Step 1 and a Step 2 drug.

Step 1 drugs usually require prior authorization. That means before you can take this drug, your doctor has to send us information that explains why you need it. If a Step 1 drug doesn't require prior authorization, we tell you in the list below.

Step 2 drugs always require prior authorization. Your doctor also needs to let us know one of the following:

- Why the Step 1 drug didn't work for you or why you can't take the Step 1 drug
- Why the Step 2 drug is best for your needs
- Details from your doctor to show that you've taken the Step 2 drug in the past 365 days

Step 3 drugs always require prior authorization. Your doctor also needs to let us know one of the following:

- Why the Step 1 and Step 2 drugs didn't work for you or why you can't take them.
- Why the Step 3 drug is best for your needs
- Details from your doctor to show that you've taken the Step 1 and/or the Step 2 drug in the past 365 days

The drugs within this list may change at any time. You will receive notice when necessary.

ACUTE HEREDITARY ANGIOEDEMA THERAPY_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

BERINERT, KALBITOR, RUCONEST

CRITERIA

For coverage of Berinert®, Kalbitor®, or Ruconest®: Documentation of trial and failure or contraindication to generic icatibant.

This specific requirement applies to new starts only.

ADAKVEO_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

ADAKVEO

CRITERIA

For Adakveo - Documentation that patient meets one of the following:

i. Patient will continue taking hydroxyurea with the requested therapy and patient has been on a maximally tolerated dose of hydroxyurea for at least six (6) months

ii. Patient has had a therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six (6) months

iii. Patient has had an intolerance or contraindication to hydroxyurea (For many patients myelosuppression is dose-dependent and reversible, intolerance due to myelosuppression will only be considered if patient continues to experience myelosuppression despite dose adjustments)

This specific requirement applies to new starts only.

CGRP AGENTS FOR MIGRAINE PROPHYLAXIS_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

VYEPTI

CRITERIA

For Vyepti®:

a. Trial and inadequate response to at least six weeks of at least one (1) prophylactic medication from one (1) of the following categories:

1. Anticonvulsants (i.e., divalproex, valproate, topiramate)
2. Beta-blockers (i.e., metoprolol, propranolol, timolol)
3. Antidepressants (i.e., amitriptyline, venlafaxine)

b. Documented trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig® and Emgality®)

This specific requirement applies to new starts only.

CINRYZE_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
CINRYZE

CRITERIA
1. For initiation of therapy (new starts), all of the following criteria (a-d) must be met:

a. Documentation of one of the following clinical criteria:
i. Self-limiting, non-inflammatory subcutaneous angioedema without urticaria, recurrent, and lasting more than 12 hours, or
ii. Self-remitting abdominal pain without clear organic etiology, recurrent, and lasting more than six hours, or
iii. Recurrent laryngeal edema AND

b. Documentation of greater than or equal to two HAE attacks per month on average for the past three months despite removal of triggers (e.g., estrogen containing oral contraceptive, angiotensin converting enzyme inhibitors) unless medically necessary, AND
c. One of the following:

i. For HAE Type I and Type II, documentation of at least two (2) complement studies taken at least one month apart with the patient in their basal condition and after the first year of life that show both of the following:
1. C4 is less than 50 percent of the lower limit of normal, and
2. One of the following:
a. C1-inhibitor (C1-INH) protein is less than 50 percent of the lower limit of normal, or
b. C1-INH function is less than 50 percent of the lower limit of normal

ii. For HAE with normal C1-INH or HAE Type III, one of the following:
1. Confirmed Factor 12 (FXII) ANGPT1, PLG, KNG1 gene mutation, or
2. Positive family history for HAE AND attacks lack response with high dose antihistamines or corticosteroids.

d. Documentation of trial and failure or contraindication to Haegarda®.

IL-5 INHIBITORS - MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
CINQAIR, FASENRA, FASENRA PEN, NUCALA

CRITERIA
1. For initiation of therapy (new starts), must meet indication-specific criteria below:

a. For eosinophilic asthma:

i. Documentation of eosinophilic asthma by one of the following:
1. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months, or
2. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids, or
3. Documentation of treatment with maximally tolerated dose of medium to high–dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist) and has been compliant to therapy in the past three months (this may be verified by pharmacy claims information)

ii. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following:
1. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5, or
2. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months, or
3. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit.

b. For Eosinophilic Granulomatosis with Polyangiitis (EGPA), mepolizumab (Nucala®) may be covered if all of the following criteria are met:

i. Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)
ii. History or presence of asthma
iii. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter
iv. Documentation of one of the following:

1. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent), OR
2. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering glucocorticoids. Standard treatment

regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

c. For Hyperesosinophilic Syndrome (HES) mepolizumab (Nucala®) may be covered if the following criteria are met:

i. Document of primary HES without an identifiable non-hematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
ii. Blood eosinophil count of at least 1,000 cells/microliter for at least six months
iii. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
1. Chronic or episodic oral corticosteroids
2. Immunosuppressive therapy
3. Cytotoxic therapy
iv. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

INTERLEUKIN-1 INHIBITORS_ILARIS_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
ILARIS

CRITERIA
Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease:
i. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), AND
ii. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)

This specific requirement applies to new starts only.

LEMTRADA_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
LEMTRADA

CRITERIA
1. For initiation of therapy (new starts), all of the following criteria must be met:

a. Documentation of confirmed diagnosis of relapsing form of multiple sclerosis or active secondary progressive disease, AND

b. Documentation of active disease (e.g. patients with frequent attacks or who are rapidly progressing in disability) after an adequate trial to ocrelizumab (Ocrevus®). An adequate trial is defined as at least 6 months, AND

c. Documentation of active disease after an adequate trial at least one additional of the following disease modifying therapies, unless all are contraindicated. An adequate trial is defined as at least 6 months of continuous therapy. Discontinuation of therapy due to drug intolerance will not be considered as an adequate trial

i. Interferon-beta 1a (Avonex®, Rebif® or Plegridy®) or interferon-beta 1b (Betaseron®)

ii. Generic dimethyl fumarate

iii. Glatiramer acetate (Copaxone®)

iv. Natalizumab (Tysabri®)

v. Teriflunomide (Aubagio®)

vi. Fingolimod (Gilenya®)

vii. Diroximel fumarate (Vumerity®)

viii. Ozanimod hydrochloride (Zeposia®)

ix. Siponimod (Mayzent®)

MEDICALLY INFUSED THERAPEUTIC IMMUNOMODUCATORS - MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

ACTEMRA 200 MG/10 ML VIAL, ACTEMRA 400 MG/20 ML VIAL, ACTEMRA 80 MG/4 ML VIAL, AVSOLA, ENTYVIO, ILUMYA, INFLECTRA, ORENCIA 250 MG VIAL, REMICADE, RENFLEXIS, SIMPONI ARIA, STELARA 130 MG/26 ML VIAL

CRITERIA

Patients not established on the requested TIMs agent (new starts), must meet ALL of the following indication-specific criteria:

i.Requests for non-preferred infliximab products (Remicade® and Avsola®) will require documentation of failure, intolerance or contraindication to the preferred infliximab products, Inflectra® and Renflexis®, in addition the indication-specific criteria below.

ii. For moderate to severe Ulcerative Colitis:

1.Preferred infliximab products (Inflectra® and Renflexis®) or vedolizumab (Entyvio®) may be covered

2.For non-preferred agents: documentation of failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®) or vedolizumab (Entyvio®)

iii.For moderate to severe Crohn's Disease:

1.Preferred infliximab products (Inflectra® and Renflexis®) may be covered

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

iv.For Rheumatoid Arthritis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

v.For moderate to severe Plaque Psoriasis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, tazarotene, topical corticosteroids, calcitriol)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vi.For Psoriatic Arthritis:

1.For all agents: Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vi.For Ankylosing Spondylitis:

1.Preferred infliximab products (Inflectra® and Renflexis®) may be covered

2.For non-preferred agents: documentation of trial, failure, intolerance, or contraindication to a preferred infliximab product (Inflectra® or Renflexis®)

vii.For giant cell arteritis: Tocilizumab (Actemra®) may be approved with documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., systemic corticosteroid therapy)

ONCOLOGY_BEVACIZUMAB_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
AVASTIN

CRITERIA
For non-preferred bevacizumab products (Avastin®): Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb).

This specific requirement applies to new starts only.

ONCOLOGY_RITUXIMAB_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

RIABNI, RITUXAN, RITUXAN HYCELA

CRITERIA

For non-preferred rituximab products Riabni® (rituximab-arrx), Rituxan® (rituximab), Rituxan Hycela® (rituximab & hyaluronidase): Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs).

This specific requirement applies to new starts only.

ONCOLOGY_TRASTUZUMAB_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

HERCEPTIN, HERCEPTIN HYLECTA, HERZUMA, ONTRUZANT, TRAZIMERA

CRITERIA

For non-preferred trastuzumab products - Herceptin®, Herceptin Hylecta®, Herzuma®, Ontruzant®,and Trazimera®: Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Ogivri® (trastuzumab-dkst) and Kanjinti® (trastuzumab-anns).

This specific requirement applies to new starts only.

OPHTHALMIC DISORDERS_DURYSTA_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
DURYSTA

CRITERIA
For Durysta:

Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin.

This specific requirement applies to new starts only.

OPHTHALMIC VEGF INHIBITORS_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
BEOVU, EYLEA, LUCENTIS, MACUGEN

CRITERIA
This specific requirement applies to new starts only.

For initiation of therapy with the requested medication (new start): Must have one (1) of the following diagnoses and meet any required criteria:
a. Neovascular (wet) age-related macular degeneration (AMD):

i. For aflibercept (Eylea®): 1.Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated (examples of contradictions to bevacizumab include but are not limited to: serous pigmented epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome), or rationale is provided why therapy with bevacizumab is not appropriate for the patient

ii. For ranibizumab (Lucentis®), pegaptanib (Macugen®) and brolucizumab (Beovu®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient

b. Diabetic macular edema or Diabetic retinopathy:
i. For aflibercept (Eylea®), one of the following: 1. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated
ii. For ranibizumab (Lucentis®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member

c. Macular edema following retinal vein occlusion
i. For aflibercept (Eylea®): 1.Documentation that bevacizumab has been ineffective, not tolerated/contraindicated, or rationale is provided why therapy with bevacizumab is not appropriate for the patient
ii. For ranibizumab (Lucentis®): Documentation that bevacizumab and aflibercept (Eylea®) has been ineffective, not tolerated/ contraindicated, or rationale is provided why therapy is not appropriate for the patient

OXLUMO_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

OXLUMO

CRITERIA

Concurrent use of pyridoxine or previous trial of at least 3 months with no significant improvement in urine oxalate concentration.

This specific requirement applies to new starts only.

RHEUMATOLOGY_RITUXIMAB_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
RIABNI, RITUXAN, RUXIENCE, TRUXIMA

CRITERIA
For approval of preferred rituximab biosimilar products: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs)

Rheumatoid Arthritis: Documentation of trial, failure, intolerance, or contraindication to at least one (1) of the following targeted immune modulators: etanercept (Enbrel®), adalimumab (Humira®), or a preferred infliximab product

Immune Thrombocytopenia (ITP): Documentation of trial, failure, intolerance, or contraindication to systemic corticosteroid therapy

Refractory Myasthenia Gravis: Documented trial, failure, intolerance or contraindication to at least two (2) of the following conventional therapies:
a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
b. Corticosteroids (e.g., prednisone, methylprednisolone)
c. Immunosuppressive agents (e.g., azathioprine, cyclosporine, mycophenolate)
d. Plasma exchange

For non-preferred rituximab products Riabni® (rituximab-arrx), Rituxan® (rituximab): Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications: Ruxience® (rituximab-pvvr) and Truxima® (rituximab-abbs).

This specific requirement applies to new starts only.

SIGNIFOR LAR_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
SIGNIFOR LAR

CRITERIA
1. For patients initiating therapy (new starts), must meet criteria for indications listed below

a. Treatment of patients with acromegaly:

i. Documentation that the patient has persistent disease (e.g., biochemical or clinical) following surgical resection or patient is ineligible for surgery, AND

ii. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy or lanreotide subcutaneous depot injection. Note: Mild symptoms of disease are typically treated with a dopamine agonist (e.g., cabergoline)

SOLIRIS_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
SOLIRIS

CRITERIA
1. For initiation of therapy (new starts), must meet the indication-specific criteria below:
a. For Paroxysmal Nocturnal Hemoglobinuria (PNH), all of the following must be met:

i. Documented, confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64), AND

ii. Severe disease as indicated by at least one of the following:
1. Documented history of thrombosis, OR
2. Documentation of at least 10% PNH type III red cells AND at least one (1) of the following:
a. Transfusion dependence (eg. hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL)
b. Disabling fatigue
c. End-organ complications
d. Frequent pain paroxysms (eg. dysphagia or abdominal pain)
e. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal

iii. Dose and frequency is in accordance with FDA-approved labeling

b. For Complement-Mediated Hemolytic Uremic Syndrome (HUS), all of the following must be met:
i. Diagnosis of non-infectious HUS (i.e. HUS is not due to infection with Shiga toxin-producing Escherichia coli)
ii. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine)
iii. Dose and frequency is in accordance with FDA-approved labeling

c. For Generalized Myasthenia Gravis (gMG), all of the following must be met:
i. Anti-acetylcholine receptor (anti-AChR) antibody positive
ii. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
iii. Myasthenia Gravis -Activities of Daily Living (MG-ADL) total score greater than five
iv. Failed treatment for at least one year with the following:

1. At least TWO immunosuppressive therapies (such as azathioprine, mycophenolate mofetil, cyclosporine and tacrolimus, corticosteroids), OR
2. ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIg) or plasma exchange (PE)
v. Dose and frequency is in accordance with FDA-approved labeling

d. For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met:
i. Diagnosis of NMOSD as defined as the following:
1. Presence of at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions), AND
2. Anti-AQP4 antibody positive

ii. Documentation that other alternative diagnoses have been excluded (e.g., Multiple Sclerosis)
iii. Trial and failure, intolerance or contraindication to rituximab
iv. Documentation that medication will not be used in combination with complement inhibitor (e.g., ravulizumab-cwvz), anti-CD20-directed (e.g., rituximab), anti-CD19 directed (e.g., inebilizumab) or IL-6 inhibition pathway therapies (e.g., satralizumab)
v. Dose and frequency is in accordance with FDA-approved labeling

SOMATOSTIN ANALOGS_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
SANDOSTATIN LAR DEPOT, SOMATULINE DEPOT

CRITERIA
For Sandostatin® Lar and Somatuline® Depot

1. For initiation of therapy (new starts), must meet the indication specific criteria below:

a. For Acromegaly:
i. Confirmed diagnosis of acromegaly
ii. Documentation of an inadequate response to surgery or pituitary irradiation, or patient is not a candidate for surgical resection and pituitary irradiation
iii. History of failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses
iv. Documentation of good response and tolerability to short-acting octreotide

b. For Carcinoid Tumors:
i. Treatment is for symptomatic diarrhea or flushing:
ii. Documentation that patient has severe diarrhea or flushing caused by a carcinoid tumor
iii. Documentation of good response and tolerability to short-acting octreotide

c. For Vasoactive Intestinal Peptide Tumors
i. Treatment is for symptomatic diarrhea
ii. Documentation that patient has severe diarrhea caused by vasoactive intestinal peptide tumors
iii. Documentation of good response and tolerability to short-acting octreotide

d. For Chemotherapy induced diarrhea, Sandostatin LAR® may be covered if all of the following criteria are met:
i. Documentation that patient has severe diarrhea caused by chemotherapy
ii. Documentation of an inadequate response or contraindication to loperamide
iii. Documentation of good response and tolerability to short-acting octreotide

e. For AIDS-related diarrhea (Sandostatin LAR® only):
i. Documentation that patient has severe diarrhea
ii. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate (Lomotil®)
iii. Documentation of good response and tolerability to short-acting octreotide

f. For oncologic diagnoses: use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

TESTOSTERONE_AVEED_TESTOPEL_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

AVEED, TESTOPEL, TESTOSTERONE 100 MG PELLET, TESTOSTERONE 200 MG PELLET, TESTOSTERONE 50 MG PELLET

CRITERIA

1. For initiation of therapy (new starts), must meet all of the following criteria

a. One of the following confirmed diagnoses:

i. Diagnosis of gender dysphoria or gender identity disorder OR

ii. Diagnosis of primary or secondary (hypogonadatropic) hypogonadism

Documented trial and failure (defined as inability to reach therapeutic levels or fluctuations in levels resulting in symptoms) of both generic topical testosterone 1% and generic injectable testosterone cypionate.

TYSABRI_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
TYSABRI

CRITERIA
1. For initiation of therapy (new starts), must meet indication-specific criteria below:

a. For Multiple Sclerosis:

i. One of the following:

1. Documentation of trial, failure, or intolerance to at least one of the following disease modifying therapies:
a. Interferon therapy (Avonex®, Rebif®Plegridy®, or Betaseron®)
b. Generic dimethyl fumarate
c. glatiramer acetate (Copaxone®)
d. teriflunomide (Aubagio®)
e. fingolimod (Gilenya®)
f. ocrelizumab (Ocrevus®)
g. ozanimod hydrochloride (Zeposia®)
h. siponimod (Mayzent®)

OR

2. Documentation that patient has highly active or aggressive disease defined as one of the following:
a. Relapse leading to deterioration in physical functioning or disabilities
b. Magnetic resonance imaging (MRI) findings of new or worsening lesions
c. Manifestations of multiple sclerosis-related cognitive impairment

AND

ii. Negative anti-JCV antibody status. If patient is anti-JCV antibody positive, the patient must meet the following criteria:

1. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil, AND
2. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

b. For Crohn’s disease:
i. Diagnosis of moderate to severe Crohn’s disease, AND
ii. Documentation of trial, failure, intolerance, or lack of response to a formulary TNF inhibitor (Remicade® and/or Humira®) indicated for Crohn’s, AND

iii. Negative anti-JCV antibody status. If patient is anti-JCV antibody positive, the patient must meet the following criteria:
1. Confirmation patient has not used any of the following immunosuppressants agents: mitoxantrone, azathioprine, methotrexate, cyclophosphamide, and mycophenolate mofeti, AND
2. Medical rationale is provided for continued use despite increased risk of developing progressive multifocal leukoencephalopathy (PML)

UPLIZNA_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY

UPLIZNA

CRITERIA

For initiation of therapy (new starts) for Neuromyelitis Optica Spectrum Disorder (NMOSD):

Trial and failure, intolerance or contraindication to rituximab

XOLAIR_MEDICARE PART B

MEDICATION(S) SUBJECT TO STEP THERAPY
XOLAIR

CRITERIA
For initiation of therapy (new starts), must meet indication-specific criteria below:

a. For asthma:
Documentation that in the past three months patient is adherent to a combination of a medium/high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information)

b. For chronic idiopathic urticaria:
1. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine), AND
2. Trial and failure of one additional medication from the following classes:
i. leukotriene receptor antagonists (e.g., montelukast),
ii. first generation H1 antihistamine (e.g., diphenhydramine), or
iii. histamine H2-receptor antagonist (e.g., famotidine, ranitidine)

c. For nasal polyps:
Documentation of one of the following:
1. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids
2. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids