

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	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	These medications have 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

IVIG is replacement therapy for primary and secondary immunodeficiencies, and IgG antibodies against bacteria, viral, parasitic and mycoplasma antigens; interference with Fc 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:

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

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 / μ L
 - 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 \geq 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 or steroids)
 - 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	<p>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)</p> <p>Prevention of measles in a susceptible person if exposed within 6 days 0.25 mL/kg intramuscularly 0.5 mL/kg intramuscularly (immunocompromised child)</p> <p>Passive immunization against varicella in immunosuppressed members if Varicella-Zoster Immune Globulin is unavailable 0.6 to 1.2 mL/kg intramuscularly</p> <p>Prophylaxis of rubella in early pregnancy in select women 0.55 mL/kg intramuscularly</p>
--------------------------------	---



References

1. Ballow M, Shehata N. Overview of intravenous immune globulin (IVIg) therapy. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate 2021 [cited 2021 Dec 8]. Available from: <http://www.utdol.com/utd/index.do>
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.
13. Gamunex®-C [package insert]. Research Triangle Park (NC): Grifols Therapeutics, Inc.; 2020 Jan.
14. Hizentra® [package insert]. Kankakee (IL): CSL Behring; 2021 Apr.
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.
18. Privigen® [package insert]. Kankakee (IL): CSL Behring; 2019 Mar.
19. Xembify® [package insert]. Research Triangle Park (NC): Grifols Therapeutics LLC; 2020 Aug.
20. Octagam 10%® [package insert]. Hoboken (NJ): Octapharma, USA Inc. 2021 Jul.
21. Updated Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed 2020 Jan 14.
22. Arnold D, Cuker A, Kelton JG. Initial treatment of immune thrombocytopenia (ITP) in adults. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 9]. Available from: <http://www.utdol.com/utd/index.do>
23. Kawasaki disease. In: Red Book: 2018 Report of the Committee on Infectious Diseases, 31st ed, Kimberlin DW, Brady MT, Jackson MA, Long SS (Eds), American Academy of Pediatrics, Itasca, IL 2018 p.490.
24. McCrindle BW, Rowley AH, Newburger JW, et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association. *Circulation* 2017; 135:e927.
25. Sundel R. Kawasaki disease: Initial treatment and prognosis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 9]. Available from: <http://www.utdol.com/utd/index.do>
26. Vleugels RA. Cutaneous dermatomyositis in adults: Overview and initial management. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 3]. Available from: <http://www.utdol.com/utd/index.do>
27. Cobos GA, Femia A, Vleugels RA. Dermatomyositis: An Update on Diagnosis and Treatment. *Am J Clin Dermatol.* 2020 Jun;21(3):339-353.
28. FDA approves Octapharma's Octagam® 10% for Treatment of Adults with Dermatomyositis [press release on the internet]. Chicago (IL): Muscular Dystrophy Association; 2021 Jul 29 [cited 2021 Nov 9]. Available from: <https://strongly.mda.org>



29. Koelba T, Ensom MH. Pharmacokinetics of intravenous immunoglobulin: a systematic review. *Pharmacotherapy*. 2006;126(6):813-27.
30. Hodkinson JP. Considerations for dosing immunoglobulin in obese patients. *Clin Exp Immunol*. 2017 Jun;188(3):353-362.
31. Ameratunga R. Initial intravenous immunoglobulin doses should be based on adjusted body weight in obese patients with primary immunodeficiency disorders. *Allergy Asthma Clin Immunol*. 2017;13:47.
32. Khan S, et al. Serum trough IgG level and annual intravenous immunoglobulin dose are not related to body size in patients on regular replacement therapy. *Drug Metab Lett*. 2011;5:132-136.
33. Figgins BS, Atiken SL, Whited LK. Optimization of intravenous immune globulin use at a comprehensive cancer center. *Am J Health Syst Pharm*. 2019 Nov;76(Supplement_4):S102-S106.
<https://www.ncbi.nlm.nih.gov/pubmed/31621877>
34. Fouche A, Oprica C, Sankaranarayanan J, Tessier N. Retrospective evaluation of IVIG use: appropriateness and potential cost savings from body-weight dosing at a Northeastern Tertiary Hospital in the United States. *J Hosp Clin Pharm* 2016;2(3):19–26.
35. Grindeland JW, Grindeland CJ, Moen C, Leedahl ND, Leedahl DD. Outcomes Associated with Standardized Ideal Body Weight Dosing of Intravenous Immune Globulin in Hospitalized Patients: A Multicenter Study. 2019 Oct. <https://journals.sagepub.com/doi/abs/10.1177/1060028019880300>
36. Hansen E, Brauner M. The Impact of Using Ideal Body Weight for Dosing of Intravenous Immune Globulin on Potential Grams Averted. 2019 Associate of VA Hematology/Oncology Annual Meeting.
<https://www.mdedge.com/fedprac/avaho/article/207830/mixed-topics/impact-using-ideal-body-weight-dosing-intravenous-immune>
37. Rocchio MA, et al. Impact of ideal bodyweight dosing for all inpatient i.v. Immune globulin indications. *Am J Health Syst Pharm*. 2013;70:751-752.
38. Stump S, Schepers AJ, Jones AR, Alexander MD, Auten JJ. Comparison of Weight-Based Dosing Strategies for Intravenous Immunoglobulin in Patients with Hematologic Malignancies. *Pharmacother*. 2017 Dec;37(12):1530-1536.
39. Leon et al. *Eur Child Adolesc Psychiatry*. 2018 May;27(5):637-643.
40. Perez EE, Orange JS, Bonilla F, Chinen J, Chinn IK, Dorsey M, et al. Update on the use of immunoglobulin in human disease: A review of evidence. Work Group report of the American Academy of Allergy, Asthma, and Immunology. *J Allergy Clin Immunol*. 2017 Mar; 139:S1-S46.
41. Koterba AP, Stein MR. Initiation of immunoglobulin therapy by subcutaneous administration in immunodeficiency patients naïve to replacement therapy. *Allergy Asthma Clin Immunol*. 2014;10(63).
42. Dalmau J, Rosenfeld MR. Paraneoplastic and autoimmune encephalitis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 8]. Available from: <http://www.utdol.com/utd/index.do>
43. Titulaer MJ, McCracken L, Gabilondo I, Armangué T, Glaser C, Iizuka T, et al. Treatment and prognostic factors for long-term outcome in patients with anti-NMDA receptor encephalitis: an observational cohort study. *Lancet Neurol*. 2013 Feb;12(2):157-65.
44. Shin YW, Lee ST, Park KI, Jung KH, Jung KY, Lee KS, et al. Treatment strategies for autoimmune encephalitis. *Ther Adv Neurol Disord*. 2017 Aug 16
45. Stingl C, Cardinale K, Van Mater H. An Update on the Treatment of Pediatric Autoimmune Encephalitis. *Curr Treatm Opt Rheumatol*. 2018 Mar; 4(1): 14–28.
46. Bien CG, Bien CI. Autoimmune encephalitis in children and adolescents. *Neurol Res Pract*. 2020 Jan 3;2:4.
47. Schick, P. Hemolytic Anemia: Treatment & Medication. Emedicine [webpage on the internet]. 2019 Mar 6 [cited 2019 Mar 7]. Available from <http://emedicine.medscape.com/article/201066-treatment>.
48. Packman CH. Hemolytic anemia due to warm autoantibodies. *Blood Rev*. Jan 2008;22(1):17-31.
49. Zeidman LS. Advances in the Management of Small Fiber Neuropathy. *Neurol Clin*. 2021 Feb;39(1):113-31.



50. Schofield JR, Chemali KR. How We Treat Autoimmune Small Fiber Polyneuropathy with Immunoglobulin Therapy. *Eur Neurol*. 2018;80(5-6):304-310.
51. Tseng B, Sheikh S, Markowitz J. Guillain-Barre Syndrome in childhood: Treatment & Medication. *Emedicine* [database on the internet]. 2014 Dec 11 [cited 2014 Oct 22]. Available from <http://emedicine.medscape.com/article/1180594-treatment>.
52. DiMario FJ. Intravenous immunoglobulin in the treatment of childhood Guillain-Barre syndrome: a randomized trial. *Pediatrics*. Jul 2005;116(1):226-8.
53. Inoue, S. Autoimmune and chronic benign neutropenia: Treatment & Medication. *Emedicine* [database on the internet]. 2017 Nov 28 [cited 2019 Feb 28]. Available from: <http://emedicine.medscape.com/article/954781-treatment>.
54. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: multiple myeloma Version 2.2019 [guideline on the internet]. Fort Washington (PA): National Comprehensive Cancer Network; 2018 Nov 16 [cited 2019 Feb 28]. Available from: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.
55. Rajkumar SV. Treatment of the complications of multiple myeloma. In: Kyle RA (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate; 2018 [cited 2019 Feb 28]. Available from: <http://www.utdol.com/utd/index.do>.
56. Bird, SJ. Treatment of myasthenia gravis. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate 2019 [cited 2019 Feb 28]. Available from <http://www.utdol.com/utd/index.do>.
57. Gilbert DL, Mink JW, Singer HS. A pediatric Neurology Perspective on pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection and Pediatric Acute-Onset Neuropsychiatric Syndrome. *J Pediatr*. 2018;199:243-251.
58. National Institute of Mental Health. PANDAS-Questions and Answers. Bethesda (MD): National Institute of Mental Health. 2019 [cited 2021 Mar 16]. Available from: <https://www.nimh.nih.gov/health/publications/pandas/index.shtml#pub3>
59. Kovacevic M, Grant P, Swedo SE. *J Child Adolesc Psychopharmacol*. 2015 Feb 1; 25(1):65-69.
60. Ahmed AR. Treatment of autoimmune mucocutaneous blistering diseases with intravenous immunoglobulin therapy. *Expert Opin Investig Drugs*. 2004;13:1019-32.
61. Hertl M, Geller S. Initial management of pemphigus vulgaris and pemphigus foliaceus. In: Basow DS (Ed). *UpToDate* [database on the Internet]. Waltham (MA): UpToDate; 2018 [cited 2019 Feb 28]. Available from: <http://www.utdol.com/utd/index.do>.
62. AIDS info: Immune Globulin. [cited 2010 May 13]. Last updated 2007 May 17. Available from: http://www.aidsinfo.nih.gov/DrugsNew/DrugDetailT.aspx?int_id=22&ClassID=0&TypeID=0.
63. Khan O, Tselis A, Boster, A. Intravenous immunoglobulin in relapsing-remitting multiple sclerosis: A dose-finding trial. *Neurology* 2009;72:2134-5.
64. Schleiss M. Cytomegalovirus Infection: Treatment & Medication. *Emedicine* [database on the internet]. 2018 Apr 6 [Cited 2019 Feb 28]. Available from: <http://emedicine.medscape.com/article/963090-treatment>.
65. Wingard JR. Prevention of infections in hematopoietic cell transplant recipients. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate 2019 Mar [cited 2019 Feb 28]. Available from <http://www.utdol.com/utd/index.do>.
66. Tomblyn M, Chiller T, Einsele H, Gress R, Sepkowitz K, Storek J, et al. Guidelines for Preventing Infectious Complications among Hematopoietic Cell Transplantation Recipients: A Global Perspective. *Biol Blood Marrow Transplant*. 2009;15:1143-1238. [cited 2020 Jan 14]. Available from: https://www.she-online.org/images/guidelines/2009_HSCT_Guideline.pdf.
67. Paris K. Specific antibody deficiency. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 5]. Available from: <http://www.utdol.com/utd/index.do>
68. Helfgott, SM. Stiff-person syndrome. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 8]. Available from: <http://www.utdol.com/utd/index.do>



69. Dalakas MC, Fujii M, Li M, Lutfi B, Kyhos J, McElroy B. High-dose intravenous immune globulin for stiff-person syndrome. *N Engl J Med*. 2001 Dec 27;345(26):1870-6.
70. Bartels C, Muller D. Systemic Lupus Erythematosus: Treatment & Medication. *Emedicine* [database on the internet]. 2018 Dec 12 [Cited 2019 Feb 28]. Available from: <http://emedicine.medscape.com/article/332244-treatment>.
71. INIS Collaborative Group, Brocklehurst P, Farrell B, King A, Juszcak E, Darlow B, et al. Treatment of neonatal sepsis with intravenous immune globulin. *N Engl J Med*. 2011 Sep 29;365(13):1201-11.
72. Rist S, Sellam J, Hachulla E, Sordet C, Puéchal X, Hatron PY et al. Experience of intravenous immunoglobulin therapy in neuropathy associated with primary Sjogren's syndrome: a national multicentric retrospective study. *Arthritis Care Res (Hoboken)*. 2011 Sep;63(9):1339-44. doi: 10.1002/acr.20495.
73. Goebel A, Baranowski A, Maurer K, Ghiai A, McCabe C, Ambler G. Intravenous immunoglobulin treatment of the complex regional pain syndrome: a randomized trial. *Ann Intern Med*. 2010 Feb 2;152(3):152-8.
74. Goebel A, Bisla J, Carganillo R, Frank B, Gupta R, Kelly J, et al. Low-dose intravenous immunoglobulin treatment for long-standing complex regional pain syndrome. *Ann Intern Med*. 2017;167(7):476.
75. Miller, ML. Treatment of recurrent and resistant dermatomyositis and polymyositis in adults. In: Basow DS (Ed). *UpToDate* [database on the internet]. Waltham (MA): UpToDate 2021 [cited 2021 Dec 20]. Available from <http://www.utdol.com/utd/index.do>.

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.

