

LCD for Intravenous Immune Globulin (L27260)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L27260

LCD Title

Intravenous Immune Globulin

Contractor's Determination Number

IVIG

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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 04/01/2008

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 01/01/2009

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" is 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 intravenous immune globulin (IVIG) addressed in this policy are specified in the related Policy Article.

If the IVIG is administered using an infusion pump, the infusion pump and related administration supplies are denied as not medically necessary because they do not meet the coverage criteria specified in the External Infusion Pumps Local Coverage Determination (LCD).

If the coverage criteria for IVIG specified in the related Policy Article (PA) are not met and the IVIG is administered with an infusion pump, the IVIG will be denied as not medically necessary (because the pump is denied as not medically necessary).

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 for IVIG. Claims submitted by entities not licensed to dispense drugs will be denied for as not medical necessity.

Refer to the External Infusion Pumps LCD for information concerning coverage of subcutaneous immune globulin.

Coverage Topic

Prescription Drugs

Coding Information

CPT/HCPCS Codes

EY - No physician or other licensed health care provider order for this item or service

HCPCS CODES:

A4223 INFUSION SUPPLIES NOT USED WITH EXTERNAL INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)

J1459 INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG

J1561 INJECTION, IMMUNE GLOBULIN, (GAMUNEX), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG

J1566 INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, LYOPHILIZED (E.G. POWDER), NOT OTHERWISE SPECIFIED, 500 MG

J1568 INJECTION, IMMUNE GLOBULIN, (OCTAGAM), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG

J1569 INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), INTRAVENOUS, NON-LYOPHILIZED, (E.G. LIQUID), 500 MG

J1572 INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG

J1573 INJECTION, HEPATITIS B IMMUNE GLOBULIN (HEPAGAM B), INTRAVENOUS, 0.5 ML

J2791 INJECTION, RHO(D) IMMUNE GLOBULIN (HUMAN), (RHOPHYLAC), INTRAMUSCULAR OR INTRAVENOUS, 100 IU

ICD-9 Codes that Support Medical Necessity

Not specified.

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

XX000 Not Applicable

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 each item billed 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.

The supplier must enter an ICD-9 diagnosis code corresponding to the patient's diagnosis on each claim.

When Not Otherwise Classified (NOC) drug code J1566 is billed for miscellaneous immunoglobulin drugs, the claim must be accompanied by a clear statement detailing the drug provided and the amount dispensed.

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

Medicare IOM 100-02, Benefit Policy Manual Chapter 15, §50.6

Advisory Committee Meeting Notes

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

03/20/2008

Revision History Number

001

Revision History Explanation

Revision Effective Date: 01/01/2009

HCPCS CODES:

Added J1459.

Changed code descriptor for J1572.

Deleted Q4097.

Reason for Change**Last Reviewed On Date**

02/18/2008

Related Documents**Article(s)**

[A46761 - Intravenous Immune Globulin - Policy Article - Effective January 2009](#)

LCD Attachments

There are no attachments for this LCD

Article for Intravenous Immune Globulin - Policy Article - Effective January 2009 (A46761)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A46761

Article Type

Article

Key Article

Yes

Article Title

Intravenous Immune Globulin - Policy Article - Effective January 2009

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

04/01/2008

Article Revision Effective Date

01/01/2009

Article Text**NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

Intravenous immune globulin (IVIG) is covered if all of the following criteria are met:

- 1) It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease; and
- 2) The patient has a diagnosis of primary immune deficiency disease (ICD-9 codes 279.04, 279.05, 279.06, 279.12, 279.2); and
- 3) The IVIG is administered in the home; and
- 4) The treating physician has determined that administration of the IVIG in the patient's home is medically appropriate.

If all of the criteria are not met and the IVIG is not administered with an infusion pump, the IVIG will be denied as noncovered - no benefit category.

If the criteria are not met and the IVIG is administered with an infusion pump, refer to the Intravenous Immune Globulin LCD.

Coverage under the IVIG benefit is limited to the IVIG itself, not to related supplies and services. If the IVIG is not administered with an infusion pump, related supplies will be denied as noncovered – no benefit category.

Codes J1573 and J2791 are non-covered. They are not indicated for the treatment of primary immune deficiency disease (# 2 above).

Refer to the External Infusion Pumps LCD for information concerning coverage of subcutaneous immune globulin.

CODING GUIDELINES

If the IVIG is not administered through an infusion pump and if supplies are billed, code A4223 (INFUSION SUPPLIES NOT USED WITH EXTERNAL INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY) must be used for the supplies.

If the IVIG is administered through an infusion pump refer to the External Infusion Pump LCD and Policy Article for additional information.

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

Coverage Topic

Prescription Drugs

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 Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

279.04	CONGENITAL HYPOGAMMAGLOBULINEMIA
279.05	IMMUNODEFICIENCY WITH INCREASED IGM
279.06	COMMON VARIABLE IMMUNODEFICIENCY
279.12	WISKOTT-ALDRICH SYNDROME
279.2	COMBINED IMMUNITY DEFICIENCY

ICD-9 Codes that are Not Covered

All codes not listed in the previous section.

Other Information

Revision History Explanation

Revision Effective Date: 01/01/2009

CODING GUIDELINES:

Replaced SADMERC reference with PDAC.

Related Documents

LCD(s)

[L27260 - Intravenous Immune Globulin](#)