LYMPHOCYTE IMMUNE GLOBULIN, ANTI-THYMOCYTE GLOBULIN (EQUINE) (NCD 260.7)

Guideline Number: MPG197.05

Approval Date: November 13, 2019

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POLICY SUMMARY

Overview
The lymphocyte immune globulin preparations are biologic drugs not previously approved or licensed for use in the management of renal allograft rejection. A number of other lymphocyte immune globulin products of equine, lapine, and murine origin are currently under investigation for their potential usefulness in controlling allograft rejections in human transplantation. These biologic drugs are viewed as adjunctive to traditional immunosuppressive products such as steroids and anti-metabolic drugs. At present, lymphocyte immune globulin preparations are not recommended to replace conventional immunosuppressive drugs, but to supplement them and to be used as alternatives to elevated or accelerated dosing with conventional immunosuppressive agents.

Guidelines
The FDA has approved one lymphocyte immune globulin preparation for marketing, lymphocyte immune globulin, anti-thymocyte globulin (equine). This drug is indicated for the management of allograft rejection episodes in renal transplantation. It is covered under Medicare when used for this purpose. Other forms of lymphocyte globulin preparation which the FDA approves for this indication in the future may be covered under Medicare.

It has not been proven to be safe when administered in the home setting and therefore will be denied as not medically necessary when provided in that setting.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline 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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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J7504</td>
<td>Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg</td>
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<th>Modifier</th>
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<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
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<th>Place of Service Code</th>
<th>Description</th>
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<td>12</td>
<td>Home (Not covered)</td>
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**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**REFERENCES**

**CMS National Coverage Determination (NCD)**

NCD 260.7 Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)

**CMS Local Coverage Determination (LCD)**

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<th>DME</th>
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<td>L33824 (Immunosuppressive Drugs)</td>
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**CMS Articles**

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<th>DME</th>
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<td>A52474 (Immunosuppressive Drugs - Policy Article)</td>
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<tr>
<td>A55426 (Standard Documentation Requirements for All Claims Submitted to DME MACs)</td>
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**CMS Benefit Policy Manual**

Chapter 15; § 50 Drugs and Biologicals, § 50.5.1 Immunosuppressive Drugs

**CMS Claims Processing Manual**

Chapter 17; § 80.3 Billing for Immunosuppressive Drugs - § 80.3.3 Special Requirements for Immunosuppressive Drugs

**CMS Transmittals**

Transmittal 3856, Change Request 10235, Dated September 1, 2017 (Clarification of the Billing of Immunosuppressive Drugs)

Transmittal 3932, Change Request 10370, Dated December 8, 2017 (Special Requirements for Immunosuppressive Drugs)

**MLN Matters**

Article MM10235, Clarification of the Billing of Immunosuppressive Drugs

Article MM10370, Special Requirements for Immunosuppressive Drugs

Article SE17032, Pharmacy Billing of Immunosuppressive Drugs

**Others**


MLN Connects, Dated October 10, 2019 (Proper Use of KX Modifier for Part B Immunosuppressive Drug Claims)
GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>11/13/2019</td>
<td>• Annual review; updated references section</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

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 member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.