

# Specialty Guideline Management

## Intramuscular Immune

### GamaSTAN

## 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]

## Indications

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

### FDA-approved Indications<sup>1,2</sup>

GamaSTAN is a human immune globulin indicated for:

- Prophylaxis following exposure to hepatitis A
- To prevent or modify measles in a susceptible person exposed fewer than 6 days previously
- To modify varicella
- To modify rubella in exposed women who will not consider a therapeutic abortion

### Limitations of Use

GamaSTAN is not standardized with respect to antibody titers against hepatitis B surface antigen (HBsAg) and must not be used for prophylaxis of viral hepatitis type B. Prophylactic treatment to prevent hepatitis B can best be accomplished with use of Hepatitis B Immune Globulin (Human), often in combination with Hepatitis B Vaccine.

GamaSTAN is not indicated for routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella.

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

### Prophylaxis of hepatitis A<sup>1,2,4</sup>

Authorization of 1 month may be granted for prophylaxis of hepatitis A when one of the following criteria is met:

- Member was exposed to hepatitis A virus within the past 2 weeks (e.g., household contact, sexual contact, and childcare center or classroom contact with an infected person), and is NOT exhibiting clinical manifestation of disease OR
- Member is at high risk for hepatitis A exposure (examples of populations at high risk for hepatitis A are travelers to and workers in countries of high endemicity of infection and illicit drug users).

### Prophylaxis of measles (rubeola)<sup>1,3,4</sup>

Authorization of 1 month may be granted for prophylaxis of measles in unvaccinated members who have not had measles previously and were exposed to measles within the past 6 days.

### Prophylaxis of varicella<sup>1</sup>

Authorization of 1 month may be granted for prophylaxis of varicella in immunosuppressed members when varicella zoster immune globulin (e.g., Varizig®) is not available.

### Prophylaxis of rubella<sup>1,3</sup>

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

- Member was recently exposed to rubella
- Member is currently pregnant

## Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

## References

1. GamaSTAN [package insert]. Research Triangle Park, NC: Grifols Therapeutics, Inc.; August 2022.
2. Nelson NP, Link-Gelles R, Hofmeister MG, et al. Update: Recommendations of the Advisory Committee on Immunization Practices for Use of Hepatitis A Vaccine for Postexposure Prophylaxis and for Preexposure Prophylaxis for International Travel. MMWR Morb Mortal Wkly Rep 2018;67:1216–1220.
3. Centers for Disease Control and Prevention. Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013. Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2013;62(4).
4. Centers for Disease Control and Prevention Health Information for International Travel (Yellow Book). <https://www.cdc.gov/yellow-book/hcp/contents/index.html>. Accessed May 5, 2025.