Anti-Thymocyte Globulin (Lymphocyte Immune Globulin)

Policy Number: IEXD0201.01
Effective Date: January 1, 2021

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Related Policies
None

Applicable States

This Medical Benefit Drug Policy only applies to the states of Arizona, Maryland, North Carolina, Oklahoma, Tennessee, Virginia, and Washington.

Coverage Rationale

This policy refers to the following Anti-Thymocyte Globulins (lymphocyte immune globulins):

- Atgam® (lymphocyte immune globulin, anti-thymocyte globulin [equine])
- Thymoglobulin® (anti-thymocyte globulin [rabbit])

Atgam (lymphocyte immune globulin) is proven and medically necessary when all the following criteria are met:

- Used for one of the following:
  - Management of renal transplant rejection and both of the following:
    - Administered with immunosuppressant(s)
    - Prescribed by or in consultation with a nephrologist or transplant specialist
  or
  - Aplastic anemia that is moderate to severe and all the following:
    - Patient is unsuitable for bone marrow transplantation; and
    - Patient’s aplastic anemia is not secondary to any of the following:
      - Neoplastic disease
      - Storage disease
      - Myelofibrosis
      - Fanconi syndrome
      - Exposure to myelotoxic agents or radiation

and

- Prescribed by or in consultation with a hematologist or oncologist
and

- Patient has not received any live vaccines before, during or after treatment with Atgam; and
• Medication is dosed in accordance with the United States Food and Drug Administration (FDA) approved labeling:
  o Dose does not exceed 15mg/kg/day (renal transplant)
  o Dose does not exceed 20mg/kg/day (aplastic anemia)
and
• Authorization is for no more than 2 months

Thymoglobulin (anti-thymocyte globulin [rabbit]) is proven and medically necessary when all the following criteria are met:
• Used for prophylaxis and treatment of acute renal transplant rejection; and
• Administered with immunosuppressant(s); and
• Prescribed by or in consultation with a nephrologist or transplant specialist; and
• Patient has not received any live vaccines before, during or after treatment with Thymoglobulin; and
• Medication is dosed in accordance with the United States Food and Drug Administration (FDA) approved labeling: dose does not exceed 1.5mg/kg/day; and
• Authorization is for 14 days

**Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J7504</td>
<td>Lymphocyte immune globulin, anti-thymocyte globulin, equine, parenteral, 250 mg</td>
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<tr>
<td>J7511</td>
<td>Lymphocyte immune globulin, anti-thymocyte globulin, rabbit, parenteral, 25 mg</td>
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<table>
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<tr>
<th>Diagnosis Code</th>
<th>Description</th>
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<tr>
<td>D61.0</td>
<td>Constitutional aplastic anemia</td>
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<tr>
<td>D61.1</td>
<td>Drug-induced aplastic anemia</td>
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<tr>
<td>D61.2</td>
<td>Aplastic anemia due to other external agents</td>
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<tr>
<td>D61.3</td>
<td>Idiopathic aplastic anemia</td>
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<tr>
<td>D61.8</td>
<td>Other specified aplastic anemias and other bone marrow failure syndromes</td>
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<td>D61.9</td>
<td>Aplastic anemia, unspecified</td>
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<tr>
<td>T86.11</td>
<td>Kidney transplant rejection</td>
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**Background**

Anti-thymocyte globulins can cause anaphylaxis when injected intravenously. Although Atgam is processed to reduce the level of antibodies that will react to non-T cells, physicians should be prepared for the potential risk of anaphylaxis and monitor patients for signs and symptoms during infusion.¹

Serious immune-mediated reactions, including anaphylaxis or severe cytokine release syndrome (CRS), have been reported with the use of Thymoglobulin.²

**Clinical Evidence**

Reference the Clinical Studies information provided in the product labeling.¹²
U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Atgam is a gamma immune globulin indicated for:
- Management of allograft rejection in renal transplant patients; when administered with conventional therapy at the time of rejection
- Treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation¹

Thymoglobulin is a gamma immune globulin indicated for prophylaxis and treatment of acute rejection in patients receiving a kidney transplant.²

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for anti-thymocyte globulins: Thymoglobulin® (Anti-Thymocyte Globulin [rabbit] for intravenous) and ATGAM® (lymphocyte immune globulin, anti-thymocyte globulin [equine]). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist. See the LCDs/LCAs for Immunosuppressive Drugs.

Also see the Medicare Benefit Policy Manual, Chapter15, §50.5.1 – Immunosuppressive Drugs.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals.

(Accessed July 9, 2020)

References


Policy History/Revision Information

<table>
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<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tbody>
<tr>
<td>01/01/2021</td>
<td>• New Medical Benefit Drug Policy</td>
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Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.