PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Gamastan (immune globulin (human))</th>
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<tbody>
<tr>
<td>BILLING CODE</td>
<td>J1460; J1560</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
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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: 0.1 mL/kg IM
     - Length of stay up to 2 months: 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:**

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

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**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.

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**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.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tr>
<td>01/31/2023</td>
<td>New policy for Gamastan created.</td>
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References:


Effective date: 01/01/2024
Revised date: 01/31/2023