SmartPA Criteria Proposal

Drug/Drug Class:	Immunoglobulins (IVIG and SCIG) Clinical Edit
First Implementation Date:	TBD
Proposed Date:	September 17, 2020
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 7-1-2019 to 6-30-2020			
Drug	**Claims**	**Spend**	**Average Spend per Claim**
CARIMUNE NF 12 GM VIAL	16	$26,784.00	$1,674.00
CARIMUNE NF 6 GM VIAL	2	$2,160.00	$1,080.00
CUVITRU 1 GRAM/5 ML VIAL	25	$17,635.63	$705.42
CUVITRU 10 GRAM/50 ML VIAL	8	$35,368.09	$4,421.01
CUVITRU 2 GRAM/10 ML VIAL	33	$37,303.25	$1,130.40
CUVITRU 4 GRAM/20 ML VIAL	32	$74,126.29	$2,316.44
CUVITRU 8 GRAM/ 40 ML VIAL	24	$100,480.83	$4,186.70
FLEBOGAMMA DIF 10% VIAL	8	$9,610.91	$1,201.36
GAMMAGARD LIQUID 10% VIAL	277	$1,013,404.63	$3,658.50
GAMMAGARD S-D 10 G (IGA<1) SOL	23	$99,994.17	$4,347.57
GAMMAGARD S-D 5 G (IGA<1) SOLN	15	$16,278.55	$1,085.23
GAMMAKED 10 GRAM/100 ML VIAL	17	$183,724.29	$10,807.31
GAMMAKED 20 GRAM/200 ML VIAL	1	$2,065.46	$2,065.46

GAMMAKED 5 GRAM/50 ML VIAL	12	$125,484.56	$10,457.04
GAMMAPLEX 10 GRAM/100 ML VIAL	37	$262,399.16	$7,091.86
GAMMAPLEX 20 GRAM/200 ML VIAL	21	$184,108.15	$8,767.05
GAMMAPLEX 5 GRAM/50 ML VIAL	12	$88,300.07	$7,358.33
GAMUNEX-C 1 GRAM/10 ML VIAL	24	$7,343.05	$305.96
GAMUNEX-C 10 GRAM/100 ML VIAL	614	$1,044,913.58	$1,701.81
GAMUNEX-C 2.5 GRAM/25 ML VIAL	52	$17,356.43	$333.78
GAMUNEX-C 20 GRAM/200 ML VIAL	636	$2,164,443.97	$3,403.21
GAMUNEX-C 40 GRAM/400 ML VIAL	136	$572,321.19	$4,208.24
GAMUNEX-C 5 GRAM/50 ML VIAL	442	$329,250.12	$744.91
HIZENTRA 1 GRAM/5 ML VIAL	183	$113,920.23	$622.51
HIZENTRA 10 GRAM/50 ML VIAL	126	$794,460.82	$6,305.24
HIZENTRA 2 GRAM/10 ML VIAL	104	$96,853.57	$931.28
HIZENTRA 4 GRAM/20 ML VIAL	194	$515,747.82	$2,658.49
HYQVIA 10 GM-800 UNIT PACK	18	$86,736.06	$4,818.67
HYQVIA 20 GM-1,600 UNIT PACK	17	$54,794.51	$3,223.20
HYQVIA 30 GM-2,400 UNIT PACK	4	$19,550.20	$4,887.55
HYQVIA 5 GM-400 UNIT PACK	13	$10,530.19	$810.01
OCTAGAM 10% VIAL	11	$87,758.55	$7,978.05
PANZYGA 10% (10 G/100 ML) VIAL	9	$79,490.61	$8,832.29
PANZYGA 10% (20 G/200 ML) VIAL	5	$82,739.85	$16,547.97
PANZYGA 10% (30 G/300 ML) VIAL	6	$29,846.70	$4,974.45
PANZYGA 10% (5 G/50 ML) VIAL	12	$94,399.50	$7,866.62
PRIVIGEN 10% VIAL	307	$1,034,583.79	$3,369.98

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 120 days **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 no approval criteria are 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
- 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.