Mass General Brigham
Health Plan

Intravenous Immune Globulin (IVIG)
Alyglo, Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify
Effective 01/01/2026

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 Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	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.

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				✓			✓
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

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:

IV and SC Immune Globulins

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

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

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

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

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. Member has severe disease
    b. 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
5. Appropriate dosing for member and treatment course

Off-Label Indications for IV and SC Immune Globulins

Antibody mediated rejection (AMR)

1. Diagnosis of AMR
2. Inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids

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

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.

Guillain-Barré Syndrome

1. Diagnosis of Guillain-Barré Syndrome
2. Requested dose is ≤ 2 g/kg

Immune-mediated necrotizing myopathy (IMNM)

1. Diagnosis of IMNM
2. 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. 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

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

Interstitial Lung Disease (ILD)

1. Diagnosis of ILD
2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
3. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following
    a. azathioprine
    b. mycophenolate mofetil

Multiple myeloma

1. Diagnosis of multiple myeloma
2. Recurrent infections despite prophylactic antibiotics

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, corticosteroids)
    b. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. pyridostigmine
        ii. systemic corticosteroids
        iii. one immunomodulating agent (azathioprine, cyclosporine, mycophenolate)

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)

1. Diagnosis of PANDAS
2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** antibiotics
3. Inadequate response or adverse reaction to **ONE** or contraindication **ALL** to systemic corticosteroids

Pemphigus Vulgaris (PV)

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

Polymyositis (PM)

1. Diagnosis of PM
2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
3. **ONE** of the following:
    a. Diagnosis of severe disease
    b. 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)

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

CMV-Solid organ transplant

1. Diagnosis of CMV-Solid organ transplant
2. The member will also receive antiviral therapy with ganciclovir, foscarnet, or cidofovir

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

Stiff Person Syndrome (SPS)

1. Diagnosis of SPS
2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** benzodiazepines
3. Inadequate response, adverse reaction, or contraindication to baclofen
4. Requested dose of 2 g/kg, divided over two to three infusions

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.
- **Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS):** Recertification criteria must include documentation of positive response to therapy and treatment plan.

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. 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.**

References

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2. Asceniv® [package insert]. Boca Raton (FL): ADMA Biologics; 2019 April.
3. Bivigam® [package insert]. Boca Raton (FL): Biotest Pharmaceuticals Corp.; 2019 Jul.
4. Cutaquig® [package insert]. Hoboken (NJ): Octapharma, USA Inc. 2020 Jul.
5. Cuvitru® [package insert]. Lexington (MA): Baxalta US Inc.; 2021 Sep.
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.
8. Gamastan® [package insert]. Research Triangle Park (NC): Grifols Therapeutics Inc.; 2018 Dec.
9. Gammagard Liquid® [package insert]. Lexington (MA): Baxalta US Inc; 2021 Mar.
10. Gammagard S/D® (IgA < 1 mcg/mL) [package insert]. Lexington (MA): Baxalta US Inc; 2021 Mar.
11. Gammaked® [package insert]. Fort Lee (NJ): Kedrion Biopharma, Inc; 2019 Jan.
12. Gammaplex® [package insert]. Durham (NC): BPL Inc.; 2019 Sep.
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15. Hyqvia® [package insert]. Lexington (MA): Baxalta US Inc; 2021 Mar.
16. Octagam 5%® [package insert]. Hoboken (NJ): Octapharma, USA Inc. 2019 Apr.
17. Panzyga® [package insert]. New York (NY): Pfizer labs, Inc. 2021 Jan.
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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
08/13/25 – Reviewed and updated for P&T. Part of UM annual review. Formatting and reference updates made. Effective 9/1/25
11/12/25 – Reviewed and updated for P&T. Removed Gamastan S/D as product has been discontinued. Effective 1/1/26