Mass General Brigham
Health Plan

Intravenous Immune Globulin (IVIG): Asceniv™, Bivigam®, Cutaquig®, Cuvitru®, Flebogamma®, Gammagard® Liquid, Gammagard® S/D, Gammaked®, Gammaplex®, Gamunex®-C, Gamastan® S/D, Hizentra®, Hyqvia®, Octagam®, Panzyga®, Privigen®, Xembify® Effective 10/02/2023

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		
Exceptions	N/A		

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

No PA	Drugs that Require PA
	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
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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

Guillain-Barré Syndrome
BOTH of the following:

1. Diagnosis of Guillain-Barré Syndrome
2. Requested dose is ≤ 2 g/kg
3. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

Multiple myeloma

1. Diagnosis of multiple myeloma
2. Recurrent infections despite prophylactic antibiotics
3. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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. **If reviewing under Pharmacy Benefit:** For Asceniv®, clinical rationale for use instead of other available intravenous immune globulin products

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.**

Gamastan® S/D Dosing

Solution: 2 mL vial 10 mL vial	**Hepatitis A pre-exposure and postexposure prophylaxis** 0.02 mL/kg intramuscularly 0.06 mL/kg intramuscularly (if plan to stay in an area where Hepatitis A is common for >3 months) **Prevention of measles in a susceptible person if exposed within 6 days** 0.25 mL/kg intramuscularly 0.5 mL/kg intramuscularly (immunocompromised child) **Passive immunization against varicella in immunosuppressed members if Varicella-Zoster Immune Globulin is unavailable** 0.6 to 1.2 mL/kg intramuscularly **Prophylaxis of rubella in early pregnancy in select women** 0.55 mL/kg intramuscularly

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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.