

Reference number(s)
2067-A

## 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

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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.