

Local Coverage Determination (LCD): Intravenous Immune Globulin (L33610)

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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

L33610

Original ICD-9 LCD ID

[L27260](#)

[L27259](#)

[L27258](#)

[L27261](#)

LCD Title

Intravenous Immune Globulin

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.

The statutory coverage criteria for intravenous immune globulin (IVIG) addressed in this policy are specified in the related Policy Article.

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.

If the IVIG is administered using an infusion pump, the infusion pump and related administration supplies are denied as not reasonable and 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 reasonable and necessary (because the pump is denied as not reasonable and 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 reasonable and necessary.

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

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 practitioners 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.

DRUG WASTAGE

Claims for drugs billed to Medicare must use drug dosage formulations and/or unit dose sizes that minimize wastage. Medicare provides payment for the amount of a single use vial or other single use package of drug or biological discarded, in addition to the dose administered.

Effective for claims with dates of service on or after January 1, 2017, Medicare requires the use of the JW modifier when billing for drug wastage. Because of the HCPCS code descriptors and the associated UOS for DMEPOS items, the DME MACs expect rare use of the JW modifier on claims.

The amount of drug discarded must be billed on a separate claim line using the JW modifier. Review the POLICY

SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD-related Policy Article for additional instructions regarding the use of the JW modifier.

Effective for claims with dates of service on or after January 1, 2017, if the coverage criteria for the infusion drugs are not met, claims billed for drug wastage with the JW modifier will be denied as not reasonable and necessary.

Effective for claims with dates of service on or after January 1, 2017, claims lines billed for drug wastage without a JW modifier will be denied as not reasonable and necessary.

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.

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:**

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

JW - Drug amount discarded/not administered to any patient

HCPCS CODES:

Group 1 Codes:

CODE	DESCRIPTION
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
J1556	INJECTION, IMMUNE GLOBULIN (BIVIGAM), 500 MG
J1557	INJECTION, IMMUNE GLOBULIN, (GAMMAPLEX), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1561	INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), 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), 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
J1599	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), NOT OTHERWISE SPECIFIED, 500 MG
J2791	INJECTION, RHO(D) IMMUNE GLOBULIN (HUMAN), (RHOPHYLAC), INTRAMUSCULAR OR INTRAVENOUS, 100 IU

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

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 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

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

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R6	<p>Revision Effective Date: 01/01/2020</p> <p>GENERAL: Revised: Order information as a result of Final Rule 1713</p> <p>REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners"</p> <p>DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's"</p> <p>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>	<ul style="list-style-type: none">• Provider Education/Guidance
01/01/2017	R5	<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,</i></p>	<ul style="list-style-type: none">• Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<i>therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	
01/01/2017	R4	<p>Revision Effective Date: 01/01/2017</p> <p>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 Revised: Drug Wastage verbiage</p> <p>DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements</p> <p>Removed: Information under Miscellaneous and Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
01/01/2017	R3	<p>Revision Effective Date: 01/01/2017</p> <p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Denial language for JW Modifier when coverage criteria not met</p> <p>HCPCS MODIFIERS: Added: JW Modifier</p> <p>DOCUMENTATION REQUIREMENTS: Added: JW Modifier instructions</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Other (Addition of JW Modifier)
07/01/2016	R2	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"> • Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Revision Effective Date: 10/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR	<ul style="list-style-type: none"> • Provider

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Refill Documentation requirements Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer	Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A52509 - Intravenous Immune Globulin - 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 03/27/2018 with effective dates 01/01/2017 - 12/31/2019

Updated on 03/16/2017 with effective dates 01/01/2017 - N/A

Updated on 12/22/2016 with effective dates 01/01/2017 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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: Intravenous Immune Globulin - Policy Article (A52509)

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CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
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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

A52509

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A46761](#)

[A47336](#)

[A47173](#)

[A47177](#)

Revision Effective Date

01/01/2020

Revision Ending Date

N/A

Article Title

Intravenous Immune Globulin - 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").

Intravenous immune globulin used for the treatment of primary immunodeficiency is covered under the Intravenous Immune Globulin benefit. (IOM 100-2, Ch. 15, §50.6) In order for a beneficiary's equipment 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.

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 (See Diagnosis Codes that Support Medical Necessity section below); and
3. The IVIG is administered in the home; and
4. The treating practitioner 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.

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.

The supplier must enter a diagnosis code corresponding to the patient's diagnosis on each claim.

MODIFIERS

JW MODIFIER

Effective for claims with dates of service on or after January 1, 2017, the JW modifier must be used when billing for discarded drugs and biologicals.

Multi-use vials are not subject to payment for discarded amounts of drug or biologicals.

Because of the HCPCS code descriptors and the associated UOS for DMEPOS items, the DME MACs expect rare use of the JW modifier on claims.

There are two scenarios that can occur:

Scenario 1

When the HCPCS code Unit of Service (UOS) is less than the drug quantity contained in the single use vial or single dose package, the following applies:

- The quantity administered is billed on one claim line without the JW modifier; and
- The quantity discarded is billed on a separate claim line with the JW modifier.

In this scenario, the JW modifier must be billed on a separate line to provide payment for the amount of discarded drug or biological. For example:

- A single use vial is labeled to contain 100 mg of a drug.
- The drug's HCPCS code UOS is 1 UOS = 1 mg.
- 95 mg of the 100 mg in the vial are administered to the beneficiary.
- 5 mg remaining in the vial are discarded.
- The 95 mg dose is billed on one claim line as 95 UOS.
- The discarded 5 mg is billed as 5 UOS on a separate claim line with the JW modifier.
- Both claim line items would be processed for payment.

Scenario 2

When the HCPCS code UOS is equal to or greater than the total of the actual dose and the amount discarded, use of the JW modifier is not permitted. If the quantity of drug administered is less than a full UOS, the billed UOS is rounded to the appropriate UOS. For example:

- A single use vial is labeled to contain 100 mg of a drug.
- The drug's HCPCS code UOS is 1 UOS = 100 mg.
- 70 mg of the 100 mg in the vial are administered to the beneficiary.
- 30 mg remaining in the vial are discarded.
- The 70 mg dose is billed correctly by rounding up to one UOS (representing the entire 100 mg vial) on a single line item.
- The single line item of 1 UOS would be processed for payment of the combined total 100 mg of administered and discarded drug.
- The discarded 30 mg must not be billed as another 1 UOS on a separate line item with the JW modifier. Billing an additional 1 UOS for the discarded drug with the JW modifier is incorrect billing and will result in an overpayment.

Effective for claims with dates of service on or after January 1, 2017, suppliers must add a JW modifier to codes for infusion drugs, only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related policy have been met.

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.

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

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
D80.0	Hereditary hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G11.3	Cerebellar ataxia with defective DNA repair

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

All codes not listed in the previous section.

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	R6	<p>Revision Effective Date: 01/01/2020</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: "physician" to "practitioner" 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 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>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
08/13/2019	R5	<p>Revision Effective Date: 08/13/2019</p> <p>ICD-10 CODES THAT ARE COVERED: Added: Codes D80.2, D80.3, D80.4, D80.6, D80.7, D81.5, D82.1, D82.4, D83.1 and G11.3 per update to Medicare Benefit Policy Manual, Chapter 15, section 50.6</p> <p><i>07/25/2019: 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	R4	<p><i>02/21/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This is an article and not a local coverage determination.</i></p>
01/01/2017	R3	<p>Revision History Effective Date: 01/01/2017</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Modifier requirements</p> <p>RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article</p>
07/01/2016	R2	<p>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.</p>
10/01/2015	R1	<p>Revision Effective Date: 10/01/2015</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: Diagnosis codes from this section Added: Reference to diagnosis codes section</p>

Associated Documents

Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L33610 - Intravenous Immune Globulin

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)

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Keywords

N/A