Intramuscular Immune Globulin (GamaSTAN® S/D)

When requesting GamaSTAN® S/D, the individual requiring treatment must be diagnosed with an FDA-approved indication or an approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

GamaSTAN® S/D is a human immune globulin indicated:

- For prophylaxis following exposure to 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.
- 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.
- To modify varicella when Varicella Zoster Immune Globulin is not available
- To modify rubella in exposed women who will not consider a therapeutic abortion

Approved Off-label Compendial Use

- Pre-exposure prophylaxis of Hepatitis A virus infection

Coverage Guidelines

For all approved indications, the individual must meet **ALL** of the following criteria for approval:

- For an individual with immunoglobulin A (IgA) deficiency, does not have antibodies to IgA AND a history of hypersensitivity
- Does not have severe thrombocytopenia
- Does not have any coagulation disorders

For pre-exposure prophylaxis of Hepatitis A virus infection

- Hepatitis A vaccine is not available **OR**
- Has contraindication to Hepatitis A vaccine **OR**
- Planning to travel in areas where hepatitis A is common

For post-exposure prophylaxis of Hepatitis A virus infection

- Does not have clinical manifestations of hepatitis A **AND**
- Has been exposed to hepatitis A less than 2 weeks previously

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For post-exposure prophylaxis of measles:

- Has been exposed to measles less than 6 days previously **AND**
- Does not have laboratory evidence of measles immunity or confirmation of prior measles infection **AND**
- At increased risk for severe measles and complications

For post-exposure prophylaxis of varicella *(Note: Per Centers for Disease Control and Prevention [CDC], Intravenous immune globulin (IVIG) is recommended when Varicella-Zoster Immune Globulin is not available. Please provide clinical reason for GamaSTAN® S/D request)*

- Varicella-Zoster immune Globulin (VZIG) is not available

For post-exposure prophylaxis of rubella

- GamaSTAN® S/D will be used in a susceptible pregnant woman who is exposed to confirmed case of rubella

Approval duration: one dose (30 days)

Dosing Recommendations

For intramuscular use only. Do not administer intravenously.

For pre-exposure prophylaxis of Hepatitis A (for an individual who plan to travel in areas where hepatitis A is common):

The recommended dose varies according to planned duration of travel area as follows:

- Up to 1 month: 0.1 mL/kg
- Up to 2 months: 0.2 mL/kg
- 2 months or longer: repeat dose of 0.2 mL/kg every 2 months

For post-exposure prophylaxis of Hepatitis A:

The recommended dose is 0.1 mL/kg administered within 2 weeks of prior exposure to hepatitis A

For post-exposure prophylaxis of measles:

The recommended dose is 0.25 mL/kg administered within 6 days of exposure. 0.5 mL/kg should be administered immediately to an immunocompromised child.

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For post-exposure prophylaxis of varicella:

The recommended dose is 0.6 mL/kg to 1.2 mL/kg administered promptly if Varicella-Zoster Immune Globulin is unavailable

For post-exposure prophylaxis of rubella:

The recommended dose is 0.55 mL/kg

References

1. GamaSTAN S/D prescribing information. Research Triangle Park, NC. Grifols Therapeutics Inc. June 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed September 03, 2019.
3. AHFS Drug Information. Immune globulin. http://online.lexi.com/lco/action/doc/retrieve/docid/complete_ashp/413799. Accessed September 03, 2019.
4. Centers for Disease Control and Prevention. Varicella (Chickenpox). Available at: https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/varicella-chickenpox. Accessed September 03, 2019.
5. Centers for Disease Control and Prevention. Hepatitis A Questions and Answers for Health Professionals. Available at: https://www.cdc.gov/hepatitis/hav/havfaq.htm. Accessed July 13, 2018.

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