

When requesting GamaSTAN<sup>®</sup> S/D intramuscular injection, the individual requiring treatment must be diagnosed with one of the following FDA-approved or approved off-label compendial requirements and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

## FDA-approved indications<sup>1</sup>

- Prophylaxis of hepatitis A
- Prophylaxis of measles (rubeola)
- Prophylaxis of varicella
- Prophylaxis of rubella

## Approved Off-label Compendial uses<sup>2</sup>

- No off-label uses meet evidence standards

## Coverage Guidelines

The individual has one of the following diagnoses and meets the criteria for coverage:

- Prophylaxis of hepatitis A<sup>1</sup>
  - The individual was exposed to hepatitis A within the last 2 weeks or is at high risk for hepatitis A<sup>1</sup>
  - The individual does not have any clinical symptoms of hepatitis A<sup>1</sup>
- Prophylaxis of measles (rubeola)
  - The individual was exposed to measles within the last 6 days
  - The individual has not been vaccinated for measles and has not previously had the measles<sup>1</sup>
- Prophylaxis of varicella
  - The individual has been exposed to varicella in the last 10 days<sup>3</sup> or is at high risk for varicella<sup>1</sup>
  - Varicella-zoster immune globulin is currently unavailable<sup>1</sup>
- Prophylaxis of rubella
  - The individual has recently been exposed to rubella<sup>1</sup>

Approval duration: 6 months

## Safety Criteria<sup>1</sup>

- \*Thrombosis may occur with immune globulin products. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.

- \*For individuals at risk of thrombosis, do not exceed the recommended dose. Ensure adequate hydration in individuals before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in individuals at risk for hyperviscosity.
  - \*Contraindicated in isolated IgA deficiency.
  - \*Contraindicated in individuals with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.
  - \*Individuals 12 months of age or older who have received GamaSTAN<sup>®</sup> S/D should wait until 3 months after the injection to receive their measles vaccine.
- \* Prescribers are alerted to the above safety concerns via educational points in the program.

## References

1. GamaSTAN S/D prescribing information. Research Triangle Park, NC: Grifols Therapeutics Inc. September 2013.
2. Klasco RK (Ed): DRUGDEX<sup>®</sup> System. Thomson Micromedex, Greenwood Village, CO. Accessed April 19, 2017. <http://www.micromedexsolutions.com>.
3. Centers for Disease Control and Prevention: Morbidity and mortality weekly report (MMWR). Updated recommendations for Use of VarZIG – United States, 2013. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6228a4.htm>. Accessed April 24, 2017.

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