GamaSTAN S/D (Immune Globulin [Human])

Line(s) of Business:                    Effective Date:  
HMO; PPO; QUEST Integration              05/01/2016
Akamai Advantage

POLICY

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

B. EXCLUSIONS
- Isolated immunoglobulin A (IgA) deficiency
- Severe thrombocytopenia or any coagulation disorder that prevents the use of intramuscular injections

C. CRITERIA FOR APPROVAL

1. Prophylaxis of Hepatitis A
Authorization of 1 month may be granted to members who are prescribed GamaSTAN S/D for prophylaxis of hepatitis A and ONE of the following criteria is met:
   a. Member was exposed to hepatitis A virus within the past 2 weeks (e.g., household contact, sexual contact, and child care center or classroom contact with an infected person), OR
   b. 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).

2. Prophylaxis of Measles (Rubeola)
Authorization of 1 month may be granted to members who are prescribed GamaSTAN S/D for prophylaxis of measles and ALL of the following criteria are met:
   a. Member was exposed to measles within the past 6 days
   b. Member has not previously had measles
   c. Member has not previously been vaccinated against measles
3. **Prophylaxis of Varicella**
   Authorization of 1 month may be granted to members who are prescribed GamaSTAN S/D for prophylaxis of varicella and ALL of the following criteria are met:
   a. Member was recently exposed to varicella
   b. Member is immunocompromised
   c. Varicella zoster immune globulin (eg, Varizig®) is currently not available

4. **Prophylaxis of Rubella**
   Authorization of 1 month may be granted to members who are prescribed GamaSTAN S/D for prophylaxis of rubella and BOTH of the following criteria are met:
   a. Member was recently exposed to rubella
   b. Member is a pregnant woman

D. **OTHER CRITERIA**
   Members with any of the following risk factors for thrombosis must receive a dose of GamaSTAN S/D that does not exceed the dose recommended in the prescribing information:
   a. Advanced age (45 years of age or older)
   b. Prolonged immobilization
   c. Hypercoagulable condition
   d. History of venous or arterial thrombosis
   e. Use of estrogens
   f. Indwelling central vascular catheter
   g. Hyperviscosity
   h. Cardiovascular risk factor(s)

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

F. **IMPORTANT REMINDER**
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

   This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
G. REFERENCES


