

This document applies to the following:

| Product | Applies |
|---|-------------------------------------|
| Medicare Part B | <input checked="" type="checkbox"/> |
| Medicare Part B: Advanced Biosimilars First | <input checked="" type="checkbox"/> |

Medicare Part B Step Therapy Immune Globulins

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

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the immune globulin products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

Table. Immune Globulin Products

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

| | Product(s) |
|-----------|---|
| Preferred | <ul style="list-style-type: none"> • Flebogamma (intravenous) • Gammaked (subcutaneous/intravenous) • Gamunex-C (subcutaneous/intravenous) • Hizentra (subcutaneous) • Octagam (intravenous) • Privigen (intravenous) |

| | Product(s) |
|---------------|---|
| Non-preferred | <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) |

Step Therapy Criteria

Coverage for a non-preferred product is provided when either of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- 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: 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. 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.; 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.

| Reference number(s) |
|---------------------|
| 3797-D |

17. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2020.