CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Gamastan (immune globulin (human))
BILLING CODE	J1460; J1560
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Background statement: Gamastan is a human immune globulin solution for intramuscular injection, initially approved by the FDA in 1944 with prescribing information updated in 2018. Indications for Gamastan include preexposure and postexposure prophylaxis for hepatitis A, prevention or modification of measles (Rubeola) following exposure, modification of varicella following exposure, and modification of rubella in exposed women not considering therapeutic abortion. Gamastan is a polyclonal antibody which acts as a passive immunizing agent to neutralize viruses and remedy disease. Gamastan is made from human blood and carries the potential risk of transmitting infection.

Gamastan (immune globulin (human)) will be considered for coverage when the following criteria are met:

Hepatitis A

For **initial** authorization:

1. Medication is prescribed by or in consultation with an infectious disease specialist; AND
2. Member meets one of the following:
   a) Has been exposed to hepatitis A within the past 2 weeks
   b) Traveling to an area with endemic hepatitis A and Gamastan will be administered prior to departure; AND
3. Member does not have clinical manifestations of hepatitis A; AND
4. **Dosage allowed/Quantity limit**:

Administer within two weeks of prior exposure	0.1 mL/kg IM (0.05 mL/lb.)
Administer before travel to areas with endemic hepatitis A: Length of stay up to 1 month Length of stay up to 2 months	 0.1 mL/kg IM 0.2 mL/kg IM

If all the above requirements are met, one dose of the medication will be approved for 7 days.

For **reauthorization**:

1. If Gamastan was previously approved for travel to an area with endemic hepatitis A, medication will be reauthorized if member length of stay will be longer than 2 months.

Length of stay longer than 2 months	0.2 mL/kg IM; repeat every 2 months

If all the above requirements are met, the medication will be approved for member length of stay up to 12 months.

Measles (Rubeola)

For **initial** authorization:

1. Medication is prescribed by or in consultation with an infectious disease specialist; AND
2. Member has not been vaccinated against measles; AND
3. Member has not had measles previously; AND
4. Member was exposed to measles within the last 6 days; AND
5. Member meets one or more of the below criteria
   a) Member is an immunocompromised child
   b) Member is pregnant and lacks evidence for immunity to measles; AND
6. Gamastan is not administered at the same time as the measles vaccine; AND
7. **Dosage allowed/Quantity limit**:

Administer to a susceptible person within 6 days of measles exposure	0.25 mL/kg IM (0.11 mL/lb.)
Administer to an immunocompromised child within 6 days of measles exposure	0.5 mL/kg IM (max dose 15 mL)

If all the above requirements are met, one dose of the medication will be approved for 7 days.

For **reauthorization**:

1. Medication will not be reauthorized.

Varicella

For **initial** authorization:

1. Medication is prescribed by or in consultation with an infectious disease specialist; AND
2. Member is immunocompromised; AND
3. Member was exposed to varicella within the last 72 hours; AND
4. Member is unable to access Varicella Zoster Immune Globulin (Human); AND
5. **Dosage allowed/Quantity limit**: 0.6 mL/kg to 1.2 mL/kg IM

If all the above requirements are met, one dose of the medication will be approved for 7 days.

For **reauthorization**:

1. Medication will not be reauthorized.

Rubella

For **initial** authorization:
1. Medication is prescribed by or in consultation with an infectious disease specialist; AND
2. Member is pregnant; AND
3. Member was exposed to rubella within the last 72 hours; AND
4. Member will not consider therapeutic abortion; AND
5. **Dosage allowed/Quantity limit**: 0.55 mL/kg IM

If all the above requirements are met, one dose of the medication will be approved for 7 days.

For **reauthorization**:
1. Medication will not be reauthorized.

CareSource considers Gamastan (immune globulin (human)) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/31/2023	New policy for Gamastan created.

References:

1. Gamastan. Prescribing information. Grifols Therapeutics LLC; 2018. Accessed January 31, 2023.
2. Immune Globulin. Lexi-Drugs. Lexicomp Online. Wolters Kluwer Health Inc. January 31, 2023. Accessed January 31, 2023. http://online.lexi.com
3. Gamastan S/D Immune Globulin (Human). U.S. FDA. Current as of January 26, 2023. Accessed January 31, 2023. https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/gamastan-sd-immune-globulin-human
4. Grifols. Gamastan Immune Globulin (Human). Accessed January 31, 2022. https://www.gamastan.com/en/hcp
5. CDC. Update: prevention of hepatitis A after exposure to hepatitis A virus and in international travelers. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep 2007;56:1080–4.
6. Tejada-Strop A, Costafreda MI, Dimitrova Z, Kaplan GG, Teo CG. Evaluation of potencies of immune globulin products against hepatitis A. JAMA Intern Med 2017; 177:430–2.
7. Nelson NP. Updated Dosing Instructions for Immune Globulin (Human) Gamastan S/D for Hepatitis A Virus Prophylaxis. *MMWR*. 2017. 66(36): 959-960. doi: 10.15585/mmwr.mm6636a5
8. Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2020. MMWR Recomm Rep 2020;69(No. RR-5):1–38. DOI: http://dx.doi.org/10.15585/mmwr.rr6905a1
9. Krow-Lucal E, Marin M, Shepersky L, Bahta L, Loehr J, Dooling K. Measles, Mumps, Rubella Vaccine (PRIORIX): Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1465–1470. DOI: http://dx.doi.org/10.15585/mmwr.mm7146a1

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