Reference number(s)
2067-A

SPECIALTY GUIDELINE MANAGEMENT

Intramuscular Immune Globulin:
GamaSTAN® (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
GamaSTAN is a human immune globulin indicated for:

A. Hepatitis A
GamaSTAN is indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of GamaSTAN is greatest when given before or soon after exposure to hepatitis A. GamaSTAN is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

B. Measles (Rubeola)
GamaSTAN is indicated 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 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 is also indicated for pregnant women without evidence of immunity.
• Do not give GamaSTAN and measles vaccine at the same time. If a child is older than 12 months and has received GamaSTAN, give measles vaccine about five months later when the measles antibody titer will have disappeared.
If a susceptible child exposed to measles is immunocompromised, give GamaSTAN immediately.

C. Varicella
GamaSTAN is indicated to modify varicella.
• Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune Globulin (Human). If unavailable, GamaSTAN, promptly given, may also modify varicella.

D. Rubella
GamaSTAN is indicated to modify rubella in exposed women who will not consider a therapeutic abortion.
• Some studies suggest that the use of GamaSTAN in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, GamaSTAN may benefit those women who will not consider a therapeutic abortion.
• Do not give GamaSTAN for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Limitations of Use
• GamaSTAN is not standardized with respect to antibody titers against hepatitis B surface antigen (HBsAg) and must not be used for prophylaxis of viral hepatitis type B. Prophylactic treatment to prevent

hepatitis B can best be accomplished with use of Hepatitis B Immune Globulin (Human), often in combination with Hepatitis B Vaccine.
• GamaSTAN is not indicated for routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella.

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 (e.g., household contact, sexual contact, and childcare center or classroom contact with an infected person), and is NOT exhibiting clinical manifestation of disease 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)

1. 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 (e.g., immunocompromised persons, newborns/infants, pregnant women)
3. Varicella zoster immune globulin (e.g., Varizig®) is not available

D. Prophylaxis of rubella

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.; August 2022.
2. 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.

3. 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).
4. Centers for Disease Control and Prevention Health Information for International Travel (Yellow Book). Varicella (Chickenpox). https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/varicella-chickenpox. Accessed May 9, 2023.