GamaSTAN S/D

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
GamaSTAN [immune globulin (human)] 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 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, 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 hepatitis A virus vaccine (such as, contraindication to or unavailability of the vaccine); **OR**
   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.

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**
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.

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:

1. American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. Fertil Steril. 2012; 98(5):1103-1111.
2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. *MMWR Morb Mortal Wkly Rep.* 2015; 64(3):1-140. Available from: http://www.cdc.gov/std/tg2015/tg-2015-print.pdf. Accessed on: September 4, 2019.
3. Centers for Disease Control and Prevention. Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. 2020. *Recommendations and Reports.* July 3, 2020 / 69(5);1–38. Available at https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm. Accessed October 9, 2020.
4. 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 Morb Mortal Wkly Rep*. 2013; 62(RR-4):1-40. Available from: http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf. Accessed on: October 9, 2020.
5. Centers for Disease Control and Prevention. Control and Prevention of Rubella: Evaluation and Management of Suspected Outbreaks, Rubella in Pregnant Women, and Surveillance for Congenital Rubella Syndrome. *MMWR Morb Mortal Wkly Rep*. 2001; 50(RR-12):1-39. Available from: http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
7. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 9, 2020.
8. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.