

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	✓	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)	Medical Benefit: Managed Medicaid		
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)	Medical Benefit: Add-on		
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

Reference #
3797-D

EXCEPTIONS CRITERIA IMMUNE GLOBULINS

PREFERRED PRODUCTS:
FLEBOGAMMA DIF, GAMMAKED, GAMUNEX-C, HIZENTRA, OCTAGAM, PRIVIGEN

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the immune globulin products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Immune Globulin Products

	Product(s)
Preferred*	<ul style="list-style-type: none"> • Flebogamma (intravenous) • Gammaked (subcutaneous/intravenous) • Gamunex-C (subcutaneous/intravenous) • Hizentra (subcutaneous) • Octagam (intravenous) • Privigen (intravenous)
Targeted	<ul style="list-style-type: none"> • Asceniv (intravenous) • Bivigam (intravenous) • Cutaquig (subcutaneous) • Cuvitru (subcutaneous) • Gammagard Liquid (subcutaneous/intravenous) • Gammaplex (intravenous) • HyQvia (subcutaneous) • Panzyga (intravenous) • Xembify (subcutaneous)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B	Reference #
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First	3797-D
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid			
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on			
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)							

Coverage for a targeted product is provided when either of the following criteria is met:

- A. Member has received treatment with the targeted product in the past 365 days.
- B. Member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products.

REFERENCES

1. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; April 2019.
2. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; December 2023.
3. Cutaquig [package insert]. Paramus, NJ: Octapharma USA, Inc.; November 2021.
4. Flebogamma Dif [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; September 2019.
5. Gammagard Liquid [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
6. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
7. Gammplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
8. Gammplex 10% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
9. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
10. Octagam 10% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
11. Octagam 5% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
12. Panzyga [package insert]. New York, NY; Pfizer; February 2021.
13. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.
14. Cuvitru [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
15. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; April 2023.
16. HyQvia [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
17. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2020.