Disclaimer: Draft articles are works in progress and not necessarily a reflection of the current billing and coding practices. The draft article information contained in this document does not represent nor does it include all information found in an active LCD-related Policy Article. For example, abridged ICD-10-CM code information relevant to the proposed LCD may be included; unchanged ICD-10-CM code information may not be included. Please refer to the active LCD-related Policy Article in effect on the Medicare Coverage Database, if applicable, for current billing and coding information.

Contractor Information:

Contractor Name	Contract Type	Contract Number	Jurisdiction
CGS Administrators, LLC	DME MAC	17013 - DME MAC	Jurisdiction B
CGS Administrators, LLC	DME MAC	18003 - DME MAC	Jurisdiction C
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	Jurisdiction A
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	Jurisdiction D

DRAFT

External Infusion Pumps - Policy Article

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”).

External infusion pumps are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(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.

Drugs are only covered as a supply to a covered DME infusion pump. Drugs billed alone (without a covered pump being used) will be denied as statutorily noncovered (no benefit).

Infusion drugs started in a practitioner's office, whether with or without a pump, must be billed to the local carrier and not the DME MAC. In these cases, the drug or biological may potentially be covered under section 1861(s)(2)(A) and (B) of the Act and is billable to the A/B MAC even though the entire administration of the drug or biological did not occur in the practitioner's office or the hospital outpatient department. Equipment, such as an external infusion pump used to begin administration of the drug or biological that the patient takes home to complete the infusion, is not separately billable as durable medical equipment for a drug or biological paid under the section 1861(s)(2)(A) and (B) incident to benefit. These claims will be rejected as wrong jurisdiction.

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, A9274) are non-covered devices because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items.

Catheter insertion devices for use with external insulin infusion pump infusion cannulas are included in the allowance for code A4224 and are not separately payable.

The DME MACs do not process claims for implantable infusion pumps (E0782, E0783, E0785, and E0786) or drugs and supplies used in conjunction with an implantable infusion pump. Claims for these items must be submitted to the A/B MAC.

Replacement batteries (K0601, K0602, K0603, K0604, K0605) are not separately payable when billed with a rented infusion pump.

Medicare only pays for one pump (K0455) for administering epoprostenol and treprostinil; the supplier is responsible for ensuring that there is an appropriate and acceptable contingency plan to address any emergency situations or mechanical failures of the equipment. A second pump provided as a backup will be denied as not separately payable.

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 required Face-to-Face Encounter and Written Order Prior to Delivery List is available here.

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 prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Coverage of an external infusion pump for the administration of continuous subcutaneous insulin as outlined in the related LCD's "Coverage Indications, Limitations, and/or Medical" section under criteria IV. C. and D. requires a frequency of glucose self-testing an average of at least 4 times per day. A beneficiary using a continuous glucose monitor (CGM) is inherently testing more than the 4 times per day glucose monitoring requirement. Documentation of the use of a CGM device in the beneficiary's medical records would meet the testing requirement in the External Infusion Pump LCD.

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.

DME INFORMATION FORM (DIF)

Providers and suppliers no longer need to submit a DME Information Form (DIF) for services rendered on or after January 1, 2023.

- For claims with dates of service on or after January 1, 2023 – Providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.

- For claims with dates of service prior to January 1, 2023 – If the CMN or DIF is required, it must be submitted with the claim, or be on file with a previous claim.

For dates of service for which a DIF is required, a DIF which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request.

The DIF for External Infusion Pumps is CMS Form 10125. The initial claim must include an electronic copy of the DIF.

For claims with dates of service prior to January 1, 2023 the following requirements for new initial and revised DIFs remain in effect:

A revised DIF must be submitted if:

- A beneficiary begins using an infusion for one drug and subsequently the drug is changed, another drug is added, or if the code for a current drug changes. The additional new or changed drug or the new HCPCS code for the existing drug must be listed along with all other drugs for which the pump is used.
- There is a change in the route of administration or a change in the method of administration of a drug.
- The length of need previously entered on the DIF has expired and the ordering practitioner is extending the length of need for the item(s).

If information on an inotropic drug is requested, the supplier must submit a copy of the order and clinical documentation which includes information relating to each of the criteria (D1-D4) defined in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD. This information must come from the medical record.

For parenteral inotropic drugs, the cardiologist with training in the management of advanced heart failure who performs the initial evaluation does not need to be the prescriber for the parenteral inotropic drug. However, the prescribing practitioner must:

- Verify that an initial evaluation was performed by a cardiologist with training in the management of advanced heart failure; and
- Have documentation of the evaluation; and,
- Provide a copy of the initial evaluation and the prescription for the item(s) to the DMEPOS supplier.

Parenteral inotropic claims that are grandfathered must also be in compliance with Medicare Claims Processing Manual (CMS Internet Only Manual 100-04) Chapter 20 break-in-service rules.

If additional information on epoprostenol or treprostinil is requested, the supplier should submit signed and dated information from the treating practitioner stating the beneficiary's diagnosis, the beneficiary's current symptoms caused by pulmonary hypertension, and date and results of the pulmonary artery pressure. There must be a statement that the pulmonary hypertension is not secondary to pulmonary venous hypertension or a disorder of the respiratory system. There must be a statement of whether oral calcium channel blocking agents were tried and if so, the results, and if not, why a trial was not conducted.

MODIFIERS

JB MODIFIER

For immune globulins (J1551, J1555, J1558, J1559, J1561, J1562 and J1569) and associated infusion pump (E0779) claims where the route of administration is subcutaneous, a JB modifier must be added to each HCPCS code.

For immune globulin (J1551, J1558 and J1575) and associated infusion pump (E0781) claims where the route of administration is subcutaneous, a JB modifier must be added to each HCPCS code.

For other methods of administration, no modifier should be added.

JK AND JL MODIFIERS

The JK and JL modifiers will be effective for claims with dates of service on or after April 1, 2023, for insulin (J1817) administered through an external insulin infusion pump (E0784), and for claims with dates of service on or after July 1, 2023, for insulin (fiasp) (J1811) and insulin (lyumjev) (J1813) administration through an external insulin infusion pump (E0784).

- For a one-month or less supply of insulin, JK modifier must be added to HCPCS codes J1811, J1813 or J1817
- For a three-month supply of insulin, JL modifier must be added to HCPCS codes J1811, J1813 or J1817

Effective for claims with dates of service on or after July 1, 2023, a beneficiary’s coinsurance for a month’s supply of insulin (J1811, J1813 or J1817) furnished through an external insulin infusion pump (E0784) is not to exceed $35. In order to ensure beneficiaries are not charged more than the $35 maximum allowed for the month of July 2023, suppliers must not bill a three-month supply of insulin (J1817) between May 1, 2023 and June 30, 2023.

For claims with dates of service in May or June 2023, suppliers must only bill a one-month supply of insulin (J1817) and append the JK modifier. Claims with dates of service in May or June 2023 with the JL modifier appended will be returned as unprocessable.

JW AND JZ MODIFIERS

Effective for claims with dates of service on or after January 1, 2017, the JW modifier is required when billing for unused and discarded amounts of drugs and biologicals from single-dose containers that are administered by the supplier.

Effective for claims with dates of service on or after July 1, 2023, the JZ modifier is required when billing for drugs and biologicals from single-dose containers that are administered by the supplier but have no unused and discarded amounts. Effective for claims with dates of service on or after January 1, 2024, the JZ modifier is also required when billing for drugs and biologicals from single-dose containers that are dispensed by the supplier but have no unused and discarded amounts that are self-administered by the beneficiary or the beneficiary's caregiver.

Effective for claims with dates of service on or after January 1, 2025, the JW modifier is also required if a billing supplier is not administering a drug or biological, but there are unused and discarded amounts during the preparation process before supplying the drug or biological to the patient as described in scenario 3 below. The JZ modifier is required for drugs and biologicals that are dispensed by the supplier but have no unused and discarded amounts during the preparation process and are self-administered by the beneficiary or caregiver in the beneficiary's home.

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

The DME MACs expect rare use of the JW modifier on claims due to HCPCS code descriptors and their associated Units of Service (UOS) for DMEPOS in addition to the limited instructions for use.

Below are three (3) scenarios in regard to the JW and JZ modifiers.

Scenario 1
When the HCPCS code 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 claim 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 by the supplier.
- 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. As of July 1, 2023, the JZ modifier is required in this situation. 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 by the supplier.
- 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 claim line item with the JZ modifier.
- The single claim 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 claim 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.

Scenario 3
There are cases such as in a pharmacy where the billing supplier does not administer a drug but prepares it prior to supplying the drug to the beneficiary. Beginning January 1, 2025, the JW modifier is required if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. Such a supplier would report the JZ modifier if no amounts were discarded during the preparation process before supplying the drug to the patient. For example:

- A single-use vial is labeled to contain 50 mg of a drug.
- The drug’s HCPCS code UOS is 1 UOS = 1mg.
- A supplier prepares the prescribed dose of 45 mg to supply to the beneficiary.
- The 45 mg dose is billed on one claim line as 45 UOS.

- The discarded 5 mg is billed as 5 UOS on a separate claim line with the JW modifier.
- Both claim lines would be processed for payment.

GA, GY, GZ AND KX MODIFIERS

For claims submitted on or after March 1, 2023 suppliers must add the KX modifier to claim lines billed for the external infusion pump, drugs and supplies for dates of service on or after January 1, 2023, only if all of the coverage criteria in the "Coverage Indications, Limitations, and/or Medical Necessity" section in the related LCD have been met. Evidence supporting the use of the KX modifier must be retained in the supplier's files and available to the DME MAC upon request. The KX modifier requirement will continue to be required for HCPCS E0784 and J1817 for any date of service billed, if applicable.

If all of the criteria in the "Coverage Indications, Limitations, and/or Medical Necessity" section of the related LCD have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed for the above services without a KX, GA, or GZ modifier will be rejected as missing information for claims submitted on or after March 1, 2023 for all codes.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier.

CODING GUIDELINES

An ambulatory infusion pump (E0781) is an electrical or battery-operated device, which is used to deliver solutions containing a parenteral drug under pressure at a regulated flow rate. It is small, portable, and designed to be carried by the beneficiary.

A stationary infusion pump (E0791) is an electrical device, which serves the same purpose as an ambulatory pump but is larger and typically mounted on a pole.

A disposable drug delivery system (A4305, A4306, A9274) is a device used to deliver solutions containing injectable drugs that is not reusable, i.e., it is used by a single beneficiary for a limited time and then discarded.

An infusion controller (E1399) is an electrical device, which regulates the flow of parenteral solutions under gravity pressure.

A reusable mechanical infusion pump (E0779) is a device used to deliver solutions containing parenteral drugs under pressure at a constant flow rate determined by the tubing with which it is used. It is small, portable, and designed to be carried by the beneficiary. It must be capable of a single infusion cycle of at least 8 hours.

Code E0780 describes a mechanical infusion pump which is similar to an E0779 pump, but which is only capable of a single infusion cycle of less than 8 hours.

Code K0455 describes an ambulatory electrical infusion pump, which is used for the administration of epoprostenol (J1325) and treprostinil (J3285).

Code A4221 describes all necessary supplies, such as dressings for the catheter site and flush solutions, not directly related to non-insulin drug infusions. The catheter site may be a peripheral intravenous line, a subcutaneous infusion catheter, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or a subcutaneous port, or an epidural catheter.

Code A4222 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges. This code is not used for a syringe-type reservoir.

Code K0552 describes a syringe-type reservoir that is used with the K0455, E0779, E0780, E0781 or E0791 when used to administer a drug utilizing a syringe-type reservoir. The reservoir may be either glass or plastic and includes the needle or equivalent for drawing up or transferring the drug to the reservoir. This code does not include the drug for use in the reservoir. Code A4232 is invalid for submission to Medicare and should not be used for this purpose.

Claims for codes A4221, A4222 and K0552 must only be used with a non-insulin external infusion pump (E0779, E0780, E0781, E0791 or K0455). Claims with dates of service on or after January 01, 2017 for codes A4221, A4222 and K0552 used with an external infusion pump HCPCS code E0784 are incorrectly coded.

Code A4224 is all-inclusive and describes all necessary supplies (excluding the insulin reservoir – see code A4225) used with an external infusion pump (E0784) for the administration of continuous subcutaneous insulin and includes, but is not limited to, all cannulas, needles, dressings and infusion supplies. Separate billing for any item including an item using a specific HCPCS code, if one exists, will be denied as unbundling.

Code A4225 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784).

Claims for codes A4224 and A4225 must only be used with insulin infusion pumps (E0784). Claims with dates of service on or after January 01, 2017 for codes A4224 and A4225 used with an external infusion pump other than code E0784 are incorrectly coded.

HCPCS Supply Codes Associated with External Infusion Pumps HCPCS Codes

The following table describes HCPCS supply codes that are used with different types of external infusion pumps. The HCPCS codes listed in the "Associated Codes" column should be used with the corresponding "Pump HCPCS code." Claims for supply codes listed in the "Non-Associated Codes" column will be denied as incorrect coding, if they are being used with an external infusion pump listed in the "Pump HCPCS Code" column of the same line.

Pump HCPCS Code	Associated Codes	Non-Associated Codes
E0779	A4221, A4222*, K0552*	A4224, A4225
E0780	A4221, A4222*, K0552*	A4224, A4225
E0781	A4221, A4222*, K0552*	A4224, A4225
E0784	A4224, A4225, A4238**, A4239**	A4221, A4222, K0552
E0791	A4221, A4222*, K0552*	A4224, A4225
K0455	A4221, A4222*, K0552*	A4224, A4225

*For E0779, E0780, E0781, E0791 and K0455 pumps, either A4222 and/or K0552 may be billed.

**For E0784 pumps, either A4238 or A4239 may be billed if used in conjunction with an integrated adjunctive or non-adjunctive CGM, respectively.

Prior to January 1, 2023, insulin infusion pumps with integrated continuous glucose sensing capabilities must be coded using HCPCS codes E0784 (EXTERNAL AMBULATORY INFUSION PUMP, INSULIN) and K0554 (RECEIVER (MONITOR), DEDICATED, FOR USE WITH THERAPEUTIC GLUCOSE CONTINUOUS MONITOR SYSTEM). On or after January 1, 2023, insulin infusion pumps with integrated continuous glucose sensing capabilities must be coded using HCPCS codes E0784 (EXTERNAL AMBULATORY INFUSION PUMP, INSULIN) and E2103 (NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER).

Prior to January 1, 2023, the related accessories/supplies for these integrated units must be coded using HCPCS codes A4224 (SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK), A4225 (SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH), and K0553 (SUPPLY ALLOWANCE FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE). On or after January 1, 2023, the related accessories/supplies for these integrated units must be coded using HCPCS codes A4224 (SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK), A4225 (SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH), and A4239 (SUPPLY ALLOWANCE FOR NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE).

For claims with dates of service on or before March 31, 2022, insulin infusion pumps with integrated adjunctive continuous glucose monitor receiver functionality must be coded using HCPCS codes E0784 (EXTERNAL AMBULATORY INFUSION PUMP, INSULIN) and E1399 (DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS) for an adjunctive continuous glucose monitor or receiver. Suppliers must bill as a rental (RR) both E0784 and E1399 to describe the rental of an insulin pump with integrated adjunctive CGM receiver functionality. When submitting a claim for E1399, suppliers must enter “adjunctive” in loop 2300 (claim note) and/or 2400 (line note), segment NTE02 (NTE01=ADD) of the ANSI X12N, version 5010A1 professional electronic claim format or in Item 19 of the paper claim form, so that the items can be identified as adjunctive CGM devices when processing the claim. The related accessories/supplies for these integrated units must be coded using HCPCS codes A4224 (SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK), A4225 (SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH), and A9999 (MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED) for supplies and accessories used in conjunction with an insulin pump, which also performs the functions of an adjunctive continuous

glucose monitor or receiver. Suppliers may bill 1 UOS per thirty (30) days. Code A9999 is all-inclusive; when used to bill for adjunctive CGM supplies and accessories it includes, but is not limited to, the CGM sensor, CGM transmitter and insertion devices. When submitting a claim for A9999, suppliers must enter “adjunctive” in loop 2300 (claim note) and/or 2400 (line note), segment NTE02 (NTE01=ADD) of the ANSI X12N, version 5010A1 professional electronic claim format or in Item 19 of the paper claim form, so that the items can be identified as adjunctive CGM supplies and accessories when processing the claim.

For claims with dates of service on or after April 1, 2022, insulin infusion pumps with integrated adjunctive continuous glucose monitor receiver functionality must be coded using HCPCS codes E0784 (EXTERNAL AMBULATORY INFUSION PUMP, INSULIN) and E2102 (ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER). The related accessories/supplies for these integrated units must be coded using HCPCS codes A4224 (SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK), A4225 (SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH), and A4238 (SUPPLY ALLOWANCE FOR ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE).

Please refer to the Glucose Monitors LCD-related Policy Article (A52464) for more information regarding coding guidelines for continuous glucose monitors.

Codes A4230 (INFUSION SET FOR EXTERNAL INSULIN PUMP, NON-NEEDLE CANNULAS TYPE) and A4231 (INFUSION SET FOR EXTERNAL INSULIN PUMP, NEEDLE TYPE) are not valid for claim submission to the DME MAC because they are included in code A4224.

Use A4223 for infusion supplies not used with a covered external infusion pump.

Drugs used in a durable external infusion pump must be coded using the appropriate HCPCS codes. If the drug does not have a distinct code, then use the unclassified drug code J7799. Do not use code J9999 - this code is not valid for claims billed to the DME MAC.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier. If the drug does not have a unique code, use the unclassified drug code, J3490.

Use code J2274 only for morphine sulfate that is labeled "preservative free.” Morphine sulfate that is not labeled "preservative free" must be coded J2270.

Use code J1811, J1813 or J1817 for insulin administered through an external insulin pump (E0784).

Codes A4602, K0604 and K0605 describe lithium batteries commonly used in external infusion pumps. Note that each code has an associated voltage. Claims for lithium batteries for external insulin infusion pumps (E0784) that do not use a voltage described by either code A4602, K0604 and K0605 must be billed using code A9999.

Levodopa-Carbidopa enteral suspension is supplied as a single-use cassette. One unit of service contains 2000 mg levodopa and 500 mg carbidopa in 100 mL of enteral suspension.

Claims for levodopa-carbidopa enteral suspension for dates of service on or after January 09, 2015 through December 31, 2015, must be submitted using the DME miscellaneous code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME).

Claims for levodopa-carbidopa enteral suspension for dates of service on or after January 01, 2016 must be submitted using the HCPCS code J7340 (CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION, 100 ML).

Establishment of the transabdominal port with a PEG-J for the administration of levodopa-carbidopa enteral suspension is performed under endoscopic guidance by a gastroenterologist or other healthcare provider experienced in this procedure. The PEG-J is considered a supply provided incident to a physician's service, and claims for this item are processed by the A/B MAC contractor. Claims to the DME MAC for the PEG-J will be rejected as wrong jurisdiction.

Claims for foslevodopa/foscarbidopa injection for continuous subcutaneous infusion with dates of service on or after October 17, 2024 through June 30, 2025 must be submitted using the DME miscellaneous HCPCS code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME).

Claims for foslevodopa/foscarbidopa injection for continuous subcutaneous infusion with dates of service on or after July 1, 2025 must be submitted using HCPCS code J7356 (INJECTION, FOSCARBIDOPA 0.25 MG/FOSLEVODOPA 5 MG).

Foslevodopa/foscarbidopa injection for continuous subcutaneous infusion is supplied in 10mL single use vials. Each vial contains 120 mg foscarbidopa and 2400 mg foslevodopa per 10mL (12 mg foscarbidopa and 240 mg foslevodopa per mL). One (1) unit of service (UOS) is foscarbidopa 0.25 mg/foslevodopa 5 mg.

Claims for the VYAFUSER pump, used to administer foslevodopa/foscarbidopa continuous subcutaneous infusion, for dates of service prior to January 24, 2025 must be submitted using the HCPCS code E1399 (DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS).

Claims for the VYAFUSER pump, used to administer foslevodopa/foscarbidopa continuous subcutaneous infusion, for dates of service on or after January 24, 2025 must be submitted using the HCPCS code E0781 (AMBULATORY INFUSION PUMP, SINGLE OR MULTIPLE CHANNELS, ELECTRIC OR BATTERY OPERATED, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT).

One unit of service (UOS) of blinatumomab (J9039) equals one (1) microgram (mcg), and thus, 1 vial equals 35 UOS. Reconstituted blinatumomab must be prepared using the combination of vials that result in the least amount of wastage for the dosage amount being administered. There are four alternative infusion protocols that can be used. For each protocol, the following apply:

- For beneficiaries using a 2-day infusion protocol, five (5) vials (175 UOS) should be used to reconstitute three bags, each containing 56 mcg (56 UOS) of blinatumomab, which can be refrigerated (2°C to 8°C), and used within six-days.
- For beneficiaries using a 3-day infusion protocol, three (3) vials (105 UOS) should be used to reconstitute one bag, containing 84 mcg (84 UOS) of blinatumomab, which is infused over 3 days.
- For beneficiaries using a 4-day infusion protocol, four (4) vials (140 UOS) should be used to reconstitute one bag, containing 112 mcg (112 UOS) of blinatumomab, which is infused over 4 days.
- For beneficiaries utilizing a 7-day infusion protocol, six (6) vials (210 UOS) should be used to reconstitute one bag (containing 210 mcg of blinatumomab), which is infused over 7 days.

Claims for blinatumomab for dates of service on or after December 03, 2014 through December 31, 2015, must be submitted using the DME miscellaneous code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME).

Claims for blinatumomab for dates of service on or after January 01, 2016, must be submitted using the HCPCS code J9039 (INJECTION, BLINATUMOMAB, 1 MICROGRAM).

HYQVIA is administered subcutaneously through an E0781 pump that is pre-programmed, and the E0781 pump must be delivered to the Medicare beneficiary in a “locked mode” (i.e., the patient is unable to self-adjust the infusion rate).

Claims for HYQVIA for dates of service on or after September 12, 2015 through December 31, 2015, must be submitted using the DME miscellaneous code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME).

Claims for HYQVIA for dates of service on or after January 01, 2016 must be submitted using the HCPCS code J1575 (INJECTION, IMMUNE GLOBULIN/HYALURONIDASE, (HYQVIA), 100 MG IMMUNEGLOBULIN).

Code J7999 (COMPOUNDED DRUG, NOT OTHERWISE CLASSIFIED) must be used for any compounded drugs administered using an external infusion pump for dates of service on or after January 01, 2016.

When Q9977 or J7999 is billed for a compounded drug, the claim must be accompanied by the standard written order information, and a clear statement of the amount dispensed.

Claims for CUVITRU for dates of service on or before December 31, 2017 must be submitted using the HCPCS code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). One UOS equals one hundred (100) milligrams (mg).

Claims for CUVITRU for dates of service on or after January 01, 2018 must be submitted using HCPCS code J1555 (INJECTION, IMMUNE GLOBULIN (CUVITRU), 100 MG). One UOS equals one hundred (100) mg.

Claims for Xembify for dates of service on or after July 3, 2019 through June 30, 2020 must be submitted using the HCPCS code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). One UOS equals one hundred (100) mg. Claims for Xembify for dates of service on or after July 1, 2020 must be submitted using the HCPCS code J1558 (INJECTION, IMMUNE GLOBULIN (XEMBIFY), 100 MG).

Claims for Cutaquig for dates of service on or after December 12, 2018 through June 30, 2022 must be submitted using the HCPCS code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). One UOS equals one hundred (100) mg. Claims for Cutaquig for dates of service on or after July 1, 2022 must be submitted using HCPCS code J1551 (INJECTION, IMMUNE GLOBULIN (CUTAQUIG), 100 MG).

Claims for Hizentra for beneficiaries with CIDP for dates of service on or after July 18, 2021 must be submitted using the HCPCS code J1559 (INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG). One UOS equals one hundred (100) mg.

Specific infusion pump HCPCS codes are used with specific SCIg preparations according to the table below.

Infusion Pump	SCIg Preparation
E0779	J1555, J1559, J1561, J1562, J1569
E0781	J1575
E0779 or E0781	J1551, J1558

Professional Services

Professional services include nursing services, training and education (not otherwise paid for as durable medical equipment), remote monitoring, and monitoring services for the provision of home infusion therapy furnished by a qualified home infusion supplier with administration of certain transitional home infusion drugs administered through an item of DME.

For claims with dates of service on or after January 01, 2019 through December 31, 2020, codes G0068, G0069, and G0070 are used to bill for the professional services rendered on the applicable infusion drug administration calendar day for each payment category. Providers should report visit length in 15-minute increments (15 minutes = 1unit). Suppliers must ensure that the appropriate drug associated with the visit is billed with the visit or no more than 30 days prior to the visit.

In the event that multiple visits occur on the same date of service, suppliers must only bill for one visit and should report the highest paying visit with the applicable drug. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.

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

Coding Information

ICD-10-CM Codes that Support Medical Necessity

Group 4 Paragraph
[revision] For HCPCS codes J7340, J7356:

ICD-10-CM Codes that DO NOT Support Medical Necessity
[no change]

Associated Documents:

This draft document is an attachment to the proposed External Infusion Pumps LCD (DL33794) that has a Proposed LCD Posting Date of 07/24/2025.