# SPECIALTY GUIDELINE MANAGEMENT

## Intramuscular Immune Globulin:

# GamaSTAN® (Immune Globulin [Human]) GamaSTAN® S/D (Immune Globulin [Human])

#### **POLICY**

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

# **FDA-Approved Indications**

- A. Pre- or post-exposure prophylaxis of hepatitis A
- B. Postexposure prophylaxis/modification of measles (rubeola) in susceptible persons
- C. Postexposure prophylaxis of varicella in immunosuppressed patients when varicella-zoster immune globulin is not available
- D. Postexposure prophylaxis of rubella during pregnancy

All other indications are considered experimental/investigational and not medically necessary.

#### II. CRITERIA FOR INITIAL APPROVAL

#### A. Prophylaxis of hepatitis A

Authorization of 1 month may be granted for prophylaxis of hepatitis A when one of the following criteria is met:

- 1. Member was exposed to hepatitis A virus within the past 2 weeks (eg, household contact, sexual contact, and child care center or classroom contact with an infected person), OR
- 2. Member is at high risk for hepatitis A exposure (examples of populations at high risk for hepatitis A are travelers to and workers in countries of high endemicity of infection and illicit drug users).

## B. Prophylaxis of measles (rubeola)

Authorization of 1 month may be granted for prophylaxis of measles in unvaccinated members who have not had measles previously and were exposed to measles within the past 6 days.

## C. Prophylaxis of varicella

Authorization of 1 month may be granted for prophylaxis of varicella when all of the following criteria are met:

- 1. Member was exposed to varicella within the past 10 days
- 2. Member is at high risk for severe varicella (eg, immunocompromised persons, newborns/infants, pregnant women)
- 3. Varicella zoster immune globulin (eg, Varizig®) is not available

## D. Prophylaxis of rubella

GamaSTANSD PA ALL Rx

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Reference number(s) 2067-A

Authorization of 1 month may be granted for prophylaxis of rubella when both of the following criteria are met:

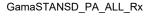
- 1. Member was recently exposed to rubella
- 2. Member is currently pregnant

#### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

### **IV. REFERENCES**

- 1. GAMASTAN [package insert]. Research Triangle Park, NC: Grifols Therapeutics, Inc.; February 2018.
- 2. GamaSTAN S/D [package insert]. Research Triangle Park, NC: Grifols Therapeutics, Inc.; February 2018.
- 3. Nelson NP, Link-Gelles R, Hofmeister MG, et al. Update: Recommendations of the Advisory Committee on Immunization Practices for Use of Hepatitis A Vaccine for Postexposure Prophylaxis and for Preexposure Prophylaxis for International Travel. MMWR Morb Mortal Wkly Rep 2018;67:1216–1220.
- 4. Centers for Disease Control and Prevention. Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013. Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2013;62(4).
- 5. Centers for Disease Control and Prevention Health Information for International Travel (Yellow Book). Varicella (Chickenpox). https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/varicella-chickenpox. Accessed June 10, 2020.



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