Avastin Clinical Criteria

POLICY:

Vascular Endothelial Growth Factor (VEGF) Inhibitors	
Preferred	Mvasi (bevacizumab-awwb)
Non-preferred	Avastin (bevacizumab) Alymsys (bevacizumab-maly) Vegzelma (bevacizumab-adcd) Zirabev (bevacizumab-bvzr)

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
Chart notes must be submitted to confirm diagnosis and previous treatment(s).
Non-preferred drugs will be approved when ALL of the following criteria are met:

A. ONE of the following:
- **a.** Documented trial and failure with ALL preferred agents listed above;

OR

- **b.** The preferred agents are not appropriate for the member and clinical rationale is provided;

AND

B. Indication, dose, frequency and duration is in accordance with FDA label or compendial supported.

AND

C. Authorization is for no more than 12 months

Hemlibra Clinical Criteria

POLICY:
Hemlibra will be considered medically necessary once the following coverage criteria is met and may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Hemophilia A with or without Factor VIII Inhibitors:**
    - **A.** Member has ONE of the following diagnoses of hemophilia A:
        - **a.** Hemophilia A with factor VIII inhibitors defined as ONE of the following:
            - **i.** Positive Factor VIII inhibitor titer > 5 Bethesda Units (BU)**;**
            - **OR**
            - **ii.** Positive Factor VIII inhibitor titer ≤ 5 Bethesda Units (BU) and the member has had an anamnestic or an inadequate clinical response to Factor VIII products;
        - **OR**
        - **b.** Hemophilia A without factor VIII inhibitors defined as ONE of the following:
            - **i.** Pretreatment Factor VIII levels ≤ 2% of normal;
            - **OR**
            - **ii.** Pretreatment Factor VIII levels > 2% and < 40% of normal plus ONE of the following scenarios:
                - **1.** Member has experienced a severe, traumatic, or spontaneous bleeding episode(s);
                - **OR**
                - **2.** Member has experienced a joint bleed, hemophilia-related joint damage or has a joint that is at risk of recurrent bleeding
            - **OR**
            - **iii.** Member is in a clinical situation that poses a bleeding risk in which the prescriber determines Hemlibra necessary;
    - **AND**
    - **B.** Member will be prescribed Hemlibra for prophylaxis therapy to prevent or reduce frequency of bleeding episodes;
    - **AND**
    - **C.** Hemlibra will be prescribed through the consultation of a hematologist;
    - **AND**
    - **D.** Prescriber attests to one of the following:
        - **a.** If member is currently receiving a bypassing agent (e.g., Feiba, NovoSeven RT, Sevenfact) for prophylatic use, therapy will be discontinued the day before starting Hemlibra
        - **OR**

b. If member is currently receiving a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) for prophylatic use, therapy will be discontinued within the first week of Hemlibra.

AND

E. Prophylatic use of bypassing agents and Factor VIII products will not occur while using Hemlibra but the use of bypassing agents and Factor VIII products for breakthrough bleeding is permitted.

AND

F. If the member is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeding, then ALL of the following must be considered:

a. Dose of aPCC will not exceed 100 U/kg/24 hours

AND

b. Monitoring will be conducted for thromboembolism and thromotic microangiopathy (TMA);

AND

G. Hemlibra will be prescribed based on the approved FDA dosing schedule;

AND

H. Authorization is for no more than 6 months

RENEWAL REQUEST:

1. Hemophilia A with or without Factor VIII inhibitors:

A. Initial conditions of coverage have been met;

AND

B. Member has experienced a positive clinical response to Hemlibra as defined as reduction in frequency of breathrough bleeds;

AND

C. Member is not using Hemlibra in combination with ANY of the following products prophylactically;

a. Bypassing agent (e.g., Feiba, NovoSeven RT, Sevenfact)

OR

b. Factor VIII products (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha);

AND

D. If member is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeding, prescriber will continue to monitor the member for thromboembolism and thrombotic microangiopathy (TMA);

AND

E. Authorization is for no more than 12 months

Herceptin Clinical Criteria

Monoclonal antibody - Trastuzumab	
Preferred	Herzuma (trastuzumab-pkrb, biosimilar, 10 mg) Kanjinti (trastuzumab-anns, biosimilar, 10 mg) Ogivri (trastuzumab-dkst, biosimilar, 10 mg) Ontruzant (trastuzumab-dttb, biosimilar, 10 mg) Trazimera (trastuzumab-qyyp, biosimilar, 10 mg)
Non-preferred	Herceptin (trastuzumab, excludes biosimilar, 10 mg)

POLICY:
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

Non-preferred drugs will be approved when ALL of the following criteria are met:

A. ONE of the following:
- **a.** Documented trial and failure with ALL preferred agents listed above;

OR
- **b.** The preferred agents are not appropriate for the member and clinical rationale is provided;

AND

B. Indication, dose, frequency and duration is in accordance with FDA label or compendial supported

AND

C. Authorization is for no more than 12 months

Ocrevus Clinical Criteria

POLICY:
Ocrevus will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Relapsing Forms of Multiple Sclerosis**
   - **A.** Member is 18 years of age and older;
   - **AND**
   - **B.** Confirmed diagnosis is consistent with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting, and active secondary progressive disease as defined by the following:
     - **a.** History of two or more clinical MS attacks who have objective clinical evidence of two or more lesions or objective clinical evidence of one lesion with reasonable historical evidence of a prior attack involving a lesion in a distinct anatomic location, confirmed by an MRI of the brain;
   - **AND**
   - **C.** Member will not concomitantly use any other disease modifying therapies while taking Ocrevus;
   - **AND**
   - **D.** Member does not have active hepatitis B virus infection;
   - **AND**
   - **E.** Member must be pre-medicated with 100 mg of methylprednisolone (or an equivalent corticosteroid) administered intravenously approximately 30 minutes prior to each infusion of Ocrevus;
   - **AND**
   - **F.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis;
   - **AND**
   - **G.** Dose is within approved FDA dosing:
     - **a.** Initial dose of 300 mg intravenous infusion, then 300mg once 2 weeks later; then subsequent doses of 600 mg once every 6 months (beginning 6 months after the first 300 mg dose);
   - **AND**
   - **H.** Authorization is for no more than 6 months

2. **Primary Progressive Multiple Sclerosis**
   - **A.** Member is 18 years of age and older;
   - **AND**
   - **B.** Confirmed diagnosis of primary progressive multiple sclerosis as defined by:
     - **a.** Evidence of one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, plus TWO of the following criteria:

i. One of more hyperintense T2 lesions characteristic of MS in one or more of the periventricular, cortical, or juxtacortical, or infratentorial areas
ii. Two of more hyperintense T2 lesions in the spinal cord
iii. Presence of CSF-specific oligoclonal bands

AND

C. Member has had additional testing/procedures performed to support the diagnosis of MS, including the following:
- **a.** MRI (brain or spinal cord)
- **b.** Lumbar puncture
- **c.** Autoantibody determination for aquaporin-4 (AQP4) and myelinoligodendrocyte glycoprotein (MOG) antibodies

AND

D. Member does not have active hepatitis B virus infection;

AND

E. Member must be pre-medicated with 100 mg of methylprednisolone (or an equivalent corticosteroid) administered intravenously approximately 30 minutes prior to each infusion of OCREVUS;

AND

F. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis;

AND

G. Dose is within approved FDA dosing:
- **a.** Initial dose of 300 mg intravenous infusion, then 300mg once 2 weeks later; then subsequent doses of 600 mg once every 6 months (beginning 6 months after the first 300 mg dose)

AND

H. Authorization is for no more than 6 months

RENEWAL REQUEST

1. All indications

A. All initial conditions of coverage have been met;

AND

B. The patient's condition has not worsened while on therapy;

AND

C. The patient has not developed significant adverse drug effects including:
- **a.** Anaphylaxis or other hypersensitivity reactions
- **b.** Life-threatening or disabling infusion reactions
- **c.** Development of an active infection, especially Hepatitis B virus
- **d.** Reduction in immunoglobulins
- **e.** Malignancies

AND

D. Continued dosing is within FDA approved dosing:
- **a.** One 600 mg intravenous infusion every 6 months

AND

E. Authorization is for no more than 12 months

Rituxan Clinical Criteria

POLICY:
Rituximab and its biosimilars will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

Ruxience is the preferred product. Rituxan, Riabni and Truxima require trial and failure with Ruxience.

	Rituximab Approvable Indications
1	Moderately to severely active Rheumatoid Arthritis (RA)
2	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauci-immune glomerulonephritis
3	Sjogren's Syndrome
4	Multiple Sclerosis (MS)
5	Myasthenia Gravis
6	Immune or Idiopathic Thrombocytopenia (ITP)
7	Autoimmune blistering disease
8	Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease)
9	Systemic Lupus Erythematosus (SLE)
10	Thrombotic thrombocytopenic purpura
11	Oncology Indications

INITIAL REQUEST:

1. **Moderately to severely active Rheumatoid Arthritis (RA)**
   - **A.** Member is 18 years of age or older;
   - **AND**
   - **B.** Prescribed by or in consultation with a Rheumatologist;
   - **AND**
   - **C.** Member has a confirmed diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by ONE of the following:
     - **a.** ≥8 tender joints or painful on motion; and ≥6 swollen joints;
     - **OR**
     - **b.** High sensitivity C-reactive protein (hs-CRP) ≥7 mg/L or ESR ≥28 mm/H;
   - **AND**
   - **D.** Member has tried, and indicated inadequate control, with ONE of the following agents (unless intolerant or contraindicated to):
     - **a.** Methotrexate in combination with another conventional Disease-modifying antirheumatic drugs (DMARD) for 3 months (see Appendix);
     - **OR**
     - **b.** Tumor necrosis factor (TNF) antagonist therapy: Humira, Enbrel, Simponi, and Cimzia;
     - **OR**

c. Previously received at least two full doses of Rituxan, Ruxience, Truxima, or Riabni for the treatment of RA (most recent dose was given within 6 months of request);

AND

E. Authorization is for no more than 12 months

2. **Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauci-immune glomerulonephritis**
   - **A.** Pediatric member is ≥2 years old;
   - **AND**
   - **B.** Treatment of GPA, MPA, Churg-Strauss, or pauci-immune glomerulonephritis;
   - **AND**
   - **C.** Authorization is for no more than 12 months

3. **Sjogren's Syndrome**
   - **A.** Member has tried, and indicated inadequate control, with ALL of the following agents (unless intolerant or contraindicated to):
     - **a.** Glucocorticoids;
     - **AND**
     - **b.** Immunosuppressive agents (cyclophosphamide, azathioprine, mycophenolate or methotrexate);
   - **AND**
   - **B.** Authorization is for no more than 12 months

4. **Multiple Sclerosis (MS)**
   - **A.** Confirmed diagnosis of relapsing remitting multiple sclerosis;
   - **AND**
   - **B.** Prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist;
   - **AND**
   - **C.** Medication will be administered 6 months after previous dose;
   - **AND**
   - **D.** Rituximab will NOT be used in combination with any ONE of the following:
     - **a.** Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide);
     - **OR**
     - **b.** B-cell targeted therapy (e.g., ocrelizumab, belimumab, ofatumumab);
     - **OR**
     - **c.** Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone);
   - **AND**
   - **E.** Authorization is for no more than 12 months

5. **Myasthenia Gravis**
    - **A.** Member has tried, and indicated inadequate control, with ALL of the following agent(s) (unless intolerant or contraindicated to):
        - **a.** Pyridostrigmine;
        - **AND**
        - **b.** Cyclophosphamide;
        - **AND**
        - **c.** At least two immunosuppressive agents (azathioprine, mycophenolate cyclosporine, or methotrexate);
    - **AND**
    - **B.** Authorization is for no more than 12 months

6. **Immune or Idiopathic Thrombocytopenia (ITP)**
    - **A.** Medication is prescribed by or in consultation with a hematologist;
    - **AND**
    - **B.** Initial treatment is for maximum of 4 doses;
    - **AND**
    - **C.** ONE of the following:
        - **a.** Member has tried, and indicated inadequate control, with at least ONE of the following (unless intolerant or contraindicated to):
            - **i.** Intravenous immunoglobulin (IVIG);
            - **OR**
            - **ii.** Anti-D (RHO) immunoglobulin;
            - **OR**
            - **iii.** Corticosteroids;
            - **OR**
            - **iv.** Splenectomy;
        - **OR**
        - **b.** Member has previously received course of a rituximab product for ITP and meets ALL of the following:
            - **i.** Medication will be administered 6 months after previous dose;
            - **AND**
            - **ii.** Documentation that member responded to therapy;
            - **AND**
            - **iii.** Prescriber confirmed member has relapsed disease;
    - **AND**
    - **D.** Authorization is for no more than 6 months

7. **Autoimmune blistering disease**
    - **A.** Prescribed by or in consultation with a dermatologist;
    - **AND**
    - **B.** Therapy will be used in combination with a systemic corticosteroid;
    - **AND**
    - **C.** Authorization is for no more than 12 months

8. **Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease)**
    - **A.** Prescribed by or in consultation with a neurologist;
    - **AND**
    - **B.** When at least one other immunotherapy was ineffective;
    - **AND**
    - **C.** The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD;
    - **AND**
    - **D.** Authorization is for no longer than 12 months

9. **Systemic Lupus Erythematosus (SLE)**
    - **A.** Prescribed by or in consultation with a rheumatologist, nephrologist, or neurologist;
    - **AND**
    - **B.** Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm);
    - **AND**
    - **C.** ONE of the following:
        - **a.** Member is receiving a stable standard treatment for SLE with ONE of the following (alone or in combination):
            - **i.** Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone);
            - **OR**
            - **ii.** Antimalarials (e.g., hydroxychloroquine);
            - **OR**
            - **iii.** Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide);
        - **OR**
        - **b.** Member has previously received course of a rituximab product for SLE and meets ALL of the following:
            - **i.** Medication will be administered 6 months after previous dose;
            - **AND**
            - **ii.** Documentation that member responded to therapy;
            - **AND**
            - **iii.** Prescriber confirmed member has relapsed disease;
    - **AND**
    - **D.** Authorization is for no more than 12 months

10. **Thrombotic thrombocytopenic purpura**
    - **A.** Prescribed by or in consultation with hematologist;
    - **AND**
    - **B.** Member has a positive ADAMTS13 protease antibody titer;
    - **AND**
    - **C.** Member meets ONE of the following:
        - **a.** Member has had a suboptimal response to therapeutic plasma exchange;

OR

b. Member has failed corticosteroid therapy;

AND

D. Authorization is for no more than 6 months

11. Oncology Indications:

A. ONE of the following:

a. Non-Hodgkin's lymphoma (NHL) in adult patients with ONE of the following:

i. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent;

OR

ii. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy;

OR

iii. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy;

OR

iv. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens;

OR

b. Chronic lymphocytic leukemia (CLL)

i. Treatment is used in combination with fludarabine and cyclophosphamide (FC) in adult patients with previously untreated and previously treated CD20-positive CLL

c. AIDS-related B-cell lymphomas;

OR

d. Burkitt lymphoma;

OR

e. Castleman's disease;

OR

f. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL);

OR

g. Diffuse large B-cell lymphoma (DLBCL);

OR

h. Follicular lymphoma (FL);

OR

i. Hairy cell leukemia (Rituxan/Ruxience/Truxima only);

OR

j. Low- or high-grade B-cell lymphoma;
OR
k. MALT lymphoma (gastric or nongastric);
OR
l. Mantle cell lymphoma;
OR
m. Marginal zone lymphoma (nodal or splenic);
OR
n. Post-transplant lymphoproliferative disorder;
OR
o. Primary cutaneous B-cell lymphoma;
OR
p. Pediatric Aggressive Mature B-Cell Lymphomas;
OR
q. Central nervous system (CNS) cancers including ONE of the following:
i. Leptomeningeal metastases from lymphomas;
OR
ii. Primary CNS lymphomas;
r. Hodgkin's lymphoma, nodular lymphocyte-predominant;

AND

B. Authorization is for no more than 12 months

RENEWAL REQUEST:

1. **Rheumatoid Arthritis**
   A. Initial conditions of coverage have been met for continued treatment in all members (including new members);
   AND
   B. Member has achieved or maintained a positive clinical response after at least two doses of therapy with Rituxan, Ruxience, Truxima, or Riabni as evidenced by disease activity improvement of at least 20% from baseline in ONE of the following:
   a. Tender joint count;
   OR
   b. Swollen joint count;
   OR
   c. Pain;
   OR
   d. Disability;
   AND
   C. Medication will be administered 6 months after previous dose;
   AND
   D. Authorization is for no more than 12 months

2. **Multiple Sclerosis**
   A. Initial conditions of coverage have been met;
   AND

B. Member has relapsing remitting multiple sclerosis (MS);
AND
C. Member has experienced disease stability or improvement while receiving Rituxan, Ruxience, Truxima, or Riabni;
AND
D. Authorization is for no more than 12 months

3. Oncology Indications

A. Initial conditions of coverage have been met;
AND
B. Member has an oncologic indication;
AND
C. Member has no evidence of disease progression or unacceptable toxicity;
AND
D. Authorization is for no more than 12 months

4. All other indications

A. Initial conditions of coverage have been met for continued treatment in all members (including new members);
AND
B. Member has received benefit from therapy;
AND
C. Authorization is for no more than 12 months

Xolair Clinical Criteria

POLICY:
The use of Xolair will be considered medically necessary once the following coverage criteria is met as add on maintenance treatment and approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Severe Asthma:**
   - **A.** 6 years of age or older with diagnosis of asthma confirmed by clinical chart notes with documentation of asthma symptoms frequently throughout the day, nighttime awakenings ≥ 7 times per week, symptoms extremely interferes with normal, lung function is defined as FEV_1 < 60% predicted; FEV1/FVC reduced > 5%, two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous or one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year
   - **B.** Baseline immunoglobulin E (IgE) level ≥ 30 IU/mL
   - **C.** Documented adherence to asthma medications at optimized doses for sufficient treatment length
   - **D.** No concomitant use of Xolair with other biologics indicated for asthma
   - **E.** Initial approval duration is for 6 months

2. **Chronic rhinosinusitis with nasal polyps/ Nasal Polyps**
   - **A.** 18 years of age or older;
   - **B.** Baseline IgE level ≥ 30 IU/mL
   - **C.** Bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
   - **D.** Nasal blockage plus rhinorrhea (anterior/posterior), reduction or loss of smell or facial pain or pressure for at least 6 month
   - **E.** Documented recent history (within 12 months) of taking at least 3 of the following topical intranasal agents for at least 3 months each: flunisolide, fluticasone, budesonide, triamcinolone acetonide;
   - **F.** Received at least one course of treatment with systemic corticosteroids in the previous 2 years (unless intolerant or contraindicated) or has had prior surgery for nasal polyps
   - **G.** Member will be using a daily intranasal corticosteroid while being treated with Nucala/Xolair, unless contraindicated or not tolerated
   - **H.** Initial approval duration is for 6 months

3. **Chronic idiopathic urticaria**
    - **A.** 12 years of age or older
    - **B.** Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
    - **C.** Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks almost every day;
    - **D.** Member has tried/failed or has history of contradiction or intolerance of at least two second generation H1-antihistamines, titrate at least two second generation H1-antihistamine to four times normal dose and a combination one second generation H1-antihistamine and one of the following (a different second generation H1-antihistamine (titrated to four times the normal dose), a 1st generation antihistamine to be taken at bedtime or leukotriene modifier
    - **E.** Member does not have known hypersensitivity to Xolair or any of its excipients
    - **F.** Initial approval duration is for 6 months

4. **IgE-Mediated Food Allergy**
    - **A.** Member is 1 year of age or older
    - **B.** Member has confirmed diagnosis of IgE-mediated food allergy as demonstrated by a clinical history of IgE-mediated allergy to one or more foods that meet ALL of the following:
    - **C.** Member demonstrated signs and symptoms of a significant systemic allergic reaction
    - **D.** System allergic reaction occurred shortly after a known ingestion of the food
    - **E.** Member's prescriber concluded that reaction warranted a prescription for an epinephrine auto-injector
    - **F.** Positive skin prick test response to one or more foods
    - **G.** Positive in vitro test for IgE to one or more foods
    - **H.** Member has baseline IgE levels ≥ 30 IU/mL;
    - **I.** Xolair is being used in conjunction to a diet that avoids food allergens
    - **J.** Member has been prescribed an epinephrine auto-injector for treating emergency allergic reactions
    - **K.** Initial approval duration is for 6 months

RENEWAL REQUEST:

1. **Severe Asthma**
    - **A.** Initial conditions of coverage have been met
    - **B.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met confirmed by clinical chart notes
    - **C.** Member experienced a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose
    - **D.** Renewal approval duration is for 12 months

2. **Chronic rhinosinusitis with nasal polyps/ Nasal Polyps**
    - **A.** Initial conditions of coverage have been met;
    - **B.** 18 years of age or older;
    - **C.** Member achieved or maintained a positive clinical response therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use) confirmed by clinical chart notes
    - **D.** Renewal approval duration is for 12 months

3. **Chronic idiopathic urticaria**
    - **A.** Initial conditions of coverage have been met
    - **B.** 12 years of age or older
    - **C.** Member achieved or maintained a positive clinical response confirmed by clinical chart notes
    - **D.** Renewal approval duration is for 12 months

4. **IgE-Mediated Food Allergy**
    - **A.** Initial coverage have been met**;**
    - **B.** 1 year of age or older
    - **C.** Member achieved or maintained a positive clinical response confirmed by clinical chart notes
    - **D.** Renewal approval duration is for 12 months

Remicade Clinical Criteria

POLICY:

Infliximab and its biosimilars will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis as prescribed by or in consultation with a gastroenterologist/rheumatologist and previous treatment(s).

Member is not using the requested medication concomitantly with any other biologic drug or targeted synthetic drug

Inflectra is the preferred product. Avsola, Ixifi, Remicade and Renflexis require trial and failure with Inflectra.

INITIAL REQUEST:

1. **Moderately to severely active crohn's disease (CD)**
   - **A.** Member is 3 years of age or older;
   - **AND**
   - **B.** ONE of the following:
     - **a.** Member has experienced an inadequate response for at least 3 months ONE of the following:
       - **i.** systemic corticosteroids; azathioprine; mercaptopurine; methotrexate;
     - **OR**
     - **b.** Member has fistulizing CD
   - **AND**
   - **C.** Authorization is for no more than 12 months

2. **Moderately to severely active ulcerative colitis (UC)**
   - **A.** Member is 6 years of age or older;
   - **AND**
   - **B.** Member has experienced an inadequate response for at least 4 weeks to ONE of the following:
     - **a.** oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), rectal mesalamine (e.g., Canasa, Rowasa rectal hydrocortisone (e.g., Colocort, Cortifoam)**,** balsalazide**,** olsalazine**,** prednisone**,** azathioprine**,** mercaptopurine**,** sulfasalazine**,** balsalazide**,** olsalazine**,** cyclosporine, tacrolimus;
   - **AND**
   - **C.** Authorization is for no more than 12 months

3. **Moderately to severely active rheumatoid arthritis (RA)**
   - **A.** Member is 18 years of age or older;
   - **AND**

B. Member has a confirmed diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by ONE of the following;

a. ≥8 tender joints or painful on motion; and ≥6 swollen joints;

OR

b. high sensitivity C-reactive protein (hs-CRP) ≥7 mg/L;

OR

c. ESR ≥28 mm/H;

AND

C. Member has tried and indicated inadequate control (unless intolerant or contraindicated to) ONE of the following:

a. Methotrexate in combination with another conventional DMARD for 3 months;

OR

b. Tumor necrosis factor inhibitor (TNFi)

AND

D. Member meets ONE of the following criteria

a. Member has been tested for ONE of the following biomarkers and the test was positive:

i. Rheumatoid factor (RF);

OR

ii. Anti-cyclic citrullinated peptide (anti-CCP);

OR

b. Member has been tested for **ALL** of the following biomarkers:

i. RF;

AND

ii. Anti-CCP;

AND

iii. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR);

AND

E. Authorization is for no more than 12 months

4. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

A. Member is 18 years of age or older;

AND

B. When ONE of the following criteria is met

a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs);

OR

b. Member has an intolerance or contraindication to two or more NSAIDs;

OR

c. Member has an intolerance or contraindication to a tumor necrosis factor inhibitor (TNFi);

AND

C. Authorization is for no longer than 12 months

5. **Active psoriatic arthritis (PsA)**
    - **A.** Member is 18 years of age or older;
    - **AND**
    - **B.** ONE of the following:
        - **a.** Member has experienced an inadequate response to ALL of the following:
            - **i.** A 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week);
            - **AND**
            - **ii.** NSAIDs for at least 4 weeks;
            - **AND**
            - **iii.** Corticosteroids stable on a dose of ≤10 mg/day prednisone or equivalent for at least 2 weeks;
        - **OR**
        - **b.** Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);
    - **AND**
    - **C.** Authorization is for no more than 12 months

6. **Moderate to severe plaque psoriasis**
    - **A.** Member is 18 years of age or older;
    - **AND**
    - **B.** Body surface area affected by plaque-type psoriasis of 10% or greater;
    - **AND**
    - **C.** ONE of the following:
        - **a.** Member has tried ALL of the following for at least 3 months (unless intolerant or contraindicated):
            - **i.** Conventional DMARD therapy (see Appendix A);
            - **AND**
            - **ii.** Phototherapy (e.g. UVB, PUVA) administered 3-5 times per week;
        - **OR**
        - **b.** Member has tried a tumor necrosis factor inhibitor (TNFi) for at least 3 months (unless intolerant or contraindicated);
    - **AND**
    - **D.** Authorization is for no more than 12 months

7. **Hidradenitis suppurativa**
    - **A.** Member has a confirmed diagnosis of moderate to severe hidradenitis suppurativa with a total abscess and inflammatory-nodule count of three or more;
    - **AND**
    - **B.** Member has a documented trial and failure or contraindication of using at least ONE regimen from each of the following treatment options within the past 12 months:
        - **a.** Intralesional corticosteroid;
        - **OR**
        - **b.** Topical Clindamycin for 3 months;
        - **OR**

c. Oral mono antibiotics for 3 months: tetracycline, minocycline, doxycycline;

OR

d. Oral combo antibiotics for 3 months: oral clindamycin and oral Rifampin;

OR

e. Oral Hormonal therapy- Spironolactone for 3 months for female members;

OR

f. Oral retinoids- Acitretin for 6 months for members with concomitant acne;

OR

g. Biologic – Humira for 3 months;

AND

C. Authorization is for no more than 12 months

8. Juvenile Idiopathic arthritis (JIA)

A. ONE of the following:

a. Member has an inadequate response to ALL of the following:

i. 1-month trial of NSAIDs;

AND

ii. 2-week trial of corticosteroids;

AND

iii. 3-month trial of methotrexate or another non-biologic DMARD;

OR

b. Member has an inadequate response to tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

9. Pyoderma gangrenosum

A. ONE of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

OR

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

10. Sarcoidosis

A. ONE of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

OR

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

11. Takayasu's arteritis

A. ONE of the following:

a. Member has experienced an inadequate response to ALL of the following:

i. Corticosteroids;

AND

ii. Immunosuppressive agent for at least 3 months therapy (e.g., cyclosporine or mycophenolate mofetil);

OR

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

12. Uveitis

A. Member has a confirmed diagnosis of non-infectious intermediate, posterior, and panuveitis with the presences of ONE of the following**:**

i. ≥2+ anterior chamber cell grade (Standardization of Uveitis Nomenclature criteria);

OR

ii. Vitreous Haze grade of ≥2+;

OR

iii. Active, inflammatory, chorioretinal and/or inflammatory retinal vascular lesion;

AND

B. Recent history (within 12 months) of taking at least ONE from each of the following treatment options**:**

a. Topical corticosteroid eye drops for 3 months;

i. prednisolone, dexamethasone, fluorometholone

OR

b. Oral Glucocorticoids for 3 months;

i. steroid equivalent to 40-60mg of prednisone

OR

c. Calcineurin Antagonist for 3 months;

i. cyclosporine, tacrolimus

OR

d. Cytotoxic agents for 3 months;

i. methotrexate, azathioprine, mycophenolate

OR

e. Biologic for 3 months;
i. Humira

AND

C. Authorization is for no more than 3 months

13. Reactive arthritis

A. ONE of the following:
a. Member has experienced an inadequate response to ALL of the following:
i. 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week);
AND
ii. NSAIDs for at least 4 weeks;
AND
iii. Corticosteroids stable on a dose of ≤10 mg/day prednisone or equivalent for at least 2 weeks;

OR

b. Member has experienced an inadequate response to a tumor necrosis factor inhibitor (TNFi);

AND

B. Authorization is for no more than 12 months

14. Immune checkpoint inhibitor toxicity

A. Member has diagnosis of immunotherapy-related myocarditis, pericarditis, arrhythmias, impaired ventricular function or conduction abnormalities;
AND
B. Member is 18 years of age or older;
AND
C. Member started pulse-dose methylprednisolone and had no improvement of toxicity within 24 hours;
AND
D. Member has received checkpoint inhibitor therapy [i.e. Keytruda (pembrolizumab), Opdivo (nivolumab)] recently;
AND
E. Authorization is for no more than 12 months

15. Acute graft versus host disease

A. Member has experienced an inadequate response to systemic corticosteroids;
OR
B. Member is intolerant to systemic corticosteroids;
OR
C. Tumor necrosis factor inhibitor (TNFi);
AND
D. Authorization is for no more than 12 months

RENEWAL REQUEST:

1. **Moderately to severely active Crohn's disease (CD)**
   - **A.** Member has achieved or maintained remission;
   OR
   - **B.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
     - **a.** Abdominal pain or tenderness;
     OR
     - **b.** Diarrhea;
     OR
     - **c.** Body weight;
     OR
     - **d.** Abdominal mass;
     OR
     - **e.** Hematocrit;
     OR
     - **f.** Endoscopic appearance of the mucosa;
     OR
     - **g.** Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score);

   AND
   - **C.** Authorization is for no more than 12 months

2. **Moderately to severely active ulcerative colitis (UC)**
   - **A.** Member has achieved or maintained remission;
   OR
   - **B.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline**:**
     - **a.** Stool frequency;
     OR
     - **b.** Rectal bleeding;
     OR
     - **c.** Urgency of defecation;
     OR
     - **d.** C-reactive protein (CRP);
     OR
     - **e.** Fecal calprotectin (FC);
     OR
     - **f.** Endoscopic appearance of the mucosa;
     OR
     - **g.** Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score);

   AND
   - **C.** Authorization is for no more than 12 months

3. **Moderately to severely active rheumatoid arthritis (RA)**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability;

    AND
    - **B.** Authorization is for no more than 12 months

4. **Active ankylosing spondylitis (AS) and active axial spondyloarthritis**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
        - **a.** Functional status;

        OR
        - **b.** Total spinal pain;

        OR
        - **c.** Inflammation (e.g., morning stiffness)

    AND
    - **B.** Authorization is for no more than 12 months

5. **Active psoriatic arthritis (PsA)**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline**:**
        - **a.** Number of swollen joints;

        OR
        - **b.** Number of tender joints;

        OR
        - **c.** Dactylitis;

        OR
        - **d.** Enthesitis;

        OR
        - **e.** Skin and/or nail involvement

    AND
    - **B.** Authorization is for no more than 12 months

6. **Moderate to severe plaque psoriasis**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
        - **a.** Reduction in body surface area (BSA) affected from baseline;

        OR
        - **b.** Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain);

    AND
    - **B.** Authorization is for no more than 12 months

7. **Hidradenitis suppurativa**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when ONE of the following is met**:**
        - **a.** Reduction in abscess and inflammatory nodule count from baseline;
        - **OR**
        - **b.** Reduced formation of new sinus tracts and scarring;
        - **OR**
        - **c.** Decrease in frequency of inflammatory lesions from baseline;
        - **OR**
        - **d.** Reduction in pain from baseline;
        - **OR**
        - **e.** Reduction in suppuration from baseline;
        - **OR**
        - **f.** Improvement in frequency of relapses from baseline;
        - **OR**
        - **g.** Improvement in quality of life from baseline;
        - **OR**
        - **h.** Improvement on a disease severity assessment tool from baseline;
    - **AND**
    - **B.** Authorization is for no more than 12 months

8. **Juvenile idiopathic arthritis (JIA)**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
        - **a.** Number of joints with active arthritis (e.g., swelling, pain, limitation of motion);
        - **OR**
        - **b.** Number of joints with limitation of movement;
        - **OR**
        - **c.** Functional ability;
    - **AND**
    - **B.** Authorization is for no more than 12 months

9. **Uveitis**
    - **A.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:
        - **a.** Reduced frequency of recurrence compared to baseline;
        - **OR**
        - **b.** Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline;
        - **OR**
        - **c.** Decreased reliance on topical corticosteroids

AND

B. Authorization is for no more than 12 months

10. Reactive arthritis

A. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ONE of the following from baseline:

a. tender joint count;

OR

b. swollen joint count;

OR

c. pain

AND

B. Authorization is for no more than 12 months

11. Immune checkpoint inhibitor toxicity and acute graft versus host disease

A. Member must meet all initial authorization criteria;

AND

B. Authorization is for no more than 4 doses

12. All other indications

A. Member has achieved or maintained a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition;

AND

B. Authorization is for no more than 12 months

Tremfya Clinical Criteria

POLICY:
Tremfya will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

Member is not using the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

INITIAL REQUEST:

1. **Psoriatic arthritis (PsA)**
   - **A.** Prescribed by or in consultation with a Dermatologist or Rheumatologist
   - **B.** Tried, and indicated inadequate control (unless intolerant or contraindicated) to NSAIDs for at least 4 weeks, corticosteroids stable on a dose of ≤10 mg/day prednisone or equivalent for at least 2 weeks and conventional/non-biologic disease modifying anti-rheumatic drug (DMARD) for at least 3 months;
   - **C.** Initial approval duration is for 12 months

2. **Moderate to severe plaque psoriasis**
   - **A.** Prescribed by or in consultation with a Dermatologist
   - **B.** Body surface area affected by plaque-type psoriasis of 10% or greater
   - **C.** Tried conventional DMARD therapy and phototherapy (e.g. UVB, PUVA) administered 3-5 times per week for at least 3 months (unless intolerant or contraindicated)
   - **D.** Initial approval duration is for 12 months

RENEWAL REQUEST:

1. **Psoriatic arthritis (PsA)**
   - **A.** Initial conditions of coverage have been met
   - **B.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in number of swollen joints, number of tender joints, dactylitis, enthesitis or skin and/or nail involvement from baseline confirmed by clinical chart notes
   - **C.** Renewal approval duration is for 12 months

2. **Moderate to severe plaque psoriasis**
   - **A.** Initial conditions of coverage have been met
   - **B.** Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is a reduction in body surface area (BSA) affected from baseline or improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain) confirmed by clinical chart notes
   - **C.** Renewal approval duration is for 12 months

Duschenne Muscular Dystrophy Agents Clinical Criteria
(Amondys, Exondys, Vyondys)

Duchenne Muscular Dystrophy agents will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Duchenne Muscular Dystrophy (DMD)**
   - **A.** Member has a diagnosis of Duchenne Muscular Dystrophy (DMD);
   - **AND**
   - **B.** Genetic testing documentation submitted to confirm DMD gene mutation of the member is amenable to ONE of the following:
     - **a.** Exon 45 skipping;
     - **OR**
     - **b.** Exon 51 skipping;
     - **OR**
     - **c.** Exon 53 skipping;
   - **AND**
   - **C.** Member has tried a stable dose of corticosteroids prior to starting therapy or has a documented reason not to be on corticosteroids;
   - **AND**
   - **D.** Member is not concurrently being treated with another exon skipping therapy for DMD;
   - **AND**
   - **E.** If request is for Amondys 45 (casimersen), Viltepso (viltolarsen) or Vyondys 53, member's kidney function was tested;
   - **AND**
   - **F.** Authorization is for no more than 6 months

RENEWAL REQUEST:

1. **Duchenne Muscular Dystrophy (DMD)**
   - **A.** Initial conditions of coverage have been met;
   - **AND**
   - **B.** Authorization is for no more than 6 months