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)

APPROVAL CRITERIA

Requests for 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 2010):
   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 2010):
   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 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**

III. Prophylaxis against hepatitis B (Label), C or E virus (HBV, HCV, or HEV) (AHFS); **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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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.

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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