Mass General Brigham
Health Plan

Complement Inhibitors and Miscellaneous Immunosuppressive Agents
Enjaymo® (sutimlimab-jome)
Soliris® (eculizumab)
Tavneos® (avacopan)
Uplizna® (inebilizumab-cdon)
Vyvgart® (efgartigimod alfa-fcab)
Effective 04/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

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).

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.

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.

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

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).

No PA	Drugs that require PA
Complement Inhibitors	
	Enjaymo® (sutimlimab-jome)
	Soliris® (eculizumab)
	Tavneos® (avacopan)
Miscellaneous Immunosuppressive Agents	
	Uplizna® (inebilizumab-cdon)
	Vyvgart® (efgartigimod alfa-fcab)

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, and documentation is provided:

Enjaymo® (sutimlimab-jome)
Prescriber provides documentation of **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. **ONE** of the following:
    a. Physician attestation of inadequate response, adverse reaction, or contraindication to a rituximab-containing regimen
    b. Requested agent is being used as a bridge therapy to initiate a rituximab-containing regimen
6. Appropriate dosing

Soliris® (eculizumab)
Atypical hemolytic-uremic syndrome (aHUS)
Prescriber provides documentation of **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
4. Physician attestation of inadequate response, adverse reaction, or contraindication to Ultomris® (ravulizumab-cwvz)

Generalized Myasthenia Gravis
Prescriber provides documentation of **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. Physician attestation of inadequate response, adverse reaction, or contraindication to Vyvgart® (efgartigimod alfa-fcab)

Neuromyelitis optica spectrum disorder (NMOSD)
Prescriber provides documentation of 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)
Prescriber provides documentation of **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
5. Physician attestation of inadequate response, adverse reaction, or contraindication to Ultomris® (ravulizumab-cwvz)

Tavneos® (avacopan)
Prescriber provides documentation of **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)

Prescriber provides documentation of **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. Physician attestation of inadequate response, adverse reaction or contraindication to Enspryng® (satralizumab-mwge)
5. Appropriate dosing

Vyvgart® (efgartigimod alfa-fcab)
Prescriber provides documentation of **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

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

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

Gereralized 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. CAD/Generalized MG (Soliris®): 6 months
    c. Generalized MG (Vyvgart®):): 2 months
2. Reauthorizations will be granted for the following:
    a. Generalized MG (Vyvgart®):): 2 months
    b. All other indications: 1 year

References

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2. Ultomiris® [package insert] Boston (MA): Alexion Pharmaceutical Inc; 2022 Apr.
3. Enspryng® [package insert]. South San Francisco (CA): Genentech.; 2020 Aug.
4. Uplizna® [package insert]. Gaithersburg (MD): Viela Bio.; 2021 Jul.
5. Vyvgart® [package insert]. Boston (MA): Argenx US, Inc. 2021 Dec.
6. Enjaymo® [prescribing information]. Waltham (MA): Bioverative USA Inc.; 2022 Feb.

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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