| Reference number(s) |
| --- |
| 6329-A |

# Standard Medicare Part B Management 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[1]

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.


© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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

## Prophylaxis of hepatitis A[1,2,4]

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)[1,3,4]

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[1]

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[1,3]

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.


© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

# Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for GamaSTAN.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for GamaSTAN are covered.

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

# 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.


© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.