| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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# GamaSTAN S/D

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 year |

| Medications |
|---|
| GamaSTAN [immune globulin (human)]<br>GamaSTAN S/D [immune globulin (human)] |

## APPROVAL CRITERIA

Requests for GamaSTAN or GamaSTAN S/D [immune globulin (human)] may be approved if the following criteria are met:

I. Individual is using as pre-exposure prophylaxis for hepatitis A virus (HAV); **AND**
II. Individual will receive the intramuscular injection prior to anticipated exposure; **AND**
III. Individual does not have clinical manifestations of hepatitis A; **AND**
IV. Individual is previously unvaccinated and one of the following (CDC 2007, CDC 2015):
   A. Individual is unable to receive HAV vaccine (such as, under the age of 12 months or contraindication to or unavailability of the vaccine); **OR**
   B. Individual is considered high-risk (such as, travel to an endemic area, older adults, immunocompromised, or diagnosis of chronic liver disease) and will receive a simultaneous dose of HAV vaccine unless contraindicated;

**OR**

V. Individual is using as post-exposure prophylaxis for hepatitis A virus (HAV); **AND**
VI. Individual will receive the intramuscular injection within 2 weeks of exposure; **AND**
VII. Individual does not have clinical manifestations of hepatitis A; **AND**
VIII. Individual is previously unvaccinated and one of the following (CDC 2007, CDC 2015):
   A. Individual is under the age of 12 months or over 40 years of age; **OR**
   B. Individual is between the ages of 12 months and 40 years and unable to receive the hepatitis A virus vaccine (such as, contraindication to or unavailability of the vaccine); **OR**

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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C. Individual is considered high-risk (such as, immunocompromised, diagnosis of chronic liver disease, or vaccine contraindication);

**OR**

IX. Individual is using for post exposure prophylaxis to prevent or modify symptoms of measles (rubeola); **AND**

X. Administered as an intramuscular injection within 6 days of exposure and not given concomitantly with a vaccine containing the measles virus; **AND**

XI. Eligible exposed, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 6 months after GamaSTAN (S/D) administration (CDC 2013); **AND**

XII. Used in the following individuals considered at risk for severe disease and complications (CDC 2013):

A. Infants less than 12 months of age; **OR**

B. Previously unvaccinated and ineligible to receive a vaccine containing the measles virus (such as, but not limited to, vaccine contraindication or an initial exposure greater than 72 hours); **OR**

C. No evidence of measles immunity, in particular in pregnant women; **OR**

D. Severely immunocompromised individuals;

**OR**

XIII. Individual is using as post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised); **AND**

XIV. The varicella-zoster immune globulin (human) (VZIG) (Label) and immune globulin intravenous (IGIV) (AHFS) are unavailable;

**OR**

XV. Individual is using as post-exposure prophylaxis administered within 72 hours of exposure to a confirmed case of rubella to modify or suppress symptoms (Label, CDC 2001); **AND**

XVI. Individual is in the early stages (first trimester) of pregnancy, and will not consider terminating the pregnancy under any circumstance.

GamaSTAN, GamaSTAN S/D [immune globulin g (human)] may **not** be approved for:

I. Individuals with isolated immunoglobulin A (IgA) deficiency; **OR**

II. Individuals with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections; **OR**

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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III. Prophylaxis against hepatitis B (Label), C or E virus (HBV, HCV, or HEV) (AHFS); **OR**
IV. Routine post-exposure prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella; **OR**
V. Allergy or asthma in individuals who have normal levels of immunoglobulin; **OR**
VI. Treatment to prevent recurrent spontaneous abortion in pregnant women with a history of recurrent spontaneous abortion (ASRM 2012).

**Note**: GamaSTAN (S/D) [immune globulin (human)] has a black box warning for thrombosis. Thrombosis may occur in the absence of known risk factors. Risk factors for thrombosis may include: advanced age; prolonged immobilization; hypercoagulable conditions; history of venous or arterial thrombosis; use of estrogens; indwelling central vascular catheters; hyperviscosity; and cardiovascular risk factors. For individuals at risk of thrombosis, the recommended dose of GamaSTAN (S/D) should not be exceeded. Adequate hydration before administration and signs and symptoms of thrombosis should be assessed.

**Key References**:


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9. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.