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# 5.20.002

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| <b>Section:</b>    | Prescription Drugs | <b>Effective Date:</b>       | April 1, 2026 |
| <b>Subsection:</b> | Biologicals        | <b>Original Policy Date:</b> | March 8, 2002 |
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**Last Review Date:** March 6, 2026

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## GamaSTAN (IGIM)

### Description

#### GamaSTAN

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#### Background

Immune globulin IM (IGIM) is human immune globulin for intramuscular administration used to provide passive immunity to neutralize viruses. GamaSTAN (IGIM) is used 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, and to modify rubella in exposed, susceptible pregnant women (1-2).

#### Regulatory Status

FDA-approved indications: GamaSTAN is a human immune globulin indicated in the following situations:

#### Hepatitis A

The prophylactic value of GamaSTAN is greatest when given before or soon after exposure to hepatitis A. GamaSTAN is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously (2).

#### Measles (Rubeola)

GamaSTAN should be given to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. GamaSTAN may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. GamaSTAN and measles vaccine should not be given at the same

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time. If a child is older than 12 months and has received GamaSTAN, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared, provided there are no contraindications to the vaccine. If a susceptible child exposed to measles is immunocompromised, GamaSTAN should be given immediately. Children who are immunocompromised should not receive measles vaccine or any other live viral vaccine (2).

### **Varicella**

Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella-Zoster Immune Globulin (Human) [VZIG]. If VZIG is unavailable, GamaSTAN, promptly given, may also modify varicella (2).

### **Rubella**

The routine use of GamaSTAN for prophylaxis of rubella in early pregnancy is of dubious value and cannot be justified. Some studies suggest that the use of GamaSTAN in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, GamaSTAN may benefit those women who will not consider a therapeutic abortion (2).

GamaSTAN has warnings regarding proper route of administration, risk of product containing infectious agents such as viruses, and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis. Thrombosis may occur even in the absence of known risk factors. Patients at increased risk may include those with hypercoagulable conditions, advanced age, prolonged immobilization, history of venous or arterial thrombosis, use of estrogens, in-dwelling vascular catheters, cardiovascular risk factors and hyperviscosity. GamaSTAN is to be used for intramuscular administration only. Anaphylaxis is more likely to occur if GamaSTAN is given intravenously. Do not administer subcutaneously or intravenously. Do not inject into a blood vessel (2).

Safety and effectiveness of GamaSTAN in pediatric patients have not been established (2).

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### **Related policies**

Atgam, IVIG, SCIG

### **Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

GamaSTAN may be considered **medically necessary** if the conditions indicated below are met.

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GamaSTAN may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnoses

Patient must have **ONE** of the following:

1. Hepatitis A, prophylaxis with **ONE** of the following:
  - a. Exposed to hepatitis A within the last 2 weeks
  - b. High risk for hepatitis A
2. Measles (Rubeola), prophylaxis
  - a. Exposed to measles within the last 6 days
3. Rubella, prophylaxis
  - a. Female
  - b. Recently exposed
4. Varicella, prophylaxis
  - a. Exposed to varicella within the last 10 days
  - b. High risk for varicella
  - c. Varicella zoster immune globulin is **NOT** available

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### Prior – Approval *Renewal* Requirements

Same as above

### Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 1 month

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### Prior – Approval *Renewal* Limits

Same as above

### Rationale

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### Summary

Immune globulin IM (IGIM) is human immune globulin for intramuscular administration, used to provide passive immunity to neutralize viruses. GamaSTAN is used for prophylaxis following exposure to hepatitis A, measles, varicella and rubella. GamaSTAN has warnings regarding proper route of administration, risk of product containing infectious agents such as viruses, and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis. Safety and effectiveness of GamaSTAN in pediatric patients have not been established (1-2)

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of GamaSTAN while maintaining optimal therapeutic outcomes.

### References

1. Immune Globulin IM, IMIG, IGIM. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; Revision year [2018]. Available from: <https://www.clinicalkey.com/pharmacology/monograph/310?sec=monindi&n=GamaSTAN%20S/D>.
2. GamaSTAN [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2022.

### Policy History

| Date           | Action  |
|----------------|---|
| December 2011  | Addition to PA  |
| December 2012  | Annual editorial review   |
| September 2013 | Annual editorial review and reference update<br>Removal of prophylaxis of serious infection in patients with immunoglobulin deficiency (e.g., Primary immunodeficiency disease) |
| December 2013  | Annual editorial review and update  |
| December 2014  | Annual editorial review and reference update  |
| December 2015  | Annual review   |
| June 2016      | Annual editorial review and reference update<br>Policy code changed from 5.05.02 to 5.20.02   |
| December 2016  | Annual editorial review and reference update<br>Addition of requirements for each indication  |
| March 2017     | Annual review   |
| December 2017  | Annual editorial review and reference update  |
| November 2018  | Annual review and reference update  |
| September 2019 | Annual review   |
| March 2020     | Annual editorial review and reference update  |
| June 2021      | Annual editorial review and reference update  |
| June 2022      | Annual review and reference update  |

# 5.05.002

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|----------------|--|
| March 2023     | Annual review and reference update. Changed policy number to 5.05.002                                |
| March 2024     | Annual review and reference update   |
| September 2024 | Annual review  |
| March 2025     | Annual review  |
| March 2026     | Annual review. Per FEP, removed mention to GamaSTAN S/D as the S/D preparation has been discontinued |

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**