

Reference number(s) 6185-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	V
Standard Control - Choice (SCCF)	V
Preferred Drug Plan Design (PDPD)	
Advanced Control Specialty (ACSF)	V
Advanced Control Specialty - Choice (ACSCF)	V
Managed Medicaid Template (MMT)	
Marketplace (MF)	
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	
Aetna Individual Lives (IVL)	
Value (VF)	

Formulary	Applies
New to Market (NTM)	
Standard Formulary Chart (SFC)	
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	
Advanced Control Specialty Formulary Chart (ACSFC)	
Value Formulary Chart (VFC)	
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Medical Benefit: Managed Medicaid (MMMB)	
Medicare Part B	
Medicare Part B: Advanced Biosimilars First	

Exceptions Criteria Immune Globulins

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control – Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF).

Plan Design Summary

This program applies to the immune globulin products specified in this document. 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 criteria applies to all members requesting treatment with a targeted product.

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

Table. Immune Globulin Products

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

Specialty Exceptions Immune Globulins SF-SCCF-ACSF-ACSCF 6185-D P2025a.docx

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	Product(s)
Preferred	 Bivigam Flebogamma DIF Gammagard Liquid Gammagard S/D Gammaked Gammaplex Gamunex-C Privigen
Targeted	AlygloAscenivOctagamPanzyga

Exception Criteria

This criteria applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when the member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products.

References

- 1. Alyglo [package insert]. Teaneck, NJ: GC Biopharma USA, Inc.; December 2023.
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- 3. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; March 2024.
- 4. Flebogamma 10% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; September 2019.
- 5. Flebogamma 5% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; September 2019.
- 6. Gammagard Liquid [package insert]. Westlake Village, CA: Baxalta US Inc.; January 2024.
- 7. Gammagard S/D [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
- 8. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
- Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
- 10. Gammaplex 10% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
- 11. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
- 12. Octagam 10% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.

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Reference number(s) 6185-D

- 13. Octagam 5% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.
- 14. Panzyga [package insert]. Hoboken, NJ: Octapharma USA.; February 2021.
- 15. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.

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