Mass General Brigham
Health Plan

Intravenous Immune Globulin (IVIG)
Alyglo, Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Gamastan S/D, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify
Effective 10/01/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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		
Notes	These agents also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
IVIG is replacement therapy for primary and secondary immunodeficiencies, and IgG antibodies against bacteria, viral, parasitic and mycoplasma antigens; interference with F_c receptors on the cells of the reticuloendothelial system for autoimmune cytopenia and ITP; provides passive immunity by increasing the antibody titer and antigen-antibody reaction potential.

Drugs that Require PA
Alyglo (immune globulin intravenous, human-stwk)
Asceniv (immune globulin IV, human-slra)
Bivigam (immune globulin IV, human)
Cutaquig (immune globulin subcutaneous injection, human-hipp)
Cuvitru (immune globulin subcutaneous injection, human)
Flebogamma (immune globulin IV, human)
Gamastan S/D (immune globulin IM, human)
Gammagard (immune globulin injection, human) (IgA~37µg/mL)
Gammagard S/D (immune globulin IV, human) (IgA<1 µg/mL)
Gammaked (immune globulin injection, human)
Gammaplex (immune globulin IV, human)
Gamunex-C (immune globulin injection, human)
Hizentra (immune globulin subcutaneous injection, human)
Hyqvia (immune globulin subcutaneous injection, human/hyaluronidase human recombinant)
Octagam (immune globulin IV, human)
Panzyga (immune globulin IV, human-ifas)

Privigen (immune globulin IV, human)
Xembify (immune globulin subcutaneous injection, human-klhw)

FDA-Approved Indications

Formulation	Route of Administration	CLL	CIDP	DM	ITP	KD	MMN	PID
Alyglo	IV							✓
Asceniv	IV							✓
Bivigam	IV							✓
Cutaquig	SC							✓
Cuvitru	SC							✓
Flebogamma 10%	IV				✓			✓
Flebogamma 5%	IV				✓			✓
Gamastan S/D §	IM							
Gammagard (IgA~37mcg/mL)	IV, SC*		✓				✓	✓
Gammagard S/D (IgA<1 mcg/mL)	IV	✓			✓	✓		✓
Gammaked	IV, SC*		✓		✓			✓
Gammaplex	IV				✓			✓
Gamunex -C	IV, SC*		✓		✓			✓
Hizentra	SC		✓					✓
Hyqvia	SC		✓					✓
Octagam 10%	IV			✓†	✓†			
Octagam 5%	IV							✓‡
Panzyga	IV		✓		✓			✓
Privigen	IV		✓		✓			✓
Xembify	SC							✓

* Subcutaneous route is only indicated for PID

† Octagam 10% strength approved for chronic ITP in adults and DM in adults

‡ Octagam 5% strength approved for PID

§ Gamastan® S/D approved for prophylaxis following exposure to hepatitis A, to prevent or modify measles in a susceptible person exposed fewer than 6 days previously, to modify varicella, and to modify rubella in exposed women who will not consider a therapeutic abortion.

Coverage Guidelines

Authorization may be granted for members who are new to the Plan currently receiving treatment with IVIG excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when following criteria are met, and documentation is provided:

<u>IV and SC Immune Globulins (except Gamastan S/D)</u>

Prevention of recurrent infection in B-cell chronic lymphocytic leukemia (CLL)

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Multifocal Motor Neuropathy (MMN)

1. Diagnosis of ONE of the following:
    a. Chronic inflammatory demyelinating polyneuropathy (CIDP)

b. Multifocal Motor Neuropathy (MMN)
c. Prevention of recurrent infection in B-cell chronic lymphocytic leukemia
2. Appropriate dosing for member and treatment course
3. For **Alyglo**, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Immune thrombocytopenia (ITP)

1. Diagnosis of immune thrombocytopenia (ITP)
2. **ONE** of the following:
    a. Platelets < 30,000 /µL
    b. Clinically significant bleeding
    c. History of significant bleeding
    d. Risk of significant bleeding
    e. Medical necessity to raise platelet count within 12 to 24 hours
3. Appropriate dosing for member and treatment course
4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Kawasaki disease (mucocutaneous lymph node syndrome)

1. Diagnosis of Kawasaki disease (mucocutaneous lymph node syndrome)
2. **ONE** of the following:
    a. Onset of illness occurred within previous 10 days
    b. Member has unexplained persistent fever
    c. Member has evidence of aneurysm
    d. Member exhibits signs of persistent inflammation
3. Appropriate dosing for member and treatment course
4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Primary Immunodeficiency Disorders (PID)

1. Diagnosis of primary immunodeficiency disorder (PID)
2. Laboratory documentation supporting diagnosis (*e.g. deficient serum IgG [or subclasses IgG1, IgG2, IgG3, IgG4], IgM, and/or IgA levels*, *assessment of functional antibody production, immunophenotype of B cells [flow cytometry] or genetic testing)*
3. Serum IgG (or subclasses IgG1, IgG2, IgG3, IgG4), IgM, and/or IgA levels are provided via medical records or written on PA with dates drawn and reference ranges (e.g., pre- or post-treatment)
4. Appropriate dosing for member and treatment course
5. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Dermatomyositis (DM)

1. Diagnosis of dermatomyositis in adults (DM)
2. Member is ≥ 18 years of age

3. Physician attestation of inadequate response or adverse drug reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
4. **ONE** of the following:
    a. Documentation of severe disease
    b. Physician attestation of inadequate response or adverse drug reaction to **ONE** or contraindication to **ALL** of the following
        i. azathioprine
        ii. chloroquine
        iii. hydroxychloroquine
        iv. methotrexate
        v. mycophenolate mofetil
        vi. rituximab
6. Appropriate dosing for member and treatment course
7. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline

Gamastan® S/D (immune globulin IM, human)

BOTH of the following:

1. **ONE** of the following:
    a. Use for protection against Hepatitis A virus in an unvaccinated member who has been exposed to the virus in the previous 2 weeks **OR** cannot receive hepatitis A vaccine (i.e., hypersensitivity or child less than one year of age)
    b. Use to prevent or modify symptoms of measles if exposed within the past 6 days
    c. Use for passive immunization against varicella in immunosuppressed member when Varicella-Zoster Immune Globulin (human) is not available
    d. Use for postexposure prophylaxis of rubella in a pregnant member
2. Appropriate dosing for member and diagnosis (see appendix)

Off-Label Indications

Antibody mediated rejection (AMR)

1. Diagnosis of AMR
2. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Autoimmune Encephalitis (Includes NMDA-receptor encephalitis)

1. Diagnosis of Autoimmune Encephalitis or Anti-NMDA receptor encephalitis
2. Requested dose is 2 g/kg/day divided over two to five days, followed by 1 g/kg once monthly
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Autoimmune Small Fiber Neuropathy and Autoimmune autonomic ganglionopathy (AAG)

1. Diagnosis of Autoimmune Small Fiber Neuropathy or AAG

2. Requested dose of IVIG is 1 g/Kg/monthly (administered in weekly divided doses). The dose may be increased up to a maximum of 2 g/Kg monthly in case of an inadequate response. A corresponding subcutaneous dose may be used.
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Guillain-Barré Syndrome
BOTH of the following:
1. Diagnosis of Guillain-Barré Syndrome
2. Requested dose is ≤ 2 g/kg
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Immune-mediated necrotizing myopathy (IMNM)
1. Diagnosis of IMNM
2. Physician attestation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids
3. **ONE** of the following:
    a. Diagnosis of severe disease
    b. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following
        i. azathioprine
        ii. chloroquine
        iii. cyclophosphamide
        iv. cyclosporin
        v. hydroxychloroquine
        vi. methotrexate
        vii. mycophenolate mofetil
        viii. plasma exchange
        ix. rituximab
        x. tacrolimus
4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Immune neutropenia (autoimmune neutropenia (AIN), Chronic benign neutropenia)
1. Diagnosis of immune neutropenia (autoimmune neutropenia (AIN), Chronic benign neutropenia)
2. Recurrent infections despite prophylactic antibiotics and colony-stimulating factors
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Interstitial Lung Disease (ILD)
1. Diagnosis of ILD
2. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids

3. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to BOTH of the following
    a. azathioprine
    b. mycophenolate mofetil
4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Multiple myeloma

1. Diagnosis of multiple myeloma
2. Recurrent infections despite prophylactic antibiotics
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Myasthenia gravis

1. Diagnosis of myasthenia gravis
2. **ONE** of the following:
    a. Member has severe or rapidly worsening disease, and IVIG will be used as initial therapy followed by longer acting immunomodulating agents (e.g., azathioprine, cyclosporine, mycophenolate orsteroids)
    b. Physician attestation of inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. pyridostigmine
        ii. systemic corticosteroids
        iii. one immunomodulating agent (azathioprine, cyclosporine, mycophenolate)
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)

1. Diagnosis of PANDAS
2. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** antibiotics
3. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication **ALL** to systemic corticosteroids
4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Pemphigus Vulgaris (PV)

1. Diagnosis of PV
2. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids
3. Physician attestation of inadequate response, adverse reaction, or contraindication to rituximab
4. Requested dose is ≤ 2 g/kg

5. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Polymyositis (PM)

1. Diagnosis of PM
2. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids
3. ONE of the following:
    a. Diagnosis of severe disease
    b. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following
        i. azathioprine
        ii. chloroquine
        iii. cyclophosphamide
        iv. cyclosporin
        v. hydroxychloroquine
        vi. methotrexate
        vii. mycophenolate mofetil
        viii. plasma exchange
        ix. rituximab
        x. tacrolimus
4. Requested dose is 1 g/kg per day on 2 consecutive days every 4 weeks (total monthly dose: 2 g/kg)
5. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Prevention of recurrent infection in pediatric HIV members

1. Indication is the prevention of recurrent infection in pediatric HIV members
2. Member is < 18 years of age
3. CD4 count is ≥ 200 cells/microliter (within the last three months)
4. Requested dose is 400 mg/kg every 28 days
5. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

CMV-Solid organ transplant

1. Diagnosis of CMV-Solid organ transplant
2. The member will also receive antiviral therapy with ganciclovir, foscarnet, or cidofovir
3. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Specific Antibody Deficiency (SAD)

1. Diagnosis of SAD and with well-documented moderate or severe polysaccharide nonresponsiveness
2. Evidence of recurrent infections requiring antibiotic therapy
3. Requested dose of 400 to 600 mg/kg IV every four weeks or a corresponding subcutaneous dose

4. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

Stiff Person Syndrome (SPS)

1. Diagnosis of SPS
2. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** benzodiazepines
3. Physician attestation of inadequate response, adverse reaction, or contraindication to baclofen
4. Requested dose of 2 g/kg, divided over two to three infusions.
5. For Alyglo, member must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

If a request for subcutaneous immune globulin without prior IVIG use is submitted, please refer to Appendix.

Continuation of Therapy

Reauthorizations for continuation of therapy may be issued for up to **1 year** or as appropriate for the diagnosis provided:

- **Prevention of recurrent infection in B-cell CLL:** Prescriber provides documentation of continued need for infection protection and clinical success to previous therapy.
- **CIDP, MMN, PID**: Resubmission by prescriber will infer a positive response to therapy.
- **ITP:** Prescriber provides documentation or laboratory results supporting continued use *(e.g. platelets < 30,000 /µL and/or has clinically significant bleeding, history of or risk of significant bleeding, medical necessity to raise platelet count within 12 to 24 hours)*
- **DM:** Prescriber provides documentation of continued need for treatment and clinical success to previous therapy.
- **Gamastan® S/D:** Prescriber provides documentation of medical necessity for continued use.
- **Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS):** Recertification criteria must include documentation of positive response to therapy and treatment plan.

Stability: If a request states a member is stable/has been on an immune globulin (other than Asceniv), the prescriber provides the appropriate diagnosis and documents a positive response to the immune globulin, the request can be approved.

Limitations

1. Initial approvals will be granted for **6 months** or as appropriate for the following:
    a. Kawasaki Disease: 1 month
    b. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS): 1 dose (1 to 2 g/kg) for 1 month
    c. Gamastan S/D: 1 month
    d. Off-label indications (except PANDAS): 3 months
2. Reauthorizations will be granted for **1 year** or as appropriate for the following:
    a. Off-label indications (except PANDAS): 6 months
3. Please note that dosing in certain off-label indications is not well established. Unless otherwise specified within the approval criteria for an off-label indication, please refer to FDA-approved label.

Appendix

Subcutaneous Immune Globulin in Treatment Naïve Members

If a request for subcutaneous immune globulin is received for a member without prior intravenous use, please review request for appropriate dosing (should be equal to IVIG or up to 1.5 times higher depending on the product). If the dosing is appropriate, requests may be approved for **6 months.**

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6. Flebogamma® 10% DIF [package insert]. Los Angeles (CA): Grifols USA, LLC.; 2019 Sep.
7. Flebogamma® 5% DIF [package insert]. Los Angeles (CA): Grifols USA, LLC.; 2019 Sep.
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9. Gammagard Liquid® [package insert]. Lexington (MA): Baxalta US Inc; 2021 Mar.
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Review History

12/18/2019 – Reviewed and approved DCC
03/18/2020 – Transitioned from SGM to Custom (effective 6/1/20)
05/19/2021 – References updates
09/22/2021 – Reviewed at September P&T; added PANDA/PANS indication effective 01/01/2022; references updated. Effective 01/01/2022
02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Removed Carimmune as product has been discontinued. Added Cutaquig, Cuvitru, Gamastan S/D, Hizentra, Hyqvia, Xembify. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Added off-label indications to policy: Antibody mediated rejection (AMR), Immune-mediated necrotizing myopathy (IMNM), Interstitial Lung Disease (ILD), Pemphigus Vulgaris (PV), Polymyositis (PM), and Prevention of recurrent infection in pediatric HIV members. Approval duration for off label indications except PANDAS were added. Appendix for Gamastan S/D dosing was added. Effective 6/5/23.
06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB. Effective 6/30/23
08/09/23 – Reviewed and updated for P&T. Stability section updated to allow the approval of requests documenting positive response to therapy and to remove the requirement for the documentation of current labs showing normal Ig levels. Formatting updates. Effective 10/2/23.
09/11/24 – Reviewed and updated for P&T. Separated all agents in this class from pharmacy, 2 policies will now exist (MB and PB). Guideline updated with expanded indication for HyQvia and Gammagard in CIDP and for Flebogamma 5% in ITP. New intravenous immune globulin Alyglo was added to criteria and to require clinical rationale for use of this product over alternatives. Effective 10/1/24