



**BlueCross
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Federal Employee Program.

Immune Globulin IM (IGIM) (GamaSTAN)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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



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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 2012.