Mass General Brigham
Health Plan

Complement Inhibitors and Miscellaneous Immunosuppressive Agents
Enjaymo (sutimlimab-jome)
Soliris (eculizumab)
Tavneos (avacopan)
Syfovre (pegcetacoplan)
Uplizna (inebilizumab-cdon)
Vyvgart (efgartigimod alfa-fcab)
Effective 03/04/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	Tavneos (avacopan) have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Enjaymo (sutimlimab-jome) is an immunoglobulin G (IgG), subclass 4 monoclonal antibody that is indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin diseases (CAD).

Rystiggo (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive.

Soliris (eculizumab) is indicated for the treatment of atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (MG), neuromyelitis optica spectrum disorder (NMOSD), and paroxysmal nocturnal hemoglobinuria (PNH).

Tavneos (avacopan) is an oral agent. It is a first-in class complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV) including the two main types: granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in combination with standard therapy including glucocorticoids.

Syfovre (pegcetacoplan) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody that is presumed to be involved in CD19 binding. Following binding, inebilizumab-cdon depletes lymphocytes derived from B-cell lineage.

Vyvgart (efgartigimod alfa-fcab) is indicated for the treatment of gMG in adult patients who are anti- AChR antibody positive.

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is a subcutaneous product combination of efgartigimod alfa, a human IgG1 antibody fragment marketed for intravenous use as Vyvgart (efgartigimod alfa), and recombinant human hyaluronidase PH20 (rHuPH20), which is Halozyme's ENHANZE® drug delivery technology to increase permeability of the subcutaneous tissue by depolymerizing hyaluronan, facilitating subcutaneous delivery of biologics.

No PA	Drugs that require PA
Complement Inhibitors	
	Enjaymo® (sutimlimab-jome) MB
	Soliris® (eculizumab) MB
	Tavneos® (avacopan)
	Syfovre (pegcetacoplan) MB
Miscellaneous Immunosuppressive Agents	
	Rystiggo (rozanolixizumab-noli) MB
	Uplizna® (inebilizumab-cdon) MB
	Vyvgart® (efgartigimod alfa-fcab) MB
	Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) MB

MB – Medical Benefit. This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with the requested product excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

Enjaymo (sutimlimab-jome)
ALL of the following:
1. Diagnosis of cold agglutinin disease (CAD)
2. Member is ≥18 years of age
3. Member has had ≥1 blood transfusion in the last 6 months
4. Hb ≤10 g/dL (dated within the last 60 days)
5. Member has received a vaccine against encapsulated bacteria (Neisseria meningitidis, Haemophilus influenzae, and Streptococcus pneumoniae) at least two weeks prior to treatment initiation
6. Appropriate dosing

Rystiggo (rozanolixizumab-noli)
Generalized Myasthenia Gravis
1. Diagnosis of Generalized Myasthenia Gravis
2. Member is ≥18 years of age
3. Member is AChR or MuSK antibody positive
4. Prescriber is a neurologist or consult notes from a neurology office are provided

5. Physician attestation of inadequate response, adverse reaction, or contraindication to pyridostigmine
6. Physician attestation of inadequate response or adverse reaction to **TWO** of the following or contraindication to **ALL** of the following immunosuppressant trials
    a. azathioprine
    b. cyclosporine
    c. glucocorticoids (e.g., prednisone)
    d. mycophenolate
    e. tacrolimus
7. **ONE** of the following:
    a. Inadequate response, adverse reaction, or contraindication to Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
    b. Member is MuSK antibody positive
8. Appropriate dosing

Soliris (eculizumab)

Atypical hemolytic-uremic syndrome (aHUS)

ALL of the following:

1. Diagnosis of atypical hemolytic-uremic syndrome (aHUS)
2. Member has received a meningococcal vaccine at least two weeks prior to treatment initiation
3. Appropriate dosing

Generalized Myasthenia Gravis

ALL of the following:

1. Diagnosis of Generalized Myasthenia Gravis
2. Member is ≥18 years of age
3. Member is AchR antibody positive
4. Prescriber is a neurologist or consult notes from a neurology office are provided
5. Physician attestation of inadequate response, adverse reaction, or contraindication to pyridostigmine
6. Physician attestation of inadequate response or adverse reaction to **TWO** of the following or contraindication to **ALL** of the following immunosuppressant trials
    a. azathioprine
    b. cyclosporine
    c. glucocorticoids (e.g., prednisone)
    d. mycophenolate
    e. tacrolimus
7. Member has received a meningococcal vaccine at least two weeks prior to treatment initiation
8. Appropriate dosing

Neuromyelitis optica spectrum disorder (NMOSD)

ALL of the following:

1. Diagnosis of neuromyelitis optica spectrum disorder
2. Documentation of a positive serologic test for anti-aquaporin-4 (AQP4)
3. Member is ≥18 years of age
4. Member has received a meningococcal vaccine at least two weeks prior to treatment initiation
5. Appropriate dosing

Paroxysmal nocturnal hemoglobinuria (PNH)

ALL of the following:

1. Appropriate diagnosis
2. Member has received a meningococcal vaccine at least two weeks prior to treatment initiation
3. Appropriate dosing
4. Member is ≥18 years of age

Syfovre (pegcetacoplan)
Dry-AMD
ALL of the following:
1. Diagnosis of GA secondary to AMD
2. Prescriber is an ophthalmologist
3. Member is ≥ 60 years of age
4. **ALL** of the following:
    a. Absence of choroidal neovascularization (CNV or Wet-AMD) in the treatment eye
    b. Normal luminance best corrected visual acuity (BCVA) ≥24 letters (20/320 Snellen equivalence)
    c. Total GA lesion area ≥2.5 and ≤17.5 mm2, with at least 1 lesion ≥1.25 mm2 if GA is multifocal.
    d. Presence of any pattern of hyperautofluorescence in the junctional zone of GA.
5. Requested dosing is 15mg (0.1 mL) once every 25 days to 60 days

Tavneos (avacopan)
ALL of the following:
1. Diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (e.g., granulomatosis with polyangiitis [GPA], microscopic polyangiitis [MPA])
2. Member is ≥18 years of age
3. Prescriber is a rheumatologist or nephrologist or consult notes from a rheumatologist or nephrologist are provided
4. Physician attestation that the requested agent will be used as adjunctive therapy with **BOTH** of the following:
    a. A systemic glucocorticoid
    b. **ONE** of the following:
        i. azathioprine
        ii. cyclophosphamide
        iii. methotrexate
        iv. mycophenolate mofetil
        v. rituximab
5. Appropriate dosing
6. Requested quantity is ≤ 6 capsules per day

Uplizna (inebilizumab-cdon)
ALL of the following:
1. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
2. Documentation of a positive serologic test for anti-aquaporin-4 (AQP4)
3. Member is ≥18 years of age
4. **If reviewing under pharmacy benefit:** Physician attestation of inadequate response, adverse reaction or contraindication to Enspryng® (satralizumab-mwge)
5. Appropriate dosing

Vyvgart (efgartigimod alfa-fcab)
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

ALL of the following:

1. Diagnosis of Generalized Myasthenia Gravis
2. Member is ≥18 years of age
3. Member is AChR antibody positive
4. Prescriber is a neurologist or consult notes from a neurology office are provided
5. Physician attestation of inadequate response, adverse reaction, or contraindication to pyridostigmine
6. Physician attestation of inadequate response or adverse reaction to **TWO** of the following or contraindication to **ALL** of the following immunosuppressant trials
    a. azathioprine
    b. cyclosporine
    c. glucocorticoids (e.g., prednisone)
    d. mycophenolate
    e. tacrolimus
7. Appropriate dosing

Continuation of Therapy

aHUS/PNH/NMOSD: Reauthorization by physician will infer a positive response to therapy.

AMD (Syfovre):

1. Positive response to therapy
2. Member has not developed nAMD (wet AMD)
3. If requested dosing is ≥ every 60 days, prescriber has assessed using less frequent dosing

CAD/Generalized MG (Soliris)/GPA/MPA: Reauthorization requires physician documentation of a positive response to therapy.

Generalized MG (Vyvgart): Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for the following:
    a. aHUS/PNH/NMOSD: 1 year
    b. Generalized MG (Rystiggo): 3 months
    c. CAD/Generalized MG (Soliris)/GPA/MPA/AMD (Syfovre): 6 months
    d. Generalized MG (Vyvgart, Vyvgart Hytrulo): 2 months
2. Reauthorizations will be granted for the following:
    a. Generalized MG (Vyvgart, Vyvgart Hytrulo): 2 months
    b. Generalized MG (Rystiggo): 3 months
    c. All other indications: 1 year
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name

formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

References

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5. Vyvgart® [package insert]. Boston (MA): Argenx US, Inc. 2021 Dec.
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Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23

04/12/23 – Reviewed and updated for P&T. Added GPA/MPA to initial approval durations. Effective 6/5/23.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement from Enjaymo, Uplizna, Soliris for requests reviewing under MB. Effective 6/30/23.

09/13/23 – Reviewed and updated for P&T. Enjaymo was updated and now requires members to have received a vaccine against encapsulated bacteria at least two weeks prior to treatment initiation. Due to the Medical Benefit Analysis, a decision was made to update Soliris (eculizumab), Vyvgart (efgartigimod alfa-fcab), Uplizna (inebilizumab-cdon) and Enjaymo (sutimlimab-jome) within this guideline to be managed through medical billing and designated with MB. Effective 10/2/23

2/14/24 – Reviewed and updated for P&T. Added Rystiggo and Vyvgart Hytrulo to policy requiring PA through MB (did not include preferred product requirement). Effective 3/4/24