

Jurisdiction Specific Medicare Part B Intramuscular Immune Globulin (IMIG)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
GamaSTAN	immune globulin [human]

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Hepatitis A exposure
- Measles (Rubeola)
- Rubella
- Varicella
- Immunoglobulin deficiency

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Hepatitis A Exposure

Authorization of 1 month may be granted for hepatitis A exposure.

Measles (Rubeola)

Authorization of 1 month may be granted for measles when all of the following criteria are met:

- The member is unvaccinated or had measles and is at high risk for complications.
- The member has been exposed to measles less than three days prior to treatment.

Rubella

Authorization of 1 month may be granted for rubella when all of the following criteria are met:

- The member is in early pregnancy.
- The member has been exposed to the virus and does not have immunity.

Varicella

Authorization of 1 month may be granted for passive immunization of varicella when all of the following criteria are met:

- The member is immunosuppressed.
- Varicella zoster immunoglobulin is not available.

Immunoglobulin Deficiency

Authorization of 1 month may be granted for prevention of serious infection when the member's circulating immunoglobulin G (IgG) levels are low.

References

1. Immune Globulins LCD (L34771) Version R22 Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 30, 2024.
2. Billing and Coding: Immune Globulins (A57554) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 30, 2024.
3. GamaSTAN [package insert]. Research Triangle Park, NC: Grifols Therapeutics, Inc.; August 2022.