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 and Ocrevus Zunovo 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.** Member has a 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 ONE of the following:
     - **a.** History of two or more clinical MS attacks who have objective clinical evidence of two or more lesions;
     - **OR**
     - **b.** 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 has tried and failed or has intolerance or contraindication to at least two therapeutic agents (e.g., dimethyl fumarate, fingolimod);
   - **OR**
   - Member will not concomitantly use any of the following while taking Ocrevus:**AND**
   - **D.** Member does not have active hepatitis B virus infection;
   - **AND**
   - **E.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis;
   - **AND**
   - **F.** Dose is within approved FDA dosing;
   - **AND**
   - **G.** Authorization is for no more than 12 months

2. **Primary Progressive Multiple Sclerosis (PPMS)**
   - **A.** Member is 18 years of age and older;
   - **AND**
   - **B.** Member has a confirmed diagnosis of primary progressive multiple sclerosis as defined by evidence of one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, plus TWO of the following criteria:
     - **a.** One of more hyperintense T2 lesions characteristic of MS in one or more of the periventricular, cortical, or juxtacortical, or infratentorial areas;
     - **b.** Two of more hyperintense T2 lesions in the spinal cord;
     - **c.** 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 has tried and failed or has intolerance or contraindication to at least two therapeutic agents (e.g., dimethyl fumarate, fingolimod);

AND

E. Member will not concomitantly use any of the following while taking Ocrevus:

- **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., rituximab, belimumab, ofatumumab, ublituximab-xiiy)

OR

- **c.** Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)

AND

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

AND

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

AND

H. Dose is within approved FDA dosing;

AND

I. Authorization is for no more than 12 months

RENEWAL REQUEST

1. **All indications**

A. Initial conditions of coverage have been met;

AND

B. Member's condition has not worsened while on therapy (i.e., stable number or decrease in relapses, recent (within 6 months) MRI shows lack of development of new asymptomatic lesions);

AND

C. Member has not developed ANY significant adverse drug effects including:

- **a.** Anaphylaxis or other hypersensitivity reactions;

OR

- **b.** Life-threatening or disabling infusion reactions;

OR

- **c.** Development of an active infection (i.e., Hepatitis B virus, herpes-related infections, progressive multifocal leukoencephalopathy);

OR

d. Malignancies;

OR

e. Immune-Mediated Colitis;

AND

D. Continued dosing is within FDA approved dosing;

AND

E. Authorization is for no more than 12 months

Rituxan Clinical Criteria

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
12	Pemphigus Vulgaris

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 (e.g., Humira, Enbrel, Simponi, 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.** 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**
    - **C.** Authorization is for no more than 6 months (initial treatment is for a maximum of 4 doses);

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

12. Pemphigus Vulgaris (PV)

A. Member is 18 years of age or older;
AND
B. Member has moderate to severe disease as assessed utilizing an objective measure (i.e. Pemphigus Disease Area Index (PDAI), Autoimmune Bullous Skin Disorder Intensity Score (ABSIS), Pemphigus Area and Activity Score (PAAS));
AND
C. Member has confirmed diagnosis of Phemphigus Vulgaris (PV) as determined by ONE of the following:
a. Clinical features (i.e., appearance of lesions, erosions and/or blisters, Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin), Characteristic scarring and lesion distribution);
OR
b. Histopathologic confirmation by skin/mucous membrane biopsy;
OR
c. Positive direct immunofluorescence (DIF) microscopy result;
OR
d. Presence of autoantibodies as detected by direct immunofluorescence or enzyme-linked immunosorbent assay (ELISA);
AND
D. Member has tried and failed the following agents in individually and in combination after at least 3 months unless intolerant or contraindicated:
a. Corticosteroids;

AND

b. DMARD (cyclophosphamide, azathioprine, methotrexate, mycophenolate);

AND

E. 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

Remicade Clinical Criteria

POLICY:

Remicade 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

INITIAL REQUEST & RENEWAL REQUEST:

A. Confirm diagnosis for FDA- or compendia-supported uses;
AND

B. Trial of a disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNFi) Food and Drug Administration (FDA)-approved for self-administration prior to initiation of requested medication;
AND

C. Authorization is for no more than 12 months

Duchenne 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