

# Local Coverage Determination (LCD): Immunosuppressive Drugs (L33824)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## LCD Information

### Document Information

**LCD ID**

L33824

**Original ICD-9 LCD ID**

[L68](#)

[L11521](#)

[L27036](#)

[L11531](#)

**LCD Title**

Immunosuppressive Drugs

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

N/A

**Original Effective Date**

For services performed on or after 10/01/2015

**Revision Effective Date**

For services performed on or after 01/01/2020

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**Notice Period Start Date**

N/A

**Notice Period End Date**

N/A

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## **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 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). Treating practitioners may bill the DME MAC for drugs if all of the following conditions are met: the treating practitioner 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 treating practitioner’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 Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) 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 treating practitioner 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

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## **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.

N/A

### **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:**

CODE	DESCRIPTION
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, (ENVARUSUS XR), ORAL, 0.25 MG
J7504	LYMPHOCYTE 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	LYMPHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, RABBIT, PARENTERAL, 25 MG
J7512	PREDNISONE, IMMEDIATE RELEASE OR DELAYED RELEASE, ORAL, 1 MG
J7513	DACLIZUMAB, PARENTERAL, 25 MG
J7515	CYCLOSPORINE, 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

CODE	DESCRIPTION
	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

### ICD-10 Codes that DO NOT Support Medical Necessity

#### Group 1 Paragraph:

Not specified

#### Group 1 Codes:

N/A

### Additional ICD-10 Information

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 the treating practitioner'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:

- SWO
- 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

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## **Revision History Information**

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R8	<b>Revision Effective Date: 01/01/2020</b>	<ul style="list-style-type: none"><li>• Provider</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:  Revised: "physician" to "treating practitioner"  GENERAL:  Revised: Order information as a result of Final Rule 1713  REFILL REQUIREMENTS:  Revised: "ordering physician" to "treating practitioner"  DOCUMENTATION REQUIREMENTS:  Revised: "physician's" to "treating practitioner's"  GENERAL DOCUMENTATION REQUIREMENTS:  Revised: Prescriptions (orders) to SWO</p> <p><i>02/06/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</i></p>	Education/Guidance
01/01/2017	R7	<p><b>Revision Effective Date: 01/01/2017</b>  GENERAL DOCUMENTATION REQUIREMENTS:  Revised: Bullet spacing</p>	<ul style="list-style-type: none"> <li>• Typographical Error</li> </ul>
01/01/2017	R6	<p>No changes have been made to this LCD</p> <p><i>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.</i></p>	<ul style="list-style-type: none"> <li>• Other</li> </ul>
01/01/2017	R5	<p><b>Revision Effective Date: 01/01/2017</b>  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</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Removed: Standard Documentation Language  Added: Direction to Standard Documentation Requirements  Removed: Information under Miscellaneous and Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS:  Added: LCD-related Standard Documentation Requirements article</p>	
07/01/2016	R4	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.	<ul style="list-style-type: none"> <li>Change in Assigned States or Affiliated Contract Numbers</li> </ul>
01/01/2016	R3	<p><b>Revision Effective Date: 01/01/2016</b></p> <p>HCPCS CODES:  Added: J7503 and J7512  Updated: J7508 narrative  Deleted: J7506</p> <p>DOCUMENTATION REQUIREMENTS:  Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2015	R2	<p><b>Revision Effective Date: 10/01/2015</b></p> <p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:  Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility</p> <p>DOCUMENTATION REQUIREMENTS:  Revised: Standard Documentation Language to add who can enter date of delivery date on the POD</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Removed: ICD-9 CM reference</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>
10/01/2015	R1	<p><b>Revision Effective Date: 10/01/2014</b></p> <p>DOCUMENTATION REQUIREMENTS:  Revised: Continued Need and Use Sections</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>

## 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 01/30/2020 with effective dates 01/01/2020 - N/A

Updated on 02/22/2019 with effective dates 01/01/2017 - 12/31/2019

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.

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# **Keywords**

N/A

**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.

## Local Coverage Article: Immunosuppressive Drugs - Policy Article (A52474)

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### Contractor Information

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CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## Article Information

### General Information

**Article ID**

A52474

**Original Effective Date**

10/01/2015

**Original ICD-9 Article ID**

[A25366](#)

[A25526](#)

[A47058](#)

[A23662](#)

**Revision Effective Date**

01/01/2020

**Revision Ending Date**

N/A

**Article Title**

Immunosuppressive Drugs - Policy Article

**Retirement Date**

N/A

**Article Type**

Article

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## Article Guidance

### Article Text:

#### **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

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

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  $\leq 225$  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. Delivery requirements:
  - For DOS prior to August 1, 2016 the drugs are furnished on or after the date of discharge from the hospital following a covered organ transplant.
  - For DOS on or after August 1, 2016 through April 2, 2019, mail-order deliveries may be mailed one or two days prior to a beneficiary's discharge from an inpatient facility to a qualified place of service (such as home or custodial facility). The DOS on the claim must be the date of discharge.
  - For DOS on or after April 3, 2019 mail-order deliveries may be mailed one or two days prior to a beneficiary's anticipated date of discharge from an inpatient facility to a qualified place of service or alternate address, such as the inpatient hospital that performed the transplant or alternative location where the beneficiary is temporarily staying (such as temporary housing). The DOS on the claim must be the date of discharge.

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.

#### 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.

### **REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)**

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

### **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 treating practitioner 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.

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# Coding Information

## CPT/HCPCS Codes

N/A

## ICD-10 Codes that Support Medical Necessity

### 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 CODE	DESCRIPTION
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
T86.20	Unspecified complication of heart transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.298	Other complications of heart transplant
T86.30	Unspecified complication of heart-lung transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection

ICD-10 CODE	DESCRIPTION
T86.39	Other complications of heart-lung transplant
T86.40	Unspecified complication of liver transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.5	Complications of stem cell transplant
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.819	Unspecified complication of lung transplant
T86.830	Bone graft rejection
T86.831	Bone graft failure
T86.832	Bone graft infection
T86.838	Other complications of bone graft
T86.839	Unspecified complication of bone graft
T86.850	Intestine transplant rejection
T86.851	Intestine transplant failure
T86.852	Intestine transplant infection
T86.858	Other complications of intestine transplant
T86.859	Unspecified complication of intestine transplant
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
T86.899	Unspecified complication of other transplanted tissue
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.24	Encounter for aftercare following lung transplant
Z48.280	Encounter for aftercare following heart-lung transplant

ICD-10 CODE	DESCRIPTION
Z48.290	Encounter for aftercare following bone marrow transplant
Z48.298	Encounter for aftercare following other organ transplant
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status

### ICD-10 Codes that DO NOT Support Medical Necessity

#### Group 1 Paragraph:

All diagnoses that are not specified in the section ICD-10 Codes that are Covered.

#### Group 1 Codes:

N/A

### Additional ICD-10 Information

N/A

### 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.

N/A

### 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

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R8	<p><b>Revision Effective Date: 01/01/2020:</b> REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713 MODIFIERS: Revised: "ordering physician" to "treating practitioner" ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity" ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/06/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R7	<p><b>Revision Effective Date: 01/01/2019</b> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Criterion V to allow drugs to be dispensed two days prior to discharge to the home Removed: Statement regarding KX modifier CODING INFORMATION: Removed: Bill type code inadvertently added</p> <p><i>02/28/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2017	R6	<p><b>Revision Effective Date: 01/01/2017</b> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES Revised: Corrected typo in beneficiary and outbeneficiary to inpatient and outpatient</p> <p><i>04/05/2018: At this time 21st Century Cures Act applies to new and revised</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<i>LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i>
01/01/2017	R5	<b>Revision Effective Date: 01/01/2017</b> POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Continued Medical Need and Continued Use sections (clerical error)
01/01/2017	R4	<b>Revision Effective Date: 01/01/2017</b> POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Modifiers requirements RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R3	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.
01/01/2016	R2	<b>Revision Effective Dates: 01/01/2016</b> CODING GUIDELINES: Removed: J7506 from billing example, replaced with J7510
10/01/2015	R1	<b>Revision Effective Date: 10/01/2015</b> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: ICD-9 diagnosis references CODING GUIDELINES: Added: J7599 billing guidelines

## Associated Documents

### 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 01/30/2020 with effective dates 01/01/2020 - N/A

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Some older versions have been archived. Please visit the [MCD Archive Site](#) to retrieve them.

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# Keywords

N/A