SmartPA Criteria Proposal

Drug/Drug Class:	Immunoglobulins (IVIG and SCIG) Clinical Edit
First Implementation Date:	February 18, 2021
Proposed Date:	September 16, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 7-1-2020 to 6-30-2021			
Drug	**Claims**	**Spend**	**Average Spend per Claim**
CARIMUNE NF 12 GM VIAL	0	-	-
CARIMUNE NF 6 GM VIAL	0	-	-
CUVITRU 1 GRAM/5 ML VIAL	29	$29,572.05	$1,019.73
CUVITRU 10 GRAM/50 ML VIAL	35	$167,887.65	$4,796.79
CUVITRU 2 GRAM/10 ML VIAL	29	$35,662.14	$1,229.73
CUVITRU 4 GRAM/20 ML VIAL	33	$75,413.48	$2,285.26
CUVITRU 8 GRAM/ 40 ML VIAL	11	$62,331.74	$5,666.52
FLEBOGAMMA DIF 10% VIAL	18	$39,122.01	$2,173.45
GAMMAGARD LIQUID 10% VIAL	302	$1,215,604.07	$4,025.18
GAMMAGARD S-D 10 G (IGA<1) SOL	18	$84,586.78	$4,699.27
GAMMAGARD S-D 5 G (IGA<1) SOLN	19	$19,116.37	$1,006.12
GAMMAKED 10 GRAM/100 ML VIAL	22	$245,136.35	$11,142.56
GAMMAKED 20 GRAM/200 ML VIAL	2	$23,674.70	$11,837.35

GAMMAKED 5 GRAM/50 ML VIAL	8	$97,822.24	$12,227.78
GAMMAPLEX 10 GRAM/100 ML VIAL	44	$231,451.24	$5,260.26
GAMMAPLEX 20 GRAM/200 ML VIAL	59	$434,700.52	$7,367.81
GAMMAPLEX 5 GRAM/50 ML VIAL	73	$254,485.65	$3,486.10
GAMUNEX-C 1 GRAM/10 ML VIAL	28	$5,484.04	$195.86
GAMUNEX-C 10 GRAM/100 ML VIAL	618	$789,870.59	$1,278.11
GAMUNEX-C 2.5 GRAM/25 ML VIAL	75	$23,738.80	$316.52
GAMUNEX-C 20 GRAM/200 ML VIAL	735	$2,550,067.72	$3,469.48
GAMUNEX-C 40 GRAM/400 ML VIAL	162	$689,821.68	$4,258.16
GAMUNEX-C 5 GRAM/50 ML VIAL	514	$483,558.18	$940.77
HIZENTRA 1 GRAM/5 ML VIAL	208	$136,755.03	$657.48
HIZENTRA 10 GRAM/50 ML VIAL	107	$594,843.14	$5,559.28
HIZENTRA 2 GRAM/10 ML VIAL	194	$252,188.94	$1,299.94
HIZENTRA 4 GRAM/20 ML VIAL	275	$777,737.89	$2,828.14
HYQVIA 10 GM-800 UNIT PACK	17	$84,218.63	$4,954.04
HYQVIA 20 GM-1,600 UNIT PACK	32	$90,420.65	$2,825.65
HYQVIA 30 GM-2,400 UNIT PACK	12	$59,379.15	$4,948.26
HYQVIA 5 GM-400 UNIT PACK	13	$10,811.65	$831.67
OCTAGAM 10% VIAL	46	$300,614.51	$6,535.10
OCTAGAM 5% VIAL	1	$6,231.57	$6,231.57
PANZYGA 10% VIAL	10	$27,340.81	$2,734.08
PRIVIGEN 10% VIAL	366	$1,295,919.29	$3,540.76
XEMBIFY 20% (1G/5ML) VIAL	1	$295.49	$295.49
XEMBIFY 20% (2G/10ML) VIAL	4	$3,250.39	$812.60
Total	**4120**	**$11,199,115.10**	**$2,718.23**

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **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

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	X

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.