

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

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 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: Biotest Pharmaceuticals Corporation; July 2019.
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5. Gammagard Liquid [package insert]. Westlake Village, CA: Baxalta US Inc.; March 2021.
6. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
7. Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
8. Gammaplex 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.; March 2022.
11. Octagam 5% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
12. Panzyga [package insert]. New York, NY; Pfizer; January 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 2022.
16. HyQvia [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
17. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2020.