GamaSTAN S/D (IGIM)

Description

GamaSTAN S/D

Background
IGIM is a transient source of IgG that specifically and nonspecifically inactivates various bacteria, viruses, and fungi. IgG antibodies activate the complement system, promote opsonization, neutralize microorganisms and their toxins, and participate in antibody dependent cytolytic reactions. Immune globulin for intramuscular use is currently indicated to provide passive immunization in the prevention or modification of certain infectious diseases (1).

Regulatory Status
FDA-approved indications:

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 3 months later when the measles antibody titer will have disappeared (2).

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).

Thrombotic events may occur with use of human immune globulin products. 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 in the 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 may be considered **medically necessary** for the treatment of the prophylaxis of Hepatitis A, Measles (Rubeola), Rubella, or Varicella.
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

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**  1 month

**Prior – Approval Renewal Limits**

**Duration**  1 month

**Rationale**
Summary
IGIM is a transient source of IgG that specifically and nonspecifically inactivates various bacteria, viruses, and fungi. IgG antibodies activate the complement system, promote opsonization, neutralize microorganisms and their toxins, and participate in antibody dependent cytolytic reactions (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

Policy History
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<td>December 2011</td>
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<td>September 2013</td>
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<td>Removal of prophylaxis of serious infection in patients with immunoglobulin deficiency (eg Primary immunodeficiency disease)</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.