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5.20.002

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	March 8, 2002
Subject:	GamaSTAN	**Page:**	1 of 5

Last Review Date: September 6, 2024

GamaSTAN S/D (IGIM)

Description

GamaSTAN S/D

Background
Immune globulin IM (IGIM) is human immune globulin for intramuscular administration used to provide passive immunity to neutralize viruses. GamaSTAN S/D (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 S/D is a human immune globulin indicated in the following situations:

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

Measles (Rubeola)
GamaSTAN S/D 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 S/D 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 S/D and measles vaccine should not be given at

the same time. If a child is older than 12 months and has received GamaSTAN S/D, 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 S/D 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 S/D, promptly given, may also modify varicella (2).

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

GamaSTAN S/D 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 S/D is to be used for intramuscular administration only. Anaphylaxis is more likely to occur if GamaSTAN S/D is given intravenously. Do not administer subcutaneously or intravenously. Do not inject into a blood vessel (2).

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

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 S/D may be considered **medically necessary** if the conditions indicated below are met.

GamaSTAN S/D 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

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 1 month

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Immune globulin IM (IGIM) is human immune globulin for intramuscular administration, used to provide passive immunity to neutralize viruses. GamaSTAN S/D is used for prophylaxis following exposure to hepatitis A, measles, varicella and rubella. GamaSTAN S/D 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 S/D 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 S/D 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 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 Policy code changed from 5.05.02 to 5.20.02
December 2016	Annual editorial review and reference update 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
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.