## Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
</tr>
</thead>
</table>
**Contractor Name**

**Contract Type**

**Contract Number**

**Jurisdiction**

- Utah
- Washington
- Wyoming
- Northern Mariana Islands

---

## LCD Information

### Document Information

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>Original Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>L33824</td>
<td>For services performed on or after 10/01/2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Original ICD-9 LCD ID</th>
<th>Revision Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>L68</td>
<td>For services performed on or after 01/01/2017</td>
</tr>
<tr>
<td>L11521</td>
<td></td>
</tr>
<tr>
<td>L27036</td>
<td></td>
</tr>
<tr>
<td>L11531</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LCD Title</th>
<th>Revision Ending Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunosuppressive Drugs</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed LCD in Comment Period</th>
<th>Retirement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source Proposed LCD</th>
<th>Notice Period Start Date</th>
<th>Notice Period End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

---

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT only copyright 2002-2018 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The Code on Dental Procedures and Nomenclature (Code) is published in Current Dental Terminology (CDT). Copyright © American Dental Association. All rights reserved. CDT and CDT-2016 are trademarks of the American Dental Association.

UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS MANUAL, 2014, is copyrighted by American Hospital Association (“AHA”), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA.” Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.

---

**CMS National Coverage Policy**

None
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The statutory coverage criteria for immunosuppressive drugs are specified in the related Policy Article.

For immunosuppressive drugs covered under this policy, the dosage, frequency and route of administration must conform to generally accepted medical practice and must be medically necessary to prevent or treat the rejection of an organ transplant.

Coverage of parenteral azathioprine (J7501) or methylprednisolone (J2920, J2930) is limited to those situations in which the medication cannot be tolerated or absorbed if taken orally and is self-administered by the beneficiary. Claims for parenteral azathioprine or methylprednisolone that do not meet this criterion will be denied as not medically necessary (CMS Benefit Policy Manual, Internet-Only Manual, CMS Pub. 100-02, Chapter 15, Section 50.4.3 [hereinafter bp102c15, §50.4.3]).

Immunosuppressive drugs are covered only for the specific labeled indications and approval for marketing by the FDA (bp 102c15, §50.5.1). Parenteral belatacept (J0485), antithymocyte globulin (J7504, J7511), muromonab-CD3 (J7505), daclizumab (J7513), cyclosporine (J7516), and tacrolimus (J7525) are not proven to be safe when administered in the home setting and therefore will be denied as not medically necessary when provided in that setting.

Drugs may be covered only if dispensed and billed to Medicare by the entity that actually dispenses the drug to the Medicare beneficiary, and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DME MAC for immunosuppressive drugs (bp102c15, §110.3). Physicians may bill the DME MAC for drugs if all of the following conditions are met: the physician is 1) enrolled as a DMEPOS supplier with the National Supplier Clearinghouse, and 2) dispensing the drug(s) to the Medicare beneficiary, and 3) authorized by the State to dispense drugs as part of the physician’s license. Claims submitted by entities not licensed to dispense drugs will be denied for lack of medical necessity.

The quantity of immunosuppressive drugs dispensed is limited to a 30-day supply. Quantities of immunosuppressive drugs dispensed in excess of a 30-day supply will be denied as not medically necessary. If a drug is denied as not medically necessary, the related supply fee (Q0510, Q0511 and Q0512) will be denied as not medically necessary (bp102c15, §50.4.3 and CMS Claims Processing Manual, Internet-Only Manual, CMS Pub. 100-04, Chapter 17, Section 80.3 [hereinafter clm104c17, §80.3]).

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If
the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be
denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs,
LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not
reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD
documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor
upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not
reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not
retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact
the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if
authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and
necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the
order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days
prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no
sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which
delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the
beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills
without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be
denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must
stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the
ordering physicians that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a one (1) -month quantity at a time.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service.
Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all
Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally
to all claims.
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

**Group 1 Paragraph:** The appearance of a code in this section does not necessarily indicate coverage.

**HCPCS MODIFIERS:**

- EY - No physician or other licensed health care provider order for this item or service
- GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit
- KX - Requirements specified in the medical policy have been met

**HCPCS CODES:**

**Group 1 Codes:**

- J0485 INJECTION, BELATACEPT, 1 MG
- J2920 INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 40 MG
- J2930 INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 125 MG
- J7500 AZATHIOPRINE, ORAL, 50 MG
- J7501 AZATHIOPRINE, PARENTERAL, 100 MG
- J7502 CYCLOSPORINE, ORAL, 100 MG
- J7503 TACROLIMUS, EXTENDED RELEASE, (ENVARSUS XR), ORAL, 0.25 MG
- J7504 LYMHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, EQUINE, PARENTERAL, 250 MG
- J7505 MUROMONAB-CD3, PARENTERAL, 5 MG
- J7507 TACROLIMUS, IMMEDIATE RELEASE, ORAL, 1 MG
- J7508 TACROLIMUS, EXTENDED RELEASE, (ASTAGRAF XL), ORAL, 0.1 MG
- J7509 METHYLPREDNISOLONE ORAL, PER 4 MG
- J7510 PREDNISOLONE ORAL, PER 5 MG
- J7511 LYMHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, RABBIT, PARENTERAL, 25 MG
- J7512 PREDNISONE, IMMEDIATE RELEASE OR DELAYED RELEASE, ORAL, 1 MG
- J7513 DACLIUMAB, PARENTERAL, 25 MG
- J7515 CYCLOSPORIN, ORAL, 25 MG
- J7516 CYCLOSPORIN, PARENTERAL, 250 MG
- J7517 MYCOPHENOLATE MOFETIL, ORAL, 250 MG
- J7518 MYCOPHENOLIC ACID, ORAL, 180 MG
- J7520 SIROLIMUS, ORAL, 1 MG
- J7525 TACROLIMUS, PARENTERAL, 5 MG
- J7527 EVEROLIMUS, ORAL, 0.25 MG
- J7599 IMMUNOSUPPRESSIVE DRUG, NOT OTHERWISE CLASSIFIED
- J8530 CYCLOPHOSPHAMIDE; ORAL, 25 MG
- J8610 METHOTREXATE; ORAL, 2.5 MG
- Q0510 PHARMACY SUPPLY FEE FOR INITIAL IMMUNOSUPPRESSIVE DRUG(S), FIRST MONTH FOLLOWING TRANSPLANT
- Q0511 PHARMACY SUPPLY FEE FOR ORAL ANTI-CANCER, ORAL ANTI-EMETIC OR IMMUNOSUPPRESSIVE DRUG(S); FOR THE FIRST PRESCRIPTION IN A 30-DAY PERIOD
- Q0512 PHARMACY SUPPLY FEE FOR ORAL ANTI-CANCER, ORAL ANTI-EMETIC OR IMMUNOSUPPRESSIVE DRUG(S); FOR A SUBSEQUENT PRESCRIPTION IN A 30-DAY PERIOD

ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:** For ICD-10 codes relating to statutory coverage, see Policy Article.

**Group 1 Codes:** N/A
General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless “there has been furnished such information as may be necessary in order to determine the amounts due such provider.” It is expected that the beneficiary’s medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices
Utilization Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity.

Sources of Information
Reserved for future use.
Bibliography
N/A

**Revision History Information**

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/2017</td>
<td>R6</td>
<td>No changes have been made to this LCD</td>
<td>Other</td>
</tr>
<tr>
<td>04/05/2018</td>
<td></td>
<td>04/05/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
<td>Provider Education/Guidance</td>
</tr>
<tr>
<td>01/01/2017</td>
<td>R5</td>
<td>Revision Effective Date: 01/01/2017</td>
<td></td>
</tr>
<tr>
<td>07/01/2016</td>
<td>R4</td>
<td>Revision Effective Date: 01/01/2016</td>
<td></td>
</tr>
<tr>
<td>01/01/2016</td>
<td>R3</td>
<td>Revision Effective Date: 10/01/2015</td>
<td></td>
</tr>
</tbody>
</table>

**Revision Effective Date: 01/01/2017**

**COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:**
- Removed: Standard Documentation Language
- Added: New reference language and directions to Standard Documentation Requirements
- Added: General Requirements
- Revised: Refill Requirements

**DOCUMENTATION REQUIREMENTS:**
- Removed: Standard Documentation Language
- Added: General Documentation Requirements
- Added: New reference language and directions to Standard Documentation Requirements

**POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:**
- Removed: Standard Documentation Language
- Added: Direction to Standard Documentation Requirements
- Removed: Information under Miscellaneous and Appendices

**RELATED LOCAL COVERAGE DOCUMENTS:**
- Added: LCD-related Standard Documentation Requirements article

Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013.

No other changes have been made to the LCDs.

**Revision Effective Date: 01/01/2016**

**HCPCS CODES:**
- Added: J7503 and J7512
- Updated: J7508 narrative

**Deleted:** J7506

**DOCUMENTATION REQUIREMENTS:**
- Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)

**Revision Effective Date: 10/01/2015**

**Added:** LCD-related Standard Documentation Requirements article

**Change in Assigned States or Affiliated Contract Numbers**

- Provider Education/Guidance
- Revisions Due To CPT/HCPCS Code Changes
- Provider Education/Guidance
<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>Revised: Standard Documentation Language to add covered prior to a beneficiary’s Medicare eligibility</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: Standard Documentation Language to add who can enter date of delivery date on the POD</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: ICD-9 CM reference</td>
<td></td>
</tr>
</tbody>
</table>

**Revision Effective Date: 10/01/2014**

**DOCUMENTATION REQUIREMENTS:**
Revised: Continued Need and Use Sections

---

**Associated Documents**

Attachments N/A

Related Local Coverage Documents Article(s) [A52474 - Immunosuppressive Drugs - Policy Article][A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs]

Related National Coverage Documents N/A

Public Version(s) Updated on 03/27/2018 with effective dates 01/01/2017 - N/A Updated on 04/21/2017 with effective dates 01/01/2017 - N/A Some older versions have been archived. Please visit the [MCD Archive Site] to retrieve them. Back to Top

---

**Keywords**

N/A Read the [LCD Disclaimer] Back to Top
END OF LOCAL COVERAGE DETERMINATION
Per the Code of Federal Regulations, 42 C.F.R § 426.325, only those portions of the currently
effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social
Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R §
426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be
challenged, include the Policy Article. Please note the distinction of the documents when reviewing
the materials.
### Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>DME MAC</td>
<td>19003 - DME MAC</td>
<td>J-D (\text{Alaska, American Samoa, Arizona, California - Entire State, Guam, Hawaii, Entire State, Idaho, Kansas, Missouri - Entire State, Montana, North Dakota, Nebraska, Nevada, Oregon, South Dakota})</td>
</tr>
</tbody>
</table>

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.
Article Information

General Information

<table>
<thead>
<tr>
<th>Article ID</th>
<th>Original Article Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A52474</td>
<td>10/01/2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Original ICD-9 Article ID</th>
<th>Revision Effective Date</th>
<th>Revision Ending Date</th>
<th>Retirement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A25366</td>
<td>01/01/2017</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>A25526</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A47058</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A23662</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Article Title</th>
<th>Article Text:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunosuppressive Drugs - Policy Article</td>
<td>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES</td>
</tr>
</tbody>
</table>
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

Immunosuppressive drugs are covered under the immunosuppressive therapy benefit [Social Security Act §1861(s)(2)(J)]. In order for a beneficiary’s immunosuppressive drugs to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met (CMS Claims Processing Manual, Internet-Only Manual, CMS Pub. 100-04, Chapter 17, Section 80.3):

Prescription drugs used in immunosuppressive therapy are covered only if all of the following criteria (I-V) are met:

I. Immunosuppressive drugs are prescribed following transplants either:
   A. Kidney, heart, liver, bone marrow/stem cell, lung, or heart/lung transplant; or,
   B. Whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy (performed on or after July 1, 1999); or
   C. Intestinal transplant (performed on or after April 1, 2001); or
   D. Pancreatic islet cell transplant or partial pancreatic tissue transplantation performed on or after October 1, 2004 that is conducted as part of a National Institutes of Health (NIH)-sponsored clinical trial; or
   E. Pancreas transplants alone (performed on or after April 26, 2006) that meet the following criteria:
      1. The transplant is performed in a facility that is Medicare-approved for kidney transplantation; and
      2. Beneficiary must have a diagnosis of type I diabetes and:
         a. Must be beta cell autoantibody positive; or
         b. Must demonstrate insulinopenia, (fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method). A fasting glucose must be obtained when performing a fasting C-peptide determination. Fasting C-peptide levels are considered valid when a concurrently obtained fasting glucose is <225 mg/dL; and
      3. Must have a history of labile (brittle or medically-uncontrollable) insulin-dependent diabetes mellitus resulting in documented recurrent, severe, acutely life-threatening metabolic complications requiring hospitalization(s). Complications may include frequent hypoglycemia where the beneficiary is unaware, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; and
      4. Must have been under the care of an endocrinologist and have clinical documentation denoting optimal and intensive management was provided for at least 12 months, having received the most medically-recognized advanced insulin formulations and delivery systems; and
      5. Must demonstrate being able to emotionally and mentally understand the significant risks associated with surgery and be able to effectively manage the lifelong need for immunosuppression; and,
      6. Must otherwise be a suitable candidate for transplantation; and

II. The transplant met Medicare coverage criteria in effect at the time (e.g., approved facility for kidney, heart, intestinal, liver, lung, or heart/lung transplant; national and/or local medical necessity criteria; etc.); and

III. The beneficiary was enrolled in Medicare Part A at the time of the transplant; and

IV. The beneficiary is enrolled in Medicare Part B at the time that the drugs are dispensed; and

V. The drugs are furnished on or after the date of discharge from the hospital following a covered organ transplant.

If criteria I-V are not met, the drug(s) will be denied as noncovered.

If criteria I, II, and III are met, the transplant is considered a "covered transplant" for purposes of this policy whether payment for the transplant was made by Medicare or by another insurer.

For islet cell transplants or partial pancreatic tissue transplants conducted as part of an NIH-sponsored clinical trial, Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services. The term "routine costs" means reasonable and necessary routine beneficiary care costs, including immunosuppressive drugs and other follow-up care. In addition, Medicare will cover transplantation of pancreatic islet cells. Coverage includes the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically
necessary inpatient and outpatient medical care and immunosuppressants.

Immunosuppressive drugs used following partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial or performed before October 1, 2004 will continue to be noncovered.

Immunosuppressive drug coverage is limited to 36 months for beneficiaries whose Medicare entitlement is based solely on end-stage renal disease (ESRD).

Immunosuppressive drugs are denied as noncovered when used for the treatment of beneficiaries with non-transplant related diagnoses (e.g., rheumatoid arthritis, connective tissue diseases, vasculitis).

Immunosuppressive drugs are denied as noncovered if they are used following a whole organ pancreas transplant that was not simultaneous with or preceded by a kidney transplant for diabetic nephropathy unless the beneficiary meets the criteria for PA listed above in I(E). Coverage of immunosuppressive drugs already exists and will continue for beneficiaries who have had a pancreas transplant simultaneous with a kidney transplant because in these situations, coverage is based on the kidney transplant.

There is no coverage under the immunosuppressive drug benefit for supplies used in conjunction with the administration of parenteral immunosuppressive drugs.

If an immunosuppressive drug is billed without a KX modifier (see Documentation Requirements section of the LCD), it will be denied as noncovered.

SUPPLY FEE INFORMATION:

One unit of service of supply fee code Q0511 is covered for the first covered immunosuppressive drug that is dispensed in a 30-day period. If covered drugs are dispensed by more than one pharmacy during a 30 day period, one unit of Q0511 is covered for each pharmacy. One unit of service of supply fee code Q0512 is covered for each subsequent covered immunosuppressive drug that is dispensed in that 30-day period (See exception below when Q0510 is covered in place of Q0511 or Q0512.) If two dosage strengths of the same drug are dispensed on the same day, one unit of service of the appropriate supply fee is payable for each one. If more than one unit of service of code Q0511 is billed per 30 days by a single pharmacy, the excess units of service will be denied as incorrect coding. If the billed units of service of Q0511 or Q0512 exceed the number of drugs on the claim, the excess units will be denied as not separately payable.

One unit of service for code Q0510 is payable in place of Q0511 or Q0512 for one drug on the first claim for immunosuppressive drugs following a transplant. For example, if three drugs are dispensed, the correct coding for the supply fees on the first claim is one unit of service of Q0510 and two units of service of Q0512. If more than one organ is transplanted at the same time (e.g., heart-lung transplant), only one unit of service of Q0510 is payable. Q0510 is payable to only one supplier after each transplant. If the beneficiary has another transplant at a later date, another unit of service of code Q0510 is payable. If more than one unit of service of code Q0510 is billed per beneficiary per transplant, the excess units of service will be denied as incorrect billing/coding.

There is no separate coding or payment for a compounding fee.

If the drug on the claim is denied as noncovered, the supply fee will be denied as noncovered.

The supply fee must be billed on the same claim as the drug. If it is not, it will be denied as incorrect billing.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered, therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription.
Ongoing immunosuppressive medication need is assumed to be established by the performance of the transplant and the successful maintenance of its function. There is no requirement for further documentation of continued need for the life of the transplant.

CONTINUED USE

Continued use describes the ongoing utilization of immunosuppressive medications by a beneficiary.

Ongoing immunosuppressive medication use is assumed to be established by the performance of the transplant and the successful maintenance of its function. Continued use of immunosuppressive medication is demonstrated by meeting the Refill Documentation requirements.

MODIFIERS

KX and GY MODIFIERS:

The KX modifier must be added to the claim line(s) for the immunosuppressive drug(s) only if all of the following four requirements are met:

A. The supplier has obtained from the ordering physician the specific date of the organ transplant, and
B. The supplier is retaining this documentation of the transplant in its files, and
C. The beneficiary was enrolled in Medicare Part A, at the time of the organ transplant (whether or not Medicare paid for the transplant), and
D. The transplant date precedes the date of service on the claim.

If these four requirements are not met, the KX modifier must not be added to the claim.

If any of criteria I – V listed above have not been met, the GY modifier must be added to the claim line(s).

The diagnosis code(s) that justify the need for these items must be included on the claim. See the below list for covered transplant diagnosis codes.

A new order is required if a new drug(s) is added to the beneficiary's immunosuppressive regimen or if there is a change in dose or frequency of administration of an already allowed drug.

If code J7599 is billed, the claim must list the name of the drug, the dosage strength, number dispensed and administration instructions.

CODING GUIDELINES

The following instructions apply to claims billed using J codes. When claims are billed in NCPDP format using NDC numbers, different instructions may apply. Refer to the NCPDP Companion Document available through the CMS website.

Code J7599 should be used for immunosuppressive drugs that do not have a specific HCPCS code.

For all immunosuppressive drugs, the number of units billed must accurately reflect the definition of one unit of service in each code narrative. For example, if fifty 10 mg prednisolone tablets are dispensed, bill J7510, 100 units (1 unit of J7510 = 5 mg). If fifty 2.5 mg prednisolone tablets are dispensed, bill J7510, 25 units.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of
all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

<table>
<thead>
<tr>
<th>Bill Type Code</th>
<th>Bill Type Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>014x</td>
<td>Hospital - Laboratory Services Provided to Non-patients</td>
</tr>
</tbody>
</table>

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered

Group 1 Paragraph:
The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the Article Text field, Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information

Group 1 Codes:

ICD-10 Codes that are covered Information Table

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T86.00</td>
<td>Unspecified complication of bone marrow transplant</td>
</tr>
<tr>
<td>T86.01</td>
<td>Bone marrow transplant rejection</td>
</tr>
<tr>
<td>T86.02</td>
<td>Bone marrow transplant failure</td>
</tr>
<tr>
<td>T86.03</td>
<td>Bone marrow transplant infection</td>
</tr>
<tr>
<td>T86.09</td>
<td>Other complications of bone marrow transplant</td>
</tr>
<tr>
<td>T86.10</td>
<td>Unspecified complication of kidney transplant</td>
</tr>
<tr>
<td>T86.11</td>
<td>Kidney transplant rejection</td>
</tr>
<tr>
<td>T86.12</td>
<td>Kidney transplant failure</td>
</tr>
<tr>
<td>T86.13</td>
<td>Kidney transplant infection</td>
</tr>
<tr>
<td>T86.19</td>
<td>Other complication of kidney transplant</td>
</tr>
<tr>
<td>T86.20</td>
<td>Unspecified complication of heart transplant</td>
</tr>
<tr>
<td>T86.21</td>
<td>Heart transplant rejection</td>
</tr>
<tr>
<td>T86.22</td>
<td>Heart transplant failure</td>
</tr>
<tr>
<td>T86.23</td>
<td>Heart transplant infection</td>
</tr>
<tr>
<td>T86.290</td>
<td>Cardiac allograft vasculopathy</td>
</tr>
<tr>
<td>T86.298</td>
<td>Other complications of heart transplant</td>
</tr>
<tr>
<td>T86.30</td>
<td>Unspecified complication of heart-lung transplant</td>
</tr>
<tr>
<td>T86.31</td>
<td>Heart-lung transplant rejection</td>
</tr>
<tr>
<td>T86.32</td>
<td>Heart-lung transplant failure</td>
</tr>
<tr>
<td>T86.33</td>
<td>Heart-lung transplant infection</td>
</tr>
<tr>
<td>T86.39</td>
<td>Other complications of heart-lung transplant</td>
</tr>
<tr>
<td>T86.40</td>
<td>Unspecified complication of liver transplant</td>
</tr>
<tr>
<td>T86.41</td>
<td>Liver transplant rejection</td>
</tr>
<tr>
<td>T86.42</td>
<td>Liver transplant failure</td>
</tr>
<tr>
<td>T86.43</td>
<td>Liver transplant infection</td>
</tr>
<tr>
<td>T86.49</td>
<td>Other complications of liver transplant</td>
</tr>
<tr>
<td>T86.5</td>
<td>Complications of stem cell transplant</td>
</tr>
<tr>
<td>T86.810</td>
<td>Lung transplant rejection</td>
</tr>
<tr>
<td>T86.811</td>
<td>Lung transplant failure</td>
</tr>
<tr>
<td>T86.812</td>
<td>Lung transplant infection</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>T86.818</td>
<td>Other complications of lung transplant</td>
</tr>
<tr>
<td>T86.819</td>
<td>Unspecified complication of lung transplant</td>
</tr>
<tr>
<td>T86.830</td>
<td>Bone graft rejection</td>
</tr>
<tr>
<td>T86.831</td>
<td>Bone graft failure</td>
</tr>
<tr>
<td>T86.832</td>
<td>Bone graft infection</td>
</tr>
<tr>
<td>T86.838</td>
<td>Other complications of bone graft</td>
</tr>
<tr>
<td>T86.839</td>
<td>Unspecified complication of bone graft</td>
</tr>
<tr>
<td>T86.850</td>
<td>Intestine transplant rejection</td>
</tr>
<tr>
<td>T86.851</td>
<td>Intestine transplant failure</td>
</tr>
<tr>
<td>T86.852</td>
<td>Intestine transplant infection</td>
</tr>
<tr>
<td>T86.858</td>
<td>Other complications of intestine transplant</td>
</tr>
<tr>
<td>T86.859</td>
<td>Unspecified complication of intestine transplant</td>
</tr>
<tr>
<td>T86.890</td>
<td>Other transplanted tissue rejection</td>
</tr>
<tr>
<td>T86.891</td>
<td>Other transplanted tissue failure</td>
</tr>
<tr>
<td>T86.892</td>
<td>Other transplanted tissue infection</td>
</tr>
<tr>
<td>T86.898</td>
<td>Other complications of other transplanted tissue</td>
</tr>
<tr>
<td>T86.899</td>
<td>Unspecified complication of other transplanted tissue</td>
</tr>
<tr>
<td>Z48.21</td>
<td>Encounter for aftercare following heart transplant</td>
</tr>
<tr>
<td>Z48.22</td>
<td>Encounter for aftercare following kidney transplant</td>
</tr>
<tr>
<td>Z48.23</td>
<td>Encounter for aftercare following liver transplant</td>
</tr>
<tr>
<td>Z48.24</td>
<td>Encounter for aftercare following lung transplant</td>
</tr>
<tr>
<td>Z48.280</td>
<td>Encounter for aftercare following heart-lung transplant</td>
</tr>
<tr>
<td>Z48.290</td>
<td>Encounter for aftercare following bone marrow transplant</td>
</tr>
<tr>
<td>Z48.298</td>
<td>Encounter for aftercare following other organ transplant</td>
</tr>
<tr>
<td>Z94.0</td>
<td>Kidney transplant status</td>
</tr>
<tr>
<td>Z94.1</td>
<td>Heart transplant status</td>
</tr>
<tr>
<td>Z94.2</td>
<td>Lung transplant status</td>
</tr>
<tr>
<td>Z94.3</td>
<td>Heart and lungs transplant status</td>
</tr>
<tr>
<td>Z94.4</td>
<td>Liver transplant status</td>
</tr>
<tr>
<td>Z94.81</td>
<td>Bone marrow transplant status</td>
</tr>
<tr>
<td>Z94.82</td>
<td>Intestine transplant status</td>
</tr>
<tr>
<td>Z94.83</td>
<td>Pancreas transplant status</td>
</tr>
<tr>
<td>Z94.84</td>
<td>Stem cells transplant status</td>
</tr>
<tr>
<td>Z94.89</td>
<td>Other transplanted organ and tissue status</td>
</tr>
</tbody>
</table>

**ICD-10 Codes that are Not Covered**

**Group 1 Paragraph:**
All diagnoses that are not specified in the section ICD-10 Codes that are Covered.

**Group 1 Codes:** N/A

ICD-10 that are not Covered Information Table

**Code Description**

04/05/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.
POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:
Added: Continued Medical Need and Continued Use sections (clerical error)

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:
Added: Modifiers requirements

RELATED LOCAL COVERAGE DOCUMENTS:
Added: LCD-related Standard Documentation Requirements Language Article

Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.

CODING GUIDELINES:
Removed: J7506 from billing example, replaced with J7510

CODING GUIDELINES:
Added: J7599 billing guidelines

Back to Top Related Local Coverage Document(s) Article(s) A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs LCD(s) L33824 - Immunosuppressive Drugs

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 03/27/2018 with effective dates 01/01/2017 - N/A Updated on 04/28/2017 with effective dates 01/01/2017 - N/A Updated on 04/21/2017 with effective dates 01/01/2017 - N/A Some older versions have been archived. Please visit MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the Article Disclaimer Back to Top