Medical Drug Clinical Criteria

Subject:	GamaSTAN [immune globulin (human)]		
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Overview

This document addresses the use of GamaSTAN and GamaSTAN S/D. Other immunoglobulins are addressed in a separate clinical guideline. GamaSTAN (S/D) is an intramuscularly (IM) administered human immune globulin. Similar to all forms of human immune globulin, GamaSTAN (S/D) is prepared from pools of human plasma collected from healthy donors. GamaSTAN differs from GamaSTAN S/D only in the manufacturing process used to produce the final product.

GamaSTAN (S/D) differs from other immunoglobulins in its method of administration (IM) and its uses. It is FDA approved for the prophylaxis of various infectious diseases:

- Pre- and post (within 2 weeks)- exposure prophylaxis of Hepatitis A virus (HAV) in persons without manifestations of the disease
- Post-exposure (within 6 days) prophylaxis and modification of measles (rubeola) in susceptible individuals
- Modification of varicella when Varicella Zoster Immune Globulin is unavailable
- Modification of rubella in exposed pregnant women who will not consider abortion

The Centers for Disease Control (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations and guidelines clarify the use of this agent in these situations, especially in light of other effective vaccines.

GamaSTAN (S/D) is contraindicated in IgA deficient patients with antibodies against IgA. GamaSTAN (S/D) has a 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 should not be exceeded. Adequate hydration before administration and signs and symptoms of thrombosis should be assessed.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

GamaSTAN; GamaSTAN S/D [Immune globulin (human)]

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 2020):
    A. Individual is unable to receive HAV vaccine (such as, under the age of 6 months, or contraindication to, or unavailability of the vaccine); **OR**
    B. Individual is considered high-risk (such as but not limited to, travel to an endemic area, over 40 years of age, 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 2020):
  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 HAV vaccine (such as, contraindication to or unavailability of the vaccine); **OR**
  C. Individual is considered high-risk (such as but not limited to, immunocompromised, diagnosis of chronic liver disease, or HAV vaccine contraindication);

OR

IX. Individual is using for post-exposure prophylaxis to prevent or modify 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.

GamaSTAN; GamaSTAN S/D [immune globulin (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**

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)

VII. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

90281	Immune globulin (Ig), human, for intramuscular use

HCPCS

J1460	Injection, gamma globulin, intramuscular, 1 cc
J1560	Injection, gamma globulin, intramuscular, over 10 cc

ICD-10 Diagnosis

	All diagnoses

Document History

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- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 11/20/2020 – Annual Review: Update age override for pre-exposure prophylactic use for hepatitis A per guidelines. Coding Reviewed: No changes.
- 11/15/2019 – Annual Review: Clarify age in pre-exposure prophylactic use for hepatitis A. Wording and formatting changes. Coding Reviewed: No changes.
- 11/16/2018 – Annual Review: Initial review of Immunoglobulins for treatment of recurrent spontaneous abortion. Add new branded form of GamaSTAN. 12/3/2018 – HCPCS review: no change. Changed ICD-10 Diagnoses to "All Diagnoses." Updated non-approvable diagnoses to coding grid.

References

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