



SmartPA Criteria

Proposal

Drug/Drug Class:	Immunoglobulins (IVIG and SCIG) Clinical Edit
First Implementation Date:	February 18, 2021
Revised Date:	October 20, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of immunoglobulins (IVIG and SCIG)

Why Issue Selected: Immunoglobulin agents, whether administered by intravenous (IVIG) or subcutaneous (SCIG) routes, are increasingly used as therapy for a variety of conditions. It is common practice to use immunoglobulins for the treatment of immunocompromised patients, but use is also expanding to treatment of inflammatory diseases and autoimmune neuropathies. Immunoglobulins have received FDA approval for several indications including primary humoral immunodeficiency, immune thrombocytopenia, B-cell chronic lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, Kawasaki syndrome, and multifocal motor neuropathy; they are also frequently used for off-label indications and refractory conditions. Because immunoglobulin formulations are produced from donated pooled human plasma, the supply is finite. Availability is determined not only on plasma donations but also manufacturing time (the process can take 9-12 months) and increasing demands for immunoglobulin agents have contributed to reported shortages in supply. Immunoglobulin agents are also costly, ranking in the top 10 specialty therapeutic classes for spend. Due to the high cost and limited supply, MO HealthNet will impose criteria to ensure appropriate utilization for outpatient therapy.

Program-Specific Information:

Date Range FFS 4-1-2021 to 3-31-2022			
Drug	Claims	Spend	Average Spend per Claim
CUVITRU 1 GRAM/5 ML VIAL	25	\$31,174.99	\$1,247.00
CUVITRU 10 GRAM/50 ML VIAL	45	\$250,612.29	\$5,569.16
CUVITRU 2 GRAM/10 ML VIAL	9	\$13,177.67	\$1,464.19
CUVITRU 4 GRAM/20 ML VIAL	22	\$45,003.71	\$2,045.62
CUVITRU 8 GRAM/ 40 ML VIAL	1	\$5,788.50	\$5,788.50
FLEBOGAMMA DIF 10% VIAL	0	-	-
GAMMAGARD LIQUID 10% VIAL	383	\$1,492,570.98	\$3,897.05
GAMMAGARD S-D 10 G (IGA<1) SOL	19	\$81,943.55	\$4,312.82
GAMMAGARD S-D 5 G (IGA<1) SOLN	19	\$13,905.51	\$791.87
GAMMAKED 10 GRAM/100 ML VIAL	28	\$274,841.80	\$9,815.78
GAMMAKED 20 GRAM/200 ML VIAL	2	\$14,708.10	\$7,354.05
GAMMAKED 5 GRAM/50 ML VIAL	0	-	-

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GAMMAPLEX 10 GRAM/100 ML VIAL	37	\$271,723.28	\$7,343.87
GAMMAPLEX 20 GRAM/200 ML VIAL	66	\$485,087.13	\$7,349.81
GAMMAPLEX 5 GRAM/50 ML VIAL	12	\$65,391.40	\$5,449.28
GAMUNEX-C 1 GRAM/10 ML VIAL	50	\$13,168.85	\$263.38
GAMUNEX-C 10 GRAM/100 ML VIAL	616	\$800,154.12	\$1,298.95
GAMUNEX-C 2.5 GRAM/25 ML VIAL	62	\$18,135.57	\$292.51
GAMUNEX-C 20 GRAM/200 ML VIAL	749	\$2,192,945.54	\$2,927.83
GAMUNEX-C 40 GRAM/400 ML VIAL	168	\$607,749.25	\$3,617.56
GAMUNEX-C 5 GRAM/50 ML VIAL	443	\$374,062.88	\$844.39
HIZENTRA 1 GRAM/5 ML SYRINGE	6	\$4,366.71	\$727.79
HIZENTRA 4 GRAM/20 ML SYRINGE	15	\$61,867.15	\$4,124.48
HIZENTRA 1 GRAM/5 ML VIAL	175	\$114,549.86	\$654.57
HIZENTRA 10 GRAM/50 ML VIAL	85	\$416,789.82	\$4,903.41
HIZENTRA 2 GRAM/10 ML VIAL	160	\$174,541.91	\$1,090.89
HIZENTRA 4 GRAM/20 ML VIAL	244	\$672,472.74	\$2,756.04
HYQVIA 10 GM-800 UNIT PACK	6	\$30,173.01	\$5,028.84
HYQVIA 20 GM-1,600 UNIT PACK	24	\$103,131.85	\$4,297.16
HYQVIA 30 GM-2,400 UNIT PACK	9	\$45,802.09	\$5,089.12
HYQVIA 5 GM-400 UNIT PACK	12	\$10,323.24	\$860.27
OCTAGAM 10% VIAL	84	\$485,740.81	\$5,782.63
OCTAGAM 5% VIAL	0	-	-
PANZYGA 10% VIAL	6	\$14,232.64	\$2,372.11
PRIVIGEN 10% VIAL	441	\$1,172,077.71	\$2,657.77
XEMBIFY 20% (1G/5ML) VIAL	10	\$4,356.58	\$435.36
XEMBIFY 20% (2G/10ML) VIAL	12	\$9,360.60	\$780.05
XEMBIFY 20% (4G/20ML) VIAL	1	\$3,307.25	\$3,307.25
XEMBIFY 20% (10G/50ML) VIAL	1	\$8,254.85	\$8,254.85
Total	4047	\$10,383,490.90	\$2,565.73

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Immunoglobulins (IVIG and SCIG)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Participant paid claim history demonstrates ≤ 3 paid claims for immunoglobulin (IVIG or SCIG) therapy in the past year **OR**
- Participant has a documented diagnosis of an approvable condition for continued use of IVIG or SCIG in the past year (see Appendix A) **OR**
- Approval based on Clinical Consultant Review

Denial Criteria

- Therapy will be denied if all approval criteria are not met

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Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

Appendix A – Approvable conditions for continued use of IVIG or SCIG (excludes those conditions treated solely in an inpatient setting)

- Chronic inflammatory demyelinating polyneuritis
- Chronic lymphocytic leukemia of B-cell type
- Cytomegaloviral pneumonitis
- Dermatomyositis
- Donor specific antibody mediated organ rejection
- Enteroviral meningitis
- Graft-versus-host disease
- Graves ophthalmopathy
- Guillain-Barre syndrome
- Henoch-Schönlein purpura
- Immune thrombocytopenic purpura
- Lambert-Eaton syndrome
- Multifocal motor neuropathy
- Multiple myeloma
- Myasthenia gravis
- Myelophthisis
- Polymyositis
- Primary immunodeficiency
- Rotaviral enteritis
- Severe combined immunodeficiency
- Stiff-person syndrome

References

- Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: a review of evidence. *J Allergy Clin Immunol.* 2017;139(3S):S1-S46. doi: 10.1016/j.jaci.2016.09.023.
- AJMC Supplement: Examining the Application of Immunoglobulin in Multiple Disease States: A Review of Evidence. *The American Journal of Managed Care.* Vol. 25, No 6, Sup. June 2019.
- IPD Analytics. *Rx Insights: Immunology. Intravenous Immune Globulin (IVIG) Versus Subcutaneous Immune Globulin (SCIG): Clinical and Cost Comparison.* July 2020.
- IPD Analytics. *Rx Insights: Hematologic. Immune Globulin Therapy Management.* October 2018.