

Immune Globulin

HCPCS – see [Other Information](#)

LOB:	MCAL
Duration of Approval:	See Table 1. Duration of Approval
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes
DHCS Available:	No

Requires Prior Authorization (PA)

- Alyglo (immune globulin, human-stwk)
- Asceniv (immune globulin, human-slra)
- Bivigam (immune globulin [human])
- Cutaquig (immune globulin, human-hipp)
- Cuvitru (immune globulin [human])
- Flebogamma (immune globulin [human])
- GamaSTAN S/D (immune globulin [human])
- Gammagard (immune globulin [human])
- Gammagard S/D (immune globulin [human])
- Gammaked (immune globulin [human])
- Gammaplex (immune globulin [human])
- Gamunex-C (immune globulin [human])
- Hizentra (immune globulin [human])
- Hyqvia (immune globulin [human]) with recombinant human hyaluronidase
- Octagam (immune globulin [human])
- Panzyga (immune globulin, human-ifas)
- Privigen (immune globulin [human])
- Qivigy (immune globulin, human-kthm)
- Xembify (immune globulin, human-klhw)
- Yimmugo (immune globulin, human-dira)

PA CRITERIA FOR APPROVAL:

New Therapy

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References), a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication, a National Comprehensive Cancer Network (NCCN)-supported indication **OR ONE** of the following off-label indications:
 - Lambert-Eaton myasthenic syndrome (LEMS) (off-label supported by AHFS)
 - Relapsing remitting multiple sclerosis (RRMS) (off-label supported by AHFS)
 - BK viremia in post-kidney transplant (off-label supported based on peer review literature)
 - Moderate to severe pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) (**Note:** May accept diagnosis [Dx] of autoimmune encephalitis or Dx code D89.89: other specified disorders involving the immune mechanism, not elsewhere classified)
 - Moderate to severe pediatric acute-onset neuropsychiatric syndrome (PANS) (**Note:** May accept Dx of autoimmune encephalitis or Dx code D89.9: disorder involving the immune mechanism, unspecified)

AND

2. The requested medication is prescribed by a specialist appropriate to the member's diagnosis **AND**
3. **Autoimmune hemolytic anemia (AIHA) (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as steroids (e.g., prednisone, methylprednisolone, prednisolone), immunosuppressive agents (e.g., azathioprine, cyclosporine, plasmapheresis,

Immune Globulin

HCPs – see [Other Information](#)

rituximab) or splenectomy **OR**

4. **Chronic inflammatory demyelinating polyneuropathy (CIDP):** Diagnosis is confirmed by electrodiagnostic testing showing evidence of motor nerves and sensory conduction abnormalities **OR**
5. **Dermatomyositis (off-label supported by Drugdex) (FDA-indicated for Octagam):** The member has a history of failure, contraindication or reasons for intolerance to corticosteroids (e.g., prednisone, prednisolone, methylprednisolone) **OR**
6. **LEMS (off-label supported by AHFS):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as plasma exchange, pyridostigmine, amifampridine, corticosteroids (e.g., prednisone, prednisolone) or immunosuppressants (e.g., azathioprine, cyclosporine, mycophenolate) (**Note:** amifampridine [Firdapse] is FDA-indicated for LEMS and PA is required under Medi-Cal Rx) **OR**
7. **Myasthenia gravis (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as plasmapheresis, pyridostigmine, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, rituximab or corticosteroids (e.g., prednisone, prednisolone, methylprednisolone) **OR**
8. **Pemphigus (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as immunosuppressive agents (e.g., azathioprine, cyclophosphamide), corticosteroids (e.g., prednisone, prednisolone, methylprednisolone) or plasmapheresis **OR**
9. **Polymyositis (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as corticosteroids (e.g., prednisone, prednisolone, methylprednisolone), azathioprine, cyclosporine, methotrexate, tacrolimus, mycophenolate, rituximab or cyclophosphamide **OR**
10. **Stiff-person syndrome (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as benzodiazepines (e.g., diazepam) or muscle relaxants (e.g., baclofen) **OR**
11. **Systemic lupus erythematosus (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to other treatments such as corticosteroids (e.g., prednisone, prednisolone, methylprednisolone) or immunosuppressive agents (e.g., hydroxychloroquine, cyclophosphamide, azathioprine) **OR**
12. **RRMS (off-label supported by Drugdex):** The member has a history of failure, contraindication or reasons for intolerance to **TWO** or more multiple sclerosis (MS) treatments such as Avonex, Betaseron, Extavia, Mayzent, Rebif, Plegridy, glatiramer/glatopa (generic for Copaxone), Tecfidera, Tysabri, Gilenya or Aubagio **OR**
13. **BK viremia in post-kidney transplant (off-label based on peer-reviewed literature) AND meets ALL of the following (a–c):**
 - a. Member has refractory BK viremia (e.g., persistent viral titers despite reduced immunosuppression)
 - b. Documentation provided showing detectable BK viral load
 - c. The requested dose does not exceed 2 g/kg per treatment course

Continuation of Therapy

Refer to reauthorization criteria in Table 1 below.

Table 1 – Duration of Approval

Indication		Frequency/Duration May be given no more frequently than:	Reauthorization Criteria/Duration
Replacement Therapy - Immunodeficiency			
Primary humoral immunodeficiency disease (PID)		One dose every three to four weeks x 12 months	Documented current immunoglobulin G (IgG) levels that are in the low to normal range and evidence of clinical improvement,
Hematologic malignancy-related	B-cell CLL, B-cell lymphoma (off-label), B-cell ALL (off-label)	400–500 mg/kg every three to four weeks x 12 months	

Immune Globulin

HCPCS – see [Other Information](#)

Indication		Frequency/Duration May be given no more frequently than:	Reauthorization Criteria/Duration
	post-hematopoietic stem cell transplant (HSCT) (off-label)	(0–100 days after HSCT) • 500 mg/kg/week x four weeks (> 100 days after HSCT) • 500 mg/kg every three to four weeks x 12 months	such as decreased occurrence of infections, x 12 months For <100 days after HSCT: Routine intravenous immunoglobulin (IVIG) is not recommended within the first 100 days after HSCT. Approve x four weeks if the above reauthorization criteria is met.
	multiple myeloma (off-label)	400–500 mg/kg every four weeks x 12 months	
Hematologic disorders (immune-mediated)			
AIHA (off-label)		One dose per month x six months • 0.2 to 0.4 g/kg daily for five days • 1 g/kg for five to seven days (average dose of 5 g/kg) • 0.45 g/kg IV daily for five days followed by a single dose 0.1–0.2 g/kg IV monthly	Documented initial response and recurrence of clinically significant, symptomatic anemia x 12 months
ITP (acute)		Up to four treatments (tx) (authorization is for up to a six-month window)	May reauthorize x three months; if immune thrombocytopenia (ITP) duration is greater than six months, may reauthorize under chronic ITP
ITP (chronic)		One tx per month x six months.	Authorization x six months. Documented initial response to IVIG and: - Continued thrombocytopenia, defined as a platelet count of <20,000 OR less than 30,000 cells/m3 and clinically significant bleeding OR - Patient is scheduled for an invasive procedure with a high risk of bleeding.
Thrombocytopenia in pregnancy (off-label)		1–2 g/kg IV weekly until the estimated date of delivery.	May reauthorize under chronic ITP
Neuroimmunologic disorders			
Acute inflammatory demyelinating polyneuropathy (including GBS) (off-label)		One tx per month x six months • 400 mg/kg IV daily for five days • 1 g/kg IV daily for two days • 2 g/kg IV as a single dose	Documented functional improvement x 12 months
CIDP		One tx every three weeks x six months	Documented functional improvement x 12 months
Dermatomyositis, refractory (off-label) (FDA-indicated for Octagam)		One tx per month x six months. • 2 g/kg IV every four weeks • 400 mg/kg IV daily for five days	Documented improvement in muscle strength and/or decreased creatine phosphokinase (CPK) levels x 12 months
Lambert-Eaton myasthenic syndrome (off-label)		2 g/kg IV (divided in two daily doses) per month x six months	Documented improvement in muscle function/strength x 12 months
Multifocal motor neuropathy (MMN)		One tx per month x six months.	Documented improvement in muscle function/strength x 12 months
Myasthenia gravis (acute and chronic) (off-label)		One tx per month x six months. • 2 g/kg IV divided over two days	Documented improvement in muscle function/strength x 12 months

Immune Globulin

HCPCS – see [Other Information](#)

Indication	Frequency/Duration May be given no more frequently than:	Reauthorization Criteria/Duration
	• 400 mg/kg/day IV for three days (total 1.2g/kg) or five days (total 2 g/kg) • 1 g/kg IV for one to two days (up to total 2 g/kg)	
Paraneoplastic syndrome (off-label)	One tx per month x six months. • 2 g/kg IV over five days • 400 mg/kg IV as a single dose	Documented functional improvement x 12 months
Polymyositis (off-label)	One tx per month x six months. • 400 mg/kg IV daily for five days • 1 g/kg IV daily for two days	Documented improvement in muscle strength and/or decreased CPK levels x 12 months
Pemphigoid, refractory (off-label)	One tx per month x six months. • 2 g/kg IV over two to five days • 400 mg/kg/day IV for five days	Documented improvement x six months
Stiff-Person syndrome (off-label)	One tx per month x six months. • 2 g/kg IV divided over two days • 0.4 g/kg IV daily for five days	Documented functional improvement up to 12 months.
Systematic lupus erythematosus (off-label)	One tx per month x six months. • 0.4 g/kg daily for five days	Documented improvement in muscle strength, skin rash or decreased CPK levels up to 12 months.
Transplant (solid organ)		
Prevention of acute rejection (pre- and perioperative) (off-label)	Up to four doses pretransplant, then one dose weekly for four weeks post-transplant. • (Heart transplant): (given w/plasmapheresis): 0.1 g/kg after each cycle and 2 g/kg over two days after the final cycle; (given w/o plasmapheresis): 2 g/kg over two days every two to four weeks • (Kidney transplant): 2 g/kg IV every month OR 100 mg/kg after reach plasmapheresis session for one to five sessions • Dosage: 2 g/kg IV divided over two days every two to four weeks has been used • Dosage: 2–3 g/kg IV divided over four days has been used • Dosage: 100 mg/kg IV either every two to four weeks has been used • Dosage: 20 g of 10% immune globulin IV has been used • Dosage: 150 g of 10% immune globulin IV divided over three rounds every four weeks has been used	Further authorization may be considered under “Treatment of Ab-mediated rejection”
Treatment of antibody (Ab)-mediated (humoral) rejection (off-label)	• (Heart transplant): 0.1 to 1 g/kg IV one to three times per week for one to four weeks (often given after each plasmapheresis) • (Lung transplant): 0.5 to 1 g/kg/dose IV • (Liver transplant): 0.1 to 0.5 g/kg IV periodically with plasma exchange for minimum of five sessions, OR 0.1 g/kg IV after reaching plasma exchange for total dose of 1-2 g/kg OR 1-2 g/kg IV total dose	Documented improvement from previous course and confirmation of another episode of rejection; one dose.

Immune Globulin

HCPs – see [Other Information](#)

Indication	Frequency/Duration May be given no more frequently than:	Reauthorization Criteria/Duration
	• (Renal transplant): 0.5 to 2 g/kg IV total dose • Up to 2 g/kg total dose	
Other Miscellaneous disorders		
BK viremia in post-kidney transplant (off-label)	Up to 2 g/kg per treatment course	Updated BK viral load still detected based on lab range; x treatment course
Kawasaki syndrome	<i>(off-label dosing):</i> • 2 g/kg IV within 10 days of illness onset. Second dose may be given at least 36 hours after the end of the first infusion (authorization is up to a two-week window)	No reauthorization
Relapsing remitting multiple sclerosis (RRMS) (off-label)	One dose per month x six months. • 1 g/kg IV monthly • 2 g/kg IV divided over three days with 0.2 g/kg IV monthly after • 0.15 to 0.2 g/kg IV monthly • 0.4 g/kg IV daily for five days (loading dose), then 0.4 g/kg every six weeks • 0.4 g/kg IV daily for five days, then repeated every two months • 0.8 g/kg IV daily x two days	Documented improvement x 12 months
PANS/PANDAS (off-label)	One dose per month x six months. • Up to 2 gm/kg IV monthly (can be divided over two or more days)	Documented improvement x 12 months

OTHER INFORMATION:

HCPs	Description	Brand name
Intravenous Immune Globulin Injections		
J1459	Injection, immune globulin, (privigen), nonlyophilized (e.g., liquid), 500 mg	Privigen (IV)
J1552	Injection, immune globulin (alyglo), 500 mg	Alyglo (IV)
J1554	Injection, immune globulin (asceniv), 500 mg	Asceniv (IV)
J1556	Injection, immune globulin, (bivigam), 500 mg	Bivigam (IV)
J1557	Injection, immune globulin, (gammalex), nonlyophilized (e.g., liquid), 500 mg	Gammalex (IV)
J1561	Injection, immune globulin, (gamunex/ c/Gammaked), nonlyophilized (e.g., liquid), 500 mg	Gammaked; (IV/SQ) Gamunex-C (IV/SQ)
J1566	Injection, immune globulin, lyophilized (e.g., powder), not otherwise specified, 500 mg	Gammagard S/D (IV/SQ)
J1568	Injection, immune globulin, (octagam), nonlyophilized (e.g., liquid), 500 mg	Octagam (IV)
J1569	Injection, immune globulin, (gammagard liquid), nonlyophilized (e.g., liquid), 500 mg	Gammagard (IV/SQ)
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, nonlyophilized (e.g. liquid), 500 mg	Flebogamma, (IV) Flebogamma DIF (IV)
J1576	Injection, immune globulin (Panzyga), intravenous, nonlyophilized (e.g., liquid), 500 mg	Panzyga (IV)
J1553	Injection, immune globulin (yimmugo), 100 mg	Yimmugo (IV)
J1577	Injection, immune globulin (qivigy), 100 mg	Qivigy (IV)

Immune Globulin

HCPCS – see [Other Information](#)

Intramuscular or Subcutaneous Immune Injections		
J1460	Injection, gamma globulin, intramuscular 1 cc	GamaSTAN S/D (IM)
J1560	Injection, gamma globulin, intramuscular over 10 cc	GamaSTAN S/D (IM)
J1551	Injection, immune globulin (cutaquig), 100 mg	Cutaquig (SQ)
J1555	Injection, immune globulin (cuvitru), 100 mg	Cuvitru (SQ)
J1558	Injection, immune globulin (xembify), 100 mg	Xembify (SQ)
J1559	Injection, immune globulin, (hizentra), 100 mg	Hizentra (SQ)
J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immunoglobulin	Hyqvia (SQ)

REFERENCES:

1. Alyglo Prescribing Information: hcp.alyglo.com/alyglo_pi.pdf. 06/2025.
2. Asceniv Prescribing Information: www.asceniv.com/hubfs/ASCENIV%2BPI.pdf. 04/2025.
3. Bivigam Prescribing Information: d1io3yog0oux5.cloudfront.net/846dba1c4e81dff8dbcbcf9b1c86405/bivigam/files/documents/BIVIGAM_20221217_Ambient.pdf. 12/2022.
4. Cutaquig Prescribing Information: labeling.pfizer.com/ShowLabeling.aspx?id=12505. 03/2025.
5. Cuvitru Prescribing Information: www.shirecontent.com/PI/PDFS/Cuvitru_USA_ENG.PDF. 11/2024.
6. Flebogamma Prescribing Information: www.fda.gov/media/83042/download. 01/2016.
7. GamaStand S/D Prescribing Information: www.fda.gov/media/86789/download. 2013.
8. Gammaked Prescribing Information: www.gammaked.com/clientuploads/GAMMAKED_Web-Fax_3052575-3052576_21686.pdf?t=1562867757. 01/2020.
9. Gammaplex Prescribing Information: www.gammaplex.com/download/GSUS10PI_Gammaplex-10.pdf. 05/2024.
10. Gammagard Prescribing Information: www.shirecontent.com/pi/pdfs/gamliquid_usa_eng.pdf. 9/2024.
11. Gamunex-C Prescribing Information: www.gamunex-c.com/documents/648456/5516391/Gamunex-C+Prescribing+Information.pdf/28391fe7-086f-b112-0bd4-9738108cd159?t=1688982731791. 01/2020.
12. Hizentra Prescribing Information: labeling.cslbehring.com/PI/US/Hizentra/EN/Hizentra-Prescribing-Information.pdf. 04/2023.
13. Hyqvia Prescribing Information: www.shirecontent.com/PI/PDFS/HYQVIA_USA_ENG.pdf. 07/2025.
14. Panzyga Prescribing Information: labeling.pfizer.com/ShowLabeling.aspx?id=12355. 04/2025.
15. Privigen Prescribing Information: labeling.cslbehring.com/PI/US/Privigen/EN/Privigen-Prescribing-Information.pdf. 05/2025.
16. Qivigy Prescribing Information: www.qivigy.com/download/QIVIGI-PI-US-K00.pdf. 09/2025.
17. Octagam Prescribing Information: labeling.pfizer.com/ShowLabeling.aspx?id=11357. 09/2023.
18. Xembify Prescribing Information: www.fda.gov/media/128601/download. 07/2024.
19. Yimmugo Prescribing Information: www.yimmugo.us/download/YIMMUGO-PI.pdf. 10/2025.
20. UpToDate. Stiff-person syndrome. www.uptodate.com/contents/stiff-person-syndrome?search=immune%20globulin%20use%20for%20stiff%20person%20syndrome§ionRank=1&usage_type=default&anchor=H22&source=machineLearning&selectedTitle=1~150&display_rank=1#H3532432148. 11/2022.
21. UpToDate. Kidney transplantation in adults: BK polyomavirus-associated nephropathy. www.uptodate.com/contents/kidney-transplantation-in-adults-bk-polyomavirus-associated-nephropathy#H2288618654. 08/2022.
22. Vu D, Shah T, Ansari J, et al. Efficacy of intravenous immunoglobulin in the treatment of persistent BK viremia and BK virus nephropathy in renal transplant recipients. *Transplant Proc.* 2015; 47(2): 394-8. pubmed.ncbi.nlm.nih.gov/25769580/
23. NCCN Guidelines. Prevention and Treatment of Cancer-Related Infections. www.nccn.org/professionals/physician_gls/pdf/infections.pdf. 04/2024.
24. NCCN Guidelines. B-Cell Lymphomas. www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. 04/2024.

Immune Globulin

HCPCS – see [Other Information](#)

25. NCCN Guidelines. Management of Immunotherapy-Related Toxicities. www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf. 12/2023.
26. NCCN Guidelines. Multiple Myeloma. www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. 04/2024.
27. Yong PL, Boyle J, Ballou M, et al. Use of intravenous immunoglobulin and adjunctive therapies in the treatment of primary immunodeficiencies: A working group report of and study by the Primary Immunodeficiency Committee of the American Academy of Allergy Asthma and Immunology. Clin Immunol. 2010 May;135(2):255-63. www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/IVIG-March-2017.pdf
28. ACOG Practice Bulletin: Thrombocytopenia in Pregnancy. Number 207. Clinical management guidelines for obstetrician-gynecologist. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2019 March;133(3):e181-193. [ACOG Thrombocytopenia 2019.pdf](http://ACOGThrombocytopenia2019.pdf)
29. Muscular Dystrophy Association. Lambert-Eaton Myasthenic Syndrome (LEMS). Medical Management. www.mda.org/disease/lambert-eaton-myasthenic-syndrome
30. Wiendi H, Abicht A, Chan A et al. Guideline for the management of myasthenic syndromes. Therapeutic Advances Neurological Disorders. 2023; 16: 1-31. www.ncbi.nlm.nih.gov/pmc/articles/PMC10752078/pdf/10.1177_17562864231213240.pdf
31. Orange JS, Hossny EM, Weiler CR et al. Use of intravenous immunoglobulin in human disease: a review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol. 2006; 117:S525-53. www.jacionline.org/action/showPdf?pii=S0091-6749%2806%2900178-3
32. American Academy of Pediatrics (AAP). Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS): Clinical Report. Pediatrics. 2025; 155(3):e2024070334. publications.aap.org/pediatrics/article/155/3/e2024070334/200384/Pediatric-Acute-Onset-Neuropsychiatric-Syndrome?autologincheck=redirected
33. Frankovich J, Swedo S, Murphy T, et al. Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II—Use of Immunomodulatory Therapies. Journal of Child and Adolescent Psychopharmacology. 2017;27(7):574-593. pmc.ncbi.nlm.nih.gov/articles/PMC9836706/pdf/cap.2016.0148.pdf
34. Pandas Physician's Network (PPN). PANS/PANDAS Diagnostic Flowchart. www.pandasppn.org/flowchart/
35. CalOptima Health Memorandum: [Assembly Bill 2105 Guidance Effective 01/01/25](#)

P&T APPROVAL HISTORY:

1. July 2000 P&T Drug Review
2. February 2015 P&T Drug Review
3. May 2016 P&T Drug Review
4. February 2017 P&T Drug Review

UMC REVIEW:

4/2026