CVS/caremark

SPECIALTY GUIDELINE MANAGEMENT

Intramuscular Immune Globulin:
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
1. Pre- or post-exposure prophylaxis of hepatitis A
2. Postexposure prophylaxis/modification of measles (rubeola) in susceptible persons
3. Postexposure prophylaxis of varicella in immunosuppressed patients when varicella-zoster immune globulin is not available
4. Postexposure prophylaxis of rubella during pregnancy

All other indications are considered experimental/investigational and are not a covered benefit.

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 members 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
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 a pregnant female

III. CONTINUATION OF THERAPY

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

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. GamaSTAN S/D [package insert]. Research Triangle Park, NC: Grifols Therapeutics, Inc.; September 2013.
2. Centers for Disease Control and Prevention. Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2007;56(41):1080-1084.
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). http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/varicella-chickenpox. Accessed July 8, 2016.