

LCD for Immunosuppressive Drugs (L11531)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11531

LCD Title

Immunosuppressive Drugs

Contractor's Determination Number

IMNO20070101

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CMS National Coverage Policy

None

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Oversight Region

Region III

DME Region LCD Covers

Jurisdiction A

Original Determination Effective Date

For services performed on or after 10/01/1993

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 07/01/2008

Revision Ending Date**Indications and Limitations of Coverage 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. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order 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 the completed order, the item will be denied as not medically necessary.

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 patient. Claims for parenteral azathioprine or methylprednisolone that do not meet this criterion will be denied as not medically necessary.

Parenteral cyclosporine (J7516), antithymocyte globulin (J7504, J7511), muromonab-CD3 (J7505), tacrolimus (J7525) and daclizumab (J7513) are not proven to be safe when administered in the home setting and therefore they 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. 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.

Coverage Topic

Immunosuppressive Drugs

Prescription Drugs

Transplants - Cornea and Bone Marrow

Transplants - Heart, Lung, Kidney, Pancreas, Liver, and Intestine/Multivisceral

Coding Information

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIER:

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 - Specific required documentation on file.

HCPCS CODES:

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

J7504 LYMPHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, EQUINE, PARENTERAL, 250 MG

J7505 MUROMONAB-CD3, PARENTERAL, 5 MG

J7506 PREDNISONE, ORAL, PER 5MG

J7507 TACROLIMUS, ORAL, PER 1 MG

J7509 METHYLPREDNISOLONE ORAL, PER 4 MG

J7510 PREDNISOLONE ORAL, PER 5 MG

J7511 LYMPHOCYTE IMMUNE GLOBULIN, ANTITHYMOCYTE GLOBULIN, RABBIT, PARENTERAL, 25MG

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
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-9 Codes that Support Medical Necessity

Not specified.

For ICD-9 codes relating to statutory coverage, see Policy Article.

Diagnoses that Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not specified.

General 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 patient's medical records will reflect the need for the care provided. The patient'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.

An order for the drug(s) must be signed and dated by the treating physician, kept on file by the

supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

For claims received on or after July 1, 2008, the KX modifier must be added to the claim line(s) for the immunosuppressive drug(s) only if the supplier obtains from the ordering physician the date of the organ transplant and the transplant date precedes the date of service on the claim. If these requirements are not met, the KX modifier may not be added to the claim.

The ICD-9 code(s) that justify the need for these items must be included on the claim. See accompanying Immunosuppressive Drugs Policy Article for covered transplant ICD-9 codes.

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

Suppliers must add the GY modifier to a code if any of criteria I-V in the accompanying Immunosuppressive Drugs Policy Article have not been met.

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

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

Appendices

Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision

Reserved for future use.

Advisory Committee Meeting Notes

Start Date of Comment Period

04/16/1993

End Date of Comment Period

05/31/1993

Start Date of Notice Period

08/01/1993

Revision History Number

IMNO017

Revision History Explanation

Revision Effective Date: 07/01/2008

HCPCS CODES AND MODIFIERS:

Added KX modifier.

DOCUMENTATION REQUIREMENTS:

Added instructions for use of KX modifier.

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11531 from DME PSC TriCenturion (77011) LCD L11531.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

DOCUMENTATION REQUIREMENTS:

Removed language discussing details of the DIF instructions.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 01/01/2006

HCPCS CODES AND MODIFIERS:

Added: Q0510, Q0511, Q0512

Deleted: G0369, G0370

DOCUMENTATION REQUIREMENTS:

Eliminated DIF completion requirement.

Revision Effective Date: 07/01/2005 (June Publication)

DOCUMENTATION REQUIREMENTS:

Restored DIF completion requirements

Revision Effective Date: 07/01/2005 (March publication)

LMRP converted to LCD and Policy Article

HCPCS CODES AND MODIFIERS:

Added new HCPCS codes G0369, G0370 and J7518

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added statement about denial of supply fees.

DOCUMENTATION REQUIREMENTS:

Added modifier GY usage

Eliminated DIF completion requirement

Revision Effective Date: 04/01/2004

HCPCS CODES AND MODIFIERS:

Deleted: J7508

Revision Effective Date: 07/01/2003

DOCUMENTATION REQUIREMENTS: Removed erroneous statement that stated treating physician was required to sign and date the DIF.

Revision Effective Date: 04/01/2003

HCPCS CODES AND MODIFIERS:

Added: EY

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added standard language concerning coverage of items without an order.

DOCUMENTATION REQUIREMENTS:

Added standard language concerning use of the EY modifier for items without an order.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

07/01/2002 – Incorporated information from Fall 2001 bulletin article about when a new DMERC Information Form (DIF) is not required.

04/01/2002 – Added new HCPCS code J7511. Added code J7511 to Coverage and Payment Rules

04/01/2001 – Removed time limit for coverage, effective for drugs furnished after 12/21/2000 (except beneficiaries eligible based solely on ESRD). Effective 4/1/2001, coverage added for intestinal transplantation.

10/01/2000 – Revised to explain revision to the DIF form which included additional responses for question #5. Updated Documentation section regarding completion of previous DIF form.

04/01/2000 – Added HCPCS codes J7500, J7501, J7502, J7504, J7513, J7515, J7516, and J7517 (crosswalk from K0119, K0120, K0121, K0123, K0412, and K0418). Added reasonable and necessary language to Coverage and Payment Rules section. Added non-coverage information to Coverage and Payment Rules section.

03/01/1998 – Clerical correction.

03/01/1997 – Added HCPCS codes J7503, J8530 & J8610. Added HCPCS codes J7505, J7506, J7509, J7510, J7599, J8530, and J8610 (crosswalk from K0124, K0125, K0166, K0167, and XX010). Removed HCPCS A9270. Deleted Indications section. Revised criteria language in the Coverage and Payment Rules section. Revised Coding Guidelines section per HCPCS changes. Added language in Documentation section regarding question #4 on the DIF form. Added table for benefit periods.

10/01/1995 – Revised CMN language in Documentation section (removed “which has been filled out”).

02/01/1994 – Added HCPCS codes J7507 & J7508. Revised Documentation section - changed Certificate of Medical Necessity (CMN) language to DIF.

12/01/1993 – Added HCPCS XX010 (not otherwise classified). Added XX010 information in Coding Guidelines section. HAO corrected to HAO typo in Documentation section

Reason for Change

CMS Requirement

Last Reviewed On Date

05/28/2008

Related Documents

Article(s)

[A23662 - Immunosuppressive Drugs - Policy Article - July 2008](#)

LCD Attachments

There are no attachments for this LCD

Article for Immunosuppressive Drugs - Policy Article - July 2008 (A23662)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A23662

Article Type

Article

Key Article

Yes

Article Title

Immunosuppressive Drugs - Policy Article - July 2008

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[Primary Geographic Jurisdiction](#)

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

07/01/2005

Article Revision Effective Date

07/01/2008

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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

- I. Immunosuppressive drugs are prescribed following either:
 - A. kidney (V42.0), heart (V42.1), liver (V42.7), bone marrow (V42.81)/stem cell (V42.82), lung (V42.6), or heart/lung (V42.1 and V42.6) transplant; or,
 - B. whole organ pancreas (V42.83) transplant performed concurrent with or subsequent to a kidney transplant(V42.0) because of diabetic nephropathy (performed on or after July 1, 1999); or,
 - C. intestinal transplant (V42.84) (performed on or after April 1, 2001); or,
 - D. pancreatic islet cell transplant (V42.89) performed on or after October 1, 2004 that is conducted as part of a National Institutes of Health (NIH)-sponsored clinical trial;
 - 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. Patient 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
 - F. 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 patient is unaware, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; and
 - G. 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
 - H. 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,
 - I. 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 patient was enrolled in Medicare Part A at the time of the transplant; and,

- IV. The patient 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 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 patient 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 patients 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 patient meets the criteria for PA listed above in I(E). Coverage of immunosuppressive drugs already exists and will continue for patients 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 paid comparable to code Q0512. 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 patient 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 paid comparable to code Q0511 or Q0512, whichever is appropriate.

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.

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 J or K 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 prednisone tablets are dispensed, bill J7506, 100 units (1 unit of J7506 = 5 mg). If fifty 2.5 mg prednisone tablets are dispensed, bill J7506, 25 units.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

Coverage Topic

Immunosuppressive Drugs

Prescription Drugs

Transplants - Cornea and Bone Marrow

Transplants - Heart, Lung, Kidney, Pancreas, Liver, and Intestine/Multivisceral

Coding Information

ICD-9 Codes that are Covered

The presence of an ICD-9 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.

[996.81 - 996.89](#) COMPLICATIONS OF TRANSPLANTED KIDNEY - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

V42.0 KIDNEY REPLACED BY TRANSPLANT

V42.1 HEART REPLACED BY TRANSPLANT

V42.6 LUNG REPLACED BY TRANSPLANT

V42.7 LIVER REPLACED BY TRANSPLANT

V42.81 BONE MARROW REPLACED BY TRANSPLANT

V42.82 PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT

V42.83 PANCREAS REPLACED BY TRANSPLANT

V42.84 ORGAN OR TISSUE REPLACED BY TRANSPLANT INTESTINES

ICD-9 Codes that are Not Covered

All diagnoses that are not specified in the section ICD-9 Codes that are Covered.

Other Information**Other Comments****Revision History Explanation**

Revision Effective Date: 07/01/2008

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added instructions for use of KX modifier.

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A23662 from DME PSC TriCenturion (77011) Article A23662.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added Medicare coverage benefit language for pancreas transplants alone (PA).

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 01/01/2006

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Added: Q0510, Q0511, Q0512

Deleted: G0369, G0370

Added a definition for supply fee code Q0512

Revision Effective Date: 07/01/2005 (September publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Revised supply fee coverage for multiple dosage forms of the same drug.

Effective Date: 07/01/2005 (July Publication)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Revised Supply Fee guidelines

Effective Date: 07/01/2005 (March publication)

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added coverage criterion relating to pancreatic islet cell transplants

Added coding and payment guidelines for supply fees

Added covered ICD-9 diagnoses codes field

Related Documents**LCD(s)**

[L11531 - Immunosuppressive Drugs](#)