Local Coverage Determination (LCD): External Infusion Pumps (L33794)

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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

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CMS National Coverage Policy

CMS Pub. 100-03, (National Coverage Determinations Manual), Chapter 1, Section 280.14

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the

Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Payment may be made for supplies that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment. However, the coverage of such drugs or biologicals does not preclude the need for a determination that the drug or biological itself is reasonable and necessary for treatment of the illness or injury or to improve the functioning of a malformed body member.

An external infusion pump is covered for the following indications (I-V):

An infusion pump described by codes E0779, E0780, E0781, and E0791 is covered for indications I – III, V(A) – V(D), V(F), V(G), V(I) and V(J). Coverage of other pumps is addressed under indications IV, V (E), and V (H).

I. Administration of deferoxamine for the treatment of chronic iron overload.
II. Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the beneficiary refuses surgical excision of the tumor. Anticancer chemotherapy drugs used in these conditions are not required to meet the criteria described by indication V, situation A.
III. Administration of morphine when used in the treatment of intractable pain caused by cancer.
IV. Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.) if criterion A or B is met and if criterion C or D is met:
    A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
        1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
        2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory’s measurement method.
        3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.
    B. Beta cell autoantibody test is positive.
    C. The beneficiary has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
        1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
        2. History of recurring hypoglycemia
        3. Wide fluctuations in blood glucose before mealtime
        4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL

5. History of severe glycemic excursions

D. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

If criterion A or B is not met, the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary. If criterion C or D is not met, the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.

Continued coverage of an external insulin pump and supplies requires that the beneficiary be seen and evaluated by the treating practitioner at least every 3 months. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a practitioner who manages multiple beneficiaries on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

Subcutaneous insulin is administered using ambulatory infusion pump E0784. Claims for usage of infusion pumps other than E0784 will be denied as not reasonable and necessary.

The HCPCS code combination of E0784 plus K0554 is used to describe external ambulatory insulin infusion pumps that incorporate dose rate adjustment using therapeutic continuous glucose sensing. Coverage for this HCPCS code combination is only met if the beneficiary meets all the coverage criteria for insulin pumps outlined in this policy and all criteria for a therapeutic Continuous Glucose Monitor (CGM) as outlined in the Glucose Monitors policy (LCD L33822).

Refer to the GENERAL section below, and to the CODING GUIDELINES section in the LCD-related Policy Article for additional information regarding supplies used in conjunction with insulin infusion pumps (E0784).

Claims with dates of service on or after January 01, 2017 for supply HCPCS codes A4221, A4222 and K0552, when used with an external infusion pump HCPCS code E0784 will be denied as incorrect coding.

V. Administration of other drugs if either of the following sets of criteria (1) or (2) are met:

- Criteria set 1:
  - Parenteral administration of the drug in the home is reasonable and necessary
  - An infusion pump is necessary to safely administer the drug
  - The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy
  - The therapeutic regimen is proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours
- Criteria set 2:
  - Parenteral administration of the drug in the home is reasonable and necessary
  - An infusion pump is necessary to safely administer the drug
  - The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the beneficiary to return to the practitioner's office prior to the beginning of each infusion
  - Systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information

Coverage for the administration of other drugs, based on criteria set (1) or (2), using an external infusion pump is limited to the following situations (A) - (J):

A. Administration of the anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine (non-liposomal) or vinblastine by continuous infusion over at least 8 hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens

B. Administration of narcotic analgesics (except meperidine) in place of morphine to a beneficiary with

intractable pain caused by cancer that has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic analgesics

C. Administration of the following antifungal or antiviral drugs: acyclovir, foscarnet, amphotericin B, and ganciclovir

D. Administration of parenteral inotropic therapy using the drugs dobutamine (J1250), milrinone (J2260) or dopamine (J1265) for beneficiaries with American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Stage D heart failure (HF) or New York Heart Association (NYHA) Class IV HF, if a beneficiary meets all of the following criteria:
    1. Remains symptomatic despite optimal guideline directed medical therapy (GDMT) as defined below; and,
    2. As "Bridge" therapy for patients eligible for and awaiting mechanical circulatory support (MCS)/cardiac transplantation, or as palliative care for patients not eligible for either MCS/cardiac transplantation; and,
    3. Prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure; and,
    4. There has been a documented improvement in beneficiary symptoms of heart failure while on the selected inotropic drug at the time of discharge from an inpatient or skilled nursing care facility; and,
    5. An evaluation every three months by the prescribing provider or a heart failure team with oversight by a cardiologist with training in the management of advanced heart failure, which documents the beneficiary's cardiac symptoms and the continuing response and need for therapy. The heart failure team or practitioner may have no financial relationship with the supplier.

    Guideline-directed medical therapy (GDMT) is compliance with optimal medical therapy as defined by ACCF/AHA guideline–recommended therapies (primarily Class I recommendations). These include the use of diuretics, ACE inhibitors or ARB antagonists, beta-blockers, aldosterone antagonists, hydralazine & isosorbide dinitrate, and statins, as appropriate.

    For an external infusion pump and related inotropic drugs covered prior to 12/01/2015, if the Medicare coverage criteria in effect on the initial date of service were met, the pump and drug(s) will continue to be covered for claims with dates of service on or after 12/01/2015 as long as the beneficiary continues to meet medical need.

E. Administration of epoprostenol (J1325) or treprostinil (J3285) for beneficiaries with pulmonary hypertension if they meet the following disease criteria:
    1. The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and
    2. The beneficiary has primary pulmonary hypertension or pulmonary hypertension, which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria must be met:
        a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and,
        b. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; and,

c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and,
d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.
e. Epoprostenol/treprostinil is administered using ambulatory infusion pump K0455. Claims for usage of infusion pumps other than K0455 will be denied as not reasonable and necessary.

F. Gallium nitrate (J1457) is covered for the treatment of symptomatic cancer-related hypercalcemia (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.). In general, beneficiaries with serum calcium (corrected for albumin) less than 12 mg/dl would not be expected to be symptomatic.
The recommended usage for gallium nitrate is daily for five consecutive days. Use for more than 5 days will be denied as not reasonable and necessary.
More than one course of treatment for the same episode of hypercalcemia will be denied as not reasonable and necessary.

G. Ziconotide (J2278) is covered for the management of severe chronic pain in beneficiaries for whom intrathecal (IT or epidural) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

H. Subcutaneous immune globulin (J1555, J1558, J1559, J1561, J1562, J1569, J1575, and J7799 (Cutaquig ®)) is covered only if criteria 1 and 2 are met:

1. The subcutaneous immune globulin preparation is a pooled plasma derivative which is approved for the treatment of primary immune deficiency disease; and,
2. The beneficiary has a diagnosis of primary immune deficiency disease. (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.)

Coverage of subcutaneous immune globulin applies only to those products that are specifically labeled as subcutaneous administration products. Intravenous immune globulin products are not covered under this LCD.

For the administration of subcutaneous immune globulins with the following HCPCS codes - J1555, J1559, J1561, J1562, and J1569, only an E0779 infusion pump is covered. If a different pump is used, it will be denied as not reasonable and necessary.

For the administration of subcutaneous immune globulin with HCPCS code J1575, only an E0781 infusion pump is covered. If a different pump is used, it will be denied as not reasonable and necessary.

For the administration of subcutaneous immune globulin with HCPCS code J1558 and J7799 (Cutaquig) either an E0779 or an E0781 infusion pump is covered. If a different pump is used, it will be denied as not reasonable and necessary.

I. Levodopa-Carbidopa enteral suspension (J7340) is only covered for treatment of motor fluctuations in beneficiaries with Parkinson's disease (PD), who meet all of the following criteria (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.):
1. The beneficiary has been evaluated by a neurologist, who prescribes and manages treatment with the drug; and,
2. Idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD features (tremor, rigidity, postural instability); and,
3. L-dopa responsive with clearly defined "On" periods; and,
4. Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite

medical therapy with levodopa-carbidopa, and at least one other class of anti-PD therapy i.e. COMT inhibitor or MAO-B inhibitor.

Levodopa-Carbidopa enteral suspension is not reasonable and necessary for patients with any of the following:

1. Atypical Parkinson's syndrome ("Parkinson's Plus" syndrome) or secondary Parkinson's; or
2. Non-levodopa responsive PD; or,
3. Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J.

Establishment of the transabdominal port with a PEG-J 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.

J. Blinatumomab (J9039) is only covered for:
1. Up to nine (9) cycles for adult and pediatric beneficiaries with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL); or
2. Up to four (4) cycles for adult and pediatric beneficiaries with B-cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%.

(Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.)

Maximum utilization is 875 units of service (UOS), which is equivalent to 25 vials per month. Claims for more than 875 UOS (25 vials) will be denied as not reasonable and necessary. Refer to the CODING GUIDELINES section of the related Policy Article for information regarding units of service.

GENERAL

External infusion pumps and related drugs and supplies will be denied as not reasonable and necessary when the criteria described by indication (I), (II), (III), (IV) or (V) are not met.

When an infusion pump is covered, the drug necessitating the use of the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, the beneficiary, or the rental cap has been reached, the drug necessitating the use of the pump and supplies are covered as long as the coverage criteria for the pump are met.

An external infusion pump and related drugs and supplies will be denied as not reasonable and necessary in the home setting for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion.

An infusion controller device (E1399) is not reasonable and necessary.

An IV pole (E0776) is covered only when a stationary infusion pump (E0791) is covered. It is considered not reasonable and necessary if it is billed with an ambulatory infusion pump (E0779, E0780, E0781, E0784, or K0455).

Supplies for the maintenance of a parenteral drug infusion catheter (A4221) or supplies for the maintenance for an insulin infusion pump (A4224) are covered during the period of covered use of an infusion pump. They are also covered for the weeks in between covered infusion pump use, not to exceed 4 weeks per episode.

Supplies used with an external infusion pump, A4222 and K0552 or supplies used with an insulin infusion pump (A4225) are covered during the period of covered use of an infusion pump. Allowance is based on the number of cassettes or bags (A4222) prepared or syringes (A4225, K0552) used. For intermittent infusions, no more than one cassette or bag is covered for each dose of drug. For continuous infusion, the concentration of the drug and the size of the cassette, bag, or syringe should be maximized to result in the fewest cassettes, bags, or syringes in keeping with good pharmacologic and medical practice.

Claims with dates of service on or after January 01, 2017 for supply HCPCS codes A4224 and A4225 used with an external infusion pump other than HCPCS code E0784 will be denied as incorrect coding.

Drugs and supplies that are dispensed but not used for completely unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.) are covered. Suppliers are expected to anticipate changing needs for drugs (e.g., planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule.

Charges for drugs administered by a DME infusion pump may only be billed 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 infusion drugs. Drugs and related supplies and equipment billed by a supplier who does not meet these criteria will be denied as not reasonable and necessary.

Compounded drugs NOC (J7999) billed with an external infusion pump will be denied as not reasonable and necessary. Refer to the CODING GUIDELINES section of the related Policy Article for information about J7999 coding requirements.

Claims for compounded drugs that do not use code Q9977 or J7999 will be denied as incorrect coding.

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 three (3) - 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

Background

Cutaquig (Octapharma Pharmazeutika Produktionsges, Vienna, Austria) is a ready-to-use, highly purified and concentrated (16.5%) polyvalent immunoglobulin G (IgG) solution for subcutaneous antibody replacement therapy in patients with primary humoral immunodeficiency disorders. Unique properties that set Cutaquig apart from other SCIG products include a lower viscosity compared to 20% SCIG products, and its sucrose-free, maltose-stabilization. The maltose-stabilization may allow Cutaquig to be an alternative for patients who do not respond well to or have a contraindication to sucrose-stabilized SCIG products; such as, patients with diabetes or who are at risk of renal insufficiency. Cutaquig was approved by the Food & Drug Administration (FDA) on December 12, 2018 for the treatment of primary humoral immunodeficiency in adults.

For full prescribing information, see: https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f3de095f-791a-85dc-7a14-ec7790cb13aa/spl-doc#section-3.3

Literature Analysis

In a phase 3, prospective, open-label, non-controlled, single-arm multicenter study[1], Kobayashi et al. investigated the efficacy, safety, tolerability, and pharmacokinetics of Cutaquig human immunoglobulin solution for subcutaneous (SC) administration. The primary efficacy outcome of the study was the prevention of serious bacterial infections (SBI) per person-year on treatment. Secondary outcomes included the tolerability and safety of Cutaquig, and Quality of Life (QoL) measures of patients using Cutaquig. A total of 61 participants with a median age of 34.0 (2.0–73.0) were enrolled in the study and were administered Cutaquig at bioequivelant doses (dose conversion factor of 1.5) to their previously stable IVIG dose. No SBIs occurred in any patients during the study period. There were 14 mild or moderate systemic adverse events (AEs) related to Cutaquig; however, none were classified as serious. The most common site reactions were erythema, swelling, and pruritus, and were mild (89.4%) or moderate (10.3%) in intensity. Health-related quality of life (HRQL) was assessed using the Child Health Questionnaire-Parent (CHQ-PF50) in patients <14 years and Short Form-36 (SF-36) in patients ≥14 years. There was no change in HRQL over time observed in patients <14 years of age; however, there was an increase in mean summary scores (physical health and mental health) noted in patients ≥14 years. The authors concluded that Cutaquig offered protection from infection, with no SBIs and a low rate of other infections with favorable efficacy and safety profiles.

In an 8 month (8-week wash-in/wash-out period plus 6-month efficacy period) phase 3, prospective, open-label, noncontrolled, single-arm, multicenter study[2], Latysheva et al. evaluated the safety of Octanorm (Cutaquig) administered SC once weekly in adult patients with PIDD previously treated with IVIg. The primary end point of this study was the rate of SBIs. Additional efficacy end points included the annual rate of all infections, use of antibiotics, hospitalizations due to infection, QoL assessment using the 36-item Short Form Health Survey (SF-36), and IgG

trough levels. A total of 25 patients (mean age 35.2 years) who had completed ≥4 infusions of any IVIG and had ≥2 IgG trough levels of ≥5.0 g/l during these infusions were recruited, 24 patients completed the study. All patients received Octanorm (Cutaquig) once weekly (±2 days with a minimum of 4 days between doses) by SC infusion via an infusion pump. No SBIs or hospitalizations due to infection were reported through the study period. IgG trough levels were above 5 g/l in all but one patient, in whom IgG trough level dropped below 5 g/l on one occasion during the efficacy period. The rate of all infections was 2.37 (95% CI: 1.24–4.54) per person-year during the efficacy period and 2.30 (95% CI: 1.25–4.20) per person-year in the entire treatment period, with all infections being mild or moderate in severity. Ten patients required antibiotics over 19 treatment episodes. QoL assessed using the SF-36 showed improvement in seven out of the eight multi-item scales with an improvement in mean physical and mental health summary scores. Three treatment-related systemic AEs (musculoskeletal discomfort, dizziness and headache) were reported. All were mild in severity, resolved within 1 day and did not lead to withdrawal of treatment or dosage adjustment. Most infusions (85.0%) were not associated with any infusion site reaction, with the remainder associated with mild or moderate infusion site reactions described as erythema, pruritus and contact dermatitis. The authors concluded that the present study suggested Octanorm (Cutaquig) is effective and safe in adult patients with PIDD; however, also noted several limitation of study, including small sample size with no formal sample size calculations, a lack of data on prophylactic antibiotic use prior to study enrollment, and a lack of a control group.

Evidence Based Guidelines

Canadian Blood Services and the National Advisory Committee of Blood and Blood Products[3]

Summary of recommendations (in relevant part):

SCIG was considered equally efficacious to IVIG in decreasing the frequency and duration of infection. […]

8. With respect to clinical efficacy and adverse events, there is insufficient evidence to recommend one manufacturer of IG over another for currently available products.

Level of evidence: I – II-2

Grade of recommendation: I

9. With respect to clinical efficacy for reducing infections, IVIG and SCIG preparations should be considered equivalent.

Level of evidence: I and II

Grade of recommendation: B

10. When deciding on route of administration, patient preference should be taken into account.

Level of evidence: III

Grade of recommendation: A

12. Start IVIG at a dose of 400 to 600mg/kg per 4 weeks or SCIG at a dose of 100 to 150 mg/kg per week in most

patients.

Level of evidence: III

Grade of recommendation: B

Professional Society Recommendations

Workgroup Report of the American Academy of Allergy, Asthma, & Immunology[4]

Summary of recommendations (in relevant part):

IG is indicated as replacement therapy for patients with PI characterized by absent or deficient antibody production; PI is an FDA-approved indication of immunoglobulin, for which all currently available products are licensed. Route of immunoglobulin administration must be based on patient characteristics; throughout life, certain patients may be more appropriate for IV or SC therapy depending on many factors, and patients should have access to either route as needed.

Australian Society of Clinical Immunology and Allergy[5]

Summary of recommendations (in relevant part):

Both intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg) replacement therapy comprise standard of care treatment and should be available for patients in Australia and New Zealand with antibody deficiency due to a primary immune deficiency (PID) disease or secondary immune deficiency. SCIg infusions for immunoglobulin replacement therapy (IRT) are efficacious, well tolerated, have a favourable safety profile and should be available to all patients where clinically appropriate, with relevant education, training and follow up care.

Analysis of Evidence
(Rationale for Determination)

Level of evidence

Quality: Moderate

Strength: Moderate

Weight: Moderate

Conclusion

Cutaquig is a SCIG preparation approved for the treatment of PIDD. Based on the review of published clinical literature, evidence based clinical guidelines, and professional society recommendations there is sufficient evidence

that SCIGs, such as Cutaquig, are safe and efficacious, and improve the health outcomes of beneficiaries with a diagnosis of PIDD. Therefore, the External Infusion Pumps LCD (L33794) will be extended to include coverage of Cutaquig as reasonable and necessary for the treatment of beneficiaries with a diagnosis of PIDD.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

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

HCPCS MODIFIERS:

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

GA – Waiver of liability statement issued as required by payer policy, individual case

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ – Item or service expected to be denied as not reasonable and necessary

JB - Administered Subcutaneously

JW - Drug amount discarded/not administered to any patient

KX - Requirements specified in the medical policy have been met

HCPCS CODES:

EQUIPMENT

Group 1 Codes:

CODE	DESCRIPTION
E0776	IV POLE
E0779	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION 8 HOURS OR GREATER
E0780	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION LESS THAN 8 HOURS
E0781	AMBULATORY INFUSION PUMP, SINGLE OR MULTIPLE CHANNELS, ELECTRIC OR BATTERY OPERATED, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT
E0784	EXTERNAL AMBULATORY INFUSION PUMP, INSULIN
E0791	PARENTERAL INFUSION PUMP, STATIONARY, SINGLE OR MULTI-CHANNEL
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS
K0455	INFUSION PUMP USED FOR UNINTERRUPTED PARENTERAL ADMINISTRATION OF MEDICATION, (E.G., EPOPROSTENOL OR TREPROSTINOL)

Group 2 Paragraph:

SUPPLIES

Group 2 Codes:

CODE	DESCRIPTION
A4221	SUPPLIES FOR MAINTENANCE OF NON-INSULIN DRUG INFUSION CATHETER, PER WEEK (LIST DRUGS SEPARATELY)
A4222	INFUSION SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)
A4223	INFUSION SUPPLIES NOT USED WITH EXTERNAL INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)
A4224	SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK
A4225	SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH
A4305	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF 50 ML OR GREATER PER HOUR
A4306	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF LESS THAN 50 ML PER HOUR

CODE	DESCRIPTION
A4602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 1.5 VOLT, EACH
A9270	NON-COVERED ITEM OR SERVICE
A9274	EXTERNAL AMBULATORY INSULIN DELIVERY SYSTEM, DISPOSABLE, EACH, INCLUDES ALL SUPPLIES AND ACCESSORIES
K0552	SUPPLIES FOR EXTERNAL NON-INSULIN DRUG INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH
K0601	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 1.5 VOLT, EACH
K0602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 3 VOLT, EACH
K0603	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, ALKALINE, 1.5 VOLT, EACH
K0604	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 3.6 VOLT, EACH
K0605	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 4.5 VOLT, EACH

Group 3 Paragraph:

DRUGS

Group 3 Codes:

CODE	DESCRIPTION
G0068	PROFESSIONAL SERVICES FOR THE ADMINISTRATION OF ANTI-INFECTIVE, PAIN MANAGEMENT, CHELATION, PULMONARY HYPERTENSION, AND/OR INOTROPIC INFUSION DRUG(S) FOR EACH INFUSION DRUG ADMINISTRATION CALENDAR DAY IN THE INDIVIDUAL'S HOME, EACH 15 MINUTES
G0069	PROFESSIONAL SERVICES FOR THE ADMINISTRATION OF SUBCUTANEOUS IMMUNOTHERAPY FOR EACH INFUSION DRUG ADMINISTRATION CALENDAR DAY IN THE INDIVIDUAL'S HOME, EACH 15 MINUTES
G0070	PROFESSIONAL SERVICES FOR THE ADMINISTRATION OF CHEMOTHERAPY FOR EACH INFUSION DRUG ADMINISTRATION CALENDAR DAY IN THE INDIVIDUAL'S HOME, EACH 15 MINUTES
J0133	INJECTION, ACYCLOVIR, 5 MG
J0285	INJECTION, AMPHOTERICIN B, 50 MG
J0287	INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG

CODE	DESCRIPTION
J0288	INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG
J0289	INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG
J1170	INJECTION, HYDROMORPHONE, UP TO 4 MG
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
J1265	INJECTION, DOPAMINE HCL, 40 MG
J1325	INJECTION, EPOPROSTENOL, 0.5 MG
J1455	INJECTION, FOSCARNET SODIUM, PER 1000 MG
J1457	INJECTION, GALLIUM NITRATE, 1 MG
J1555	INJECTION, IMMUNE GLOBULIN (CUVITRU), 100 MG
J1558	INJECTION, IMMUNE GLOBULIN (XEMBIFY), 100 MG
J1559	INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG
J1561	INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1562	INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG
J1569	INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G., LIQUID), 500 MG
J1570	INJECTION, GANCICLOVIR SODIUM, 500 MG
J1575	INJECTION, IMMUNE GLOBULIN/HYALURONIDASE, (HYQVIA), 100 MG IMMUNEGLOBULIN
J1817	INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS
J2175	INJECTION, MEPERIDINE HYDROCHLORIDE, PER 100 MG
J2260	INJECTION, MILRINONE LACTATE, 5 MG
J2270	INJECTION, MORPHINE SULFATE, UP TO 10 MG
J2274	INJECTION, MORPHINE SULFATE, PRESERVATIVE-FREE FOR EPIDURAL OR INTRATHECAL USE, 10 MG
J2278	INJECTION, ZICONOTIDE, 1 MICROGRAM
J3010	INJECTION, FENTANYL CITRATE, 0.1 MG
J3285	INJECTION, TREPROSTINIL, 1 MG
J7340	CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION, 100 ML
J7799	NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME
J7999	COMPOUNDED DRUG, NOT OTHERWISE CLASSIFIED

CODE	DESCRIPTION
J9000	INJECTION, DOXORUBICIN HYDROCHLORIDE, 10 MG
J9039	INJECTION, BLINATUMOMAB, 1 MICROGRAM
J9040	INJECTION, BLEOMYCIN SULFATE, 15 UNITS
J9065	INJECTION, CLADRIBINE, PER 1 MG
J9100	INJECTION, CYTARABINE, 100 MG
J9190	INJECTION, FLUOROURACIL, 500 MG
J9200	INJECTION, FLOXURIDINE, 500 MG
J9360	INJECTION, VINBLASTINE SULFATE, 1 MG
J9370	VINCRISTINE SULFATE, 1 MG

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 to justify 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

American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Stage D heart failure (HF) patients have advanced structural heart disease and marked symptoms of heart failure at rest despite maximal medical therapy, and require specialized interventions. J Am Coll Cardiol. 2001;38(7):2101-2113.

New York Heart Association (NYHA) Heart Failure Symptom Class IV patients are unable to carry on any physical activity without discomfort resulting from symptoms of heart failure such as dyspnea, or have symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases. The Criteria Committee of the New York Heart Association. (1994).

Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. (9th ed.). Boston: Little, Brown & Co. pp. 253–256.

Bridge Therapy: For purposes of this policy, bridge therapy is not time-circumscribed.

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

N/A

Bibliography

1. Kobayashi RH, Gupta S, Melamed I, et al. Clinical Efficacy, Safety and Tolerability of a New Subcutaneous Immunoglobulin 16.5% (Octanorm [Cutaquig]) in the Treatment of Patients With Primary Immunodeficiencies. *Front Immunol.* 2019;10:40.
2. Latysheva E, Rodina Y, Sizyakina L, et al. Efficacy and safety of octanorm (cutaquig) in adults with primary immunodeficiencies with predominant antibody deficiency: a prospective, open-label study. *Immunotherapy*. 2020 Mar 26. doi: 10.2217/imt-2020-0012. [Epub ahead of print].
3. Shehata N, Palda V, Bowen T, et al. The use of immunoglobulin therapy for patients with primary immune deficiency: an evidence-based practice guideline. *Transfus Med Rev.* 2010;24:S28-S50.
4. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: a review of

evidence. *J Allergy Clin Immunol.* 2017;139(3):S1-S46.
5. Australian Society of Clinical Immunology and Allergy Position Statement - Subcutaneous Immunoglobulin (SCIg). 2017; https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Position_Statement_SCIg_2017.pdf. Accessed November 15, 2019
6. Bousfiha A, Jeddane L, Picard C, et al. The 2017 IUIS Phenotypic Classification for Primary Immunodeficiencies. *J Clin Immunol.* 2018;38(1):129-143.
7. Dantal J. Intravenous immunoglobulins: in-depth review of excipients and acute kidney injury risk. *Am J Nephrol.* 2013;38(4):275-284.
8. Dhainaut F, Guillaumat PO, Dib H, et al. In vitro and in vivo properties differ among liquid intravenous immunoglobulin preparations. *Vox Sang.* 2013;104(2):115-126.
9. Duff C, Ochoa D, Riley P, Murphy E, Zampelli A. Importance of ancillary supplies for subcutaneous immunoglobulin infusion: management of the local infusion site. *J Infus Nurs.* 2013;36(6):384-390.
10. The Immune Deficiency Foundation, National Immunoglobulin Treatment Survey. 2013; https://www.primaryimmune.org/sites/default/files/2013_IDF_National_Immunoglobulin_Treatment_Survey.pdf Accessed January 14, 2020.
11. Gelbmann N, Zochling A, Pichotta A, et al. Octanorm [cutaquig], a new immunoglobulin (human) subcutaneous 16.5% solution for injection (165mg/mL) - Biochemical characterization, pathogen safety, and stability. *Biologicals.* 2019;60:60-67.
12. Kobrynski L. Subcutaneous immunoglobulin therapy: a new option for patients with primary immunodeficiency diseases. *Biologics.* 2012;6:277-287.
13. Octapharma. Cutaquig (Immune Globulin Subcutaneous (Human) – hipp), 16.5% solution Highlights of Prescribing Information.U.S. Food and Drug Administration. https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f3de095f-791a-85dc-7a14-ec7790cb13aa/spl-doc#section-3.3
14. Tahara Y, Fukuda M, Yamamoto Y, et al. Metabolism of intravenously administered maltose in renal tubules in humans. *Am J Clin Nutr.* 1990;52(4):689-693.
15. Toyota T, Goto Y, Sato S, Shimojo Y, Takahashi K. Maltose metabolism in diabetic state. *Tohoku J Exp Med.* 1974;114(1):61-69.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
09/15/2020	R20	**Revision Effective Date: 09/15/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Information related to HCPCS code E0787, which is invalid for Medicare submission for DOS on or after 9/15/2020 Added: Information regarding external ambulatory insulin infusion pumps that incorporate dose rate adjustment using therapeutic continuous glucose sensing CODING INFORMATION: Removed: HCPCS code E0787 from Group 1 HCPCS Codes Removed: HCPCS code A4226 from Group 2 HCPCS	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Codes *09/17/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are due to Non-Discretionary HCPCS code changes rendering them invalid for submission to Medicare.*	
09/06/2020	R19	**Revision Effective Date: 09/06/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: J7799 (Xembify) to J1558 for Dates of Service on or after 07/01/2020 Clarification: Coverage for Xembify effective for Dates of Service on or after 07/3/2019 (FDA Approval Date) Added: Cutaquig to coverage criteria V(H) effective for Dates of Service on or after 12/12/2018 (FDA Approval Date) Added: Statement regarding covered pumps for Cutaquig SUMMARY OF EVIDENCE: Added: Information related to Cutaquig ANALYSIS OF EVIDENCE: Added: Information related to Cutaquig CODING INFORMATION: Added: HCPCS code J1558 to Group 3 table BIBLIOGRAPHY: Added: Section related to Cutaquig RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments document A58288	• Provider Education/Guidance • Reconsideration Request
05/31/2020	R18	**Revision Effective Date: 05/31/2020** Revision History Number R18 was a duplicate of Revision History Number R17 and did not represent additional updates.	• Provider Education/Guidance • Reconsideration Request
05/31/2020	R17	**Revision Effective Date: 05/31/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Statement regarding base and related accessories and supplies (BPM Ch. 15, Section 110.3)	• Provider Education/Guidance • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Revised: "physician" to "practitioner" Added: Xembify® to coverage criteria V(H) Added: Statement regarding covered pumps for Xembify® Revised: "physicians" to "practitioners" GENERAL: Revised: Order information as a result of Final Rule 1713 REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners" SUMMARY OF EVIDENCE: Added: Information related to Xembify® ANALYSIS OF EVIDENCE: Added: Information related to Xembify® CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information" DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: Prescriptions (orders) to SWO BIBLIOGRAPHY: Added: Section related to Xembify® RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments document	
01/01/2020	R16	**Revision Effective Date: 01/01/2020** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: Coverage information for E0787 Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA Added: Statement to refer to ICD-10 code list in the LCD-related Policy Article Added: E0787 to IV pole paragraph HCPCS CODES: Added: E0787 to Group 1 and A4226 to Group 2	• Revisions Due To CPT/HCPCS Code Changes
01/01/2019	R15	**Revision Effective Date: 01/01/2019**	• Revisions Due To

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Statement to refer to diagnosis code section below Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article Revised: Effective for claims with dates of service on or after 03/29/2018 allow additional cycles of Blinatumomab (J9039) HCPCS CODES: Added: HCPCS codes G0068, G0069, and G0070 to Group 3 codes ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Moved: Statement about noncovered diagnosis code moved to LCD-related Policy Article noncovered diagnosis section per CMS instruction	CPT/HCPCS Code Changes • Reconsideration Request • Other (ICD-10 code relocation per CMS instruction)
03/29/2018	R14	**Revision Effective Date: 03/29/2018** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: Expanded Coverage Indications for Blinatumomab CODING INFORMATION: Added: ICD-10 code to Group 5 *06/07/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the: LCD are applicable as noted in this policy.*	• Provider Education/Guidance
01/01/2018	R13	**Revision Effective Date: 01/01/2018** HCPCS CODES: Removed: J1555 from Group 3: Paragraph Added: J1555 to Group 3: Codes *04/19/2018: 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,*	• Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		therefore not all the fields included on the: LCD are applicable as noted in this policy.	
07/11/2017	R12	**Revision Effective Date: 07/11/2017** HCPCS CODES: Revised: Short descriptors of J2274 and J3010. Policy indicates long descriptors which have not been revised. 12/21/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Revisions Due To CPT/HCPCS Code Changes
07/11/2017	R11	**Revision Effective Date: 07/11/2017** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Expanded coverage for adult and pediatric patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL) Revised: Clarified 875 UOS equals 25 vials per month HCPCS CODE: Added: J1555 (Effective 01/01/2018) ICD-10 Codes that Support Medical Necessity: Added: C91.00 to Group 5 coverage 11/30/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes • Revisions Due To CPT/HCPCS Code Changes • Reconsideration Request
01/01/2017	R10	**Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Typographical error K0522 to correct code of K0552 Added: Coverage for Cuvitru (J7799) - effective 9/13/2016 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:	• Provider Education/Guidance • Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Revised: verbiage "prior to" to "to justify" Medicare reimbursement	
01/01/2017	R9	**Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and Directions to Standard Documentation Requirements Added: Billing instructions for A4224 and A4225 Added: General Requirements Revised: Refill Requirements Revised: Drug Waste verbiage HCPCS MODIFIERS: Added: Codes A4224 and A4225 Revised: Code narratives for HCPCS A4221, J7340 and K0552 DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and Directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Information from Miscellaneous Removed: PIM citation from under Appendices SOURCES OF INFORMATION AND BASIS FOR DECISION: Removed: Links RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R8	**Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Denial verbiage for JW Modifier when coverage criteria not met HCPCS MODIFIERS: Added: JW Modifier DOCUMENTATION REQUIREMENTS: Added: JW Modifier instructions	• Provider Education/Guidance • Other (Addition of JW Modifier)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2016	R7	**Revision Effective Date: 10/01/2016:** ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: New ICD-10 Codes to Group 1 per Annual ICD-10 Codes Updates Deleted: Non-valid ICD-10 Codes per Annual ICD-10 Codes Updates	• Revisions Due To ICD-10-CM Code Changes
07/01/2016	R6	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.	• Change in Assigned States or Affiliated Contract Numbers
01/01/2016	R5	Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: HCPCS CODE J1575 to Subcutaneous immune globulin coverage Added: HCPCS CODE J7340 to Levodopa-Carbidopa coverage Added: HCPCS CODE J9039 to Blinatumomab coverage Updated: HCPCS Code Q9977 crosswalked to J7999 HCPCS CODES: Group 3 Codes: Added: HCPCS Code J1575, J7340, J9039 (previously J7799) Deleted: HCPCS Code Q9977 ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Group 3 Codes: Added: ICD-10 Code D83.1 to Group 3 Codes Group 3 Paragraph: Added: HCPCS Code J1575 Group 4 Paragraph: Added: HCPCS Code J7340 Group 5 Paragraph: Added: HCPCS Code J9039 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015)	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes • Revisions Due To ICD-10-CM Code Changes
12/01/2015	R4	Revision Effective Date: 12/01/2015 Draft LCD promoted to final	• Provider

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Criteria for reimbursement of intravenous inotropic medication Added: Denial for Compound Drugs NOC Q9977 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Instructions for Q9977	Education/Guidance
10/01/2015	R3	Revision Effective Date: 01/01/2015 (March 2015 Publication) COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Maximum utilization for Blinatumomab; inadvertently omitted DOCUMENTATION REQUIREMENTS: Revised: Instructions for Revised DIF Added: Instructions for Recertification DIF	• Provider Education/Guidance • Typographical Error
10/01/2015	R2	Revision Effective Date: 10/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Coverage for levodopa-carbidopa enteral suspension (effective for dates of service on or after 01/09/2015) Added: Coverage for blinatumomab (effective for dates of service on or after 12/03/2014) Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility HCPCS CODES AND MODIFIERS: Added: Codes A4602 and J2274 Deleted: Codes J2271 and J2275 ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Group 4 Paragraph: Added: HCPCS Code for levodopa-carbidopa enteral suspension Group 4 Codes: Added: ICD-10 Code G20 Group 5 Paragraph: Added: HCPCS Code for blinatumomab Group 5 Codes: C91.02 Added: ICD-10 Code DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Added: Instructions for equipment retained from a prior payer Added: Repair /Replacement section	
10/01/2015	R1	Revision Effective Date: 10/01/2015 DOCUMENTATION REQUIREMENTS: Removed: Suggested form for inotrope information	• Provider Education/Guidance

Associated Documents

Attachments

EIP DIF CMS 10125
(PDF - 88 KB)

Related Local Coverage Documents

Article(s)
A52507 - External Infusion Pumps - Policy Article
A58288 - Response to Comments: External Infusion Pumps – DL33794
A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents

N/A

Public Version(s)

Updated on 09/08/2020 with effective dates 09/15/2020 - N/A
Updated on 07/17/2020 with effective dates 09/06/2020 - 09/14/2020
Updated on 04/10/2020 with effective dates 05/31/2020 - 09/05/2020
Updated on 12/13/2019 with effective dates 01/01/2020 - 05/30/2020
Updated on 02/08/2019 with effective dates 01/01/2019 - 12/31/2019
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:
External Infusion Pumps - Policy Article (A52507)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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

Article Information

General Information

Article ID
A52507

Original ICD-9 Article ID
A19713
A20210
A47226
A19834

Article Title
External Infusion Pumps - Policy 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").

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 provides 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 prior to delivery, 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.

DME INFORMATION FORM (DIF)

A DME Information Form (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.

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 (J1555, J1558, J1559, J1561, J1562, J1569, and J7799 (Cutaquig®)) 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 (J1558, J1575 and J7799 (Cutaquig)) 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.

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 Units of Service (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 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 that 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 LCD have been met.

KX, GA, GY and GZ MODIFIERS:

For all claims for external insulin infusion pumps (E0784) and insulin (J1817), if the results of the beneficiary's C-peptide level or beta cell autoantibody test meet the requirements outlined in section IV of the Coverage Indications, Limitations, and/or Medical Necessity in the related LCD, a KX modifier should be added to the HCPCS code.

In the situation above describing use of the KX modifier, if all of the coverage criteria 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.

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 pump when it is used to administer epoprostenol/treprostinil, or with an E0779 pump used to administer subcutaneous immune globulin. The reservoir may be either glass or plastic and includes the needle for drawing up the drug. 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.

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). 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). 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 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 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 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).

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 two 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 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 must be submitted using the HCPCS code J7799 (NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME). One UOS equals one hundred (100) mg.

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

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 section on "**Coverage Indications, Limitations and/or Medical Necessity**" for other coverage criteria and payment information.

For HCPCS codes E0784 and J1817:

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
E08.00	Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E08.01	Diabetes mellitus due to underlying condition with hyperosmolarity with coma
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease
E08.29	Diabetes mellitus due to underlying condition with other diabetic kidney complication
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy

ICD-10 CODE	DESCRIPTION
	without macular edema
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3291	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye
E08.3292	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, left eye
E08.3293	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3299	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3391	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E08.3392	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E08.3393	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3399	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye

ICD-10 CODE	DESCRIPTION
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3491	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye
E08.3492	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, left eye
E08.3493	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3499	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye
E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye
E08.3521	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E08.3522	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E08.3523	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E08.3529	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E08.3531	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E08.3532	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E08.3533	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E08.3539	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E08.3541	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy

ICD-10 CODE	DESCRIPTION
	with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E08.3542	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E08.3543	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E08.3549	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E08.3551	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, right eye
E08.3552	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, left eye
E08.3553	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, bilateral
E08.3559	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, unspecified eye
E08.3591	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye
E08.3592	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye
E08.3593	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral
E08.3599	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, unspecified eye
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E08.37X1	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye
E08.37X2	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye
E08.37X3	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral
E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, unspecified eye
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication

ICD-10 CODE	DESCRIPTION
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E08.59	Diabetes mellitus due to underlying condition with other circulatory complications
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.620	Diabetes mellitus due to underlying condition with diabetic dermatitis
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma
E08.649	Diabetes mellitus due to underlying condition with hypoglycemia without coma
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09.00	Drug or chemical induced diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E09.01	Drug or chemical induced diabetes mellitus with hyperosmolarity with coma
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.11	Drug or chemical induced diabetes mellitus with ketoacidosis with coma
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy

ICD-10 CODE	DESCRIPTION
E09.22	Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease
E09.29	Drug or chemical induced diabetes mellitus with other diabetic kidney complication
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3291	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E09.3292	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
ICD-10 CODE	DESCRIPTION
E09.3293	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3299	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3391	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E09.3392	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E09.3393	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral

ICD-10 CODE	DESCRIPTION
E09.3399	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3491	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E09.3492	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E09.3493	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3499	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E09.3521	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E09.3522	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E09.3523	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E09.3529	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E09.3531	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E09.3532	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy

ICD-10 CODE	DESCRIPTION
	with traction retinal detachment not involving the macula, left eye
E09.3533	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E09.3539	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E09.3541	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E09.3542	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E09.3543	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E09.3549	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E09.3551	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E09.3552	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E09.3553	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E09.3559	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E09.3591	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E09.3592	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E09.3593	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E09.3599	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E09.37X1	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E09.37X2	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye

ICD-10 CODE	DESCRIPTION
E09.37X3	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy
E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E09.59	Drug or chemical induced diabetes mellitus with other circulatory complications
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.641	Drug or chemical induced diabetes mellitus with hypoglycemia with coma
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication

ICD-10 CODE	DESCRIPTION
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complications
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye

ICD-10 CODE	DESCRIPTION
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
ICD-10 CODE	DESCRIPTION
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral

ICD-10 CODE	DESCRIPTION
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye

ICD-10 CODE	DESCRIPTION
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease

ICD-10 CODE	DESCRIPTION
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with

ICD-10 CODE	DESCRIPTION
	macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral

ICD-10 CODE	DESCRIPTION
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
ICD-10 CODE	DESCRIPTION
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified

ICD-10 CODE	DESCRIPTION
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.01	Other specified diabetes mellitus with hyperosmolarity with coma
E13.10	Other specified diabetes mellitus with ketoacidosis without coma
E13.11	Other specified diabetes mellitus with ketoacidosis with coma
E13.21	Other specified diabetes mellitus with diabetic nephropathy
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease
E13.29	Other specified diabetes mellitus with other diabetic kidney complication
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema

ICD-10 CODE	DESCRIPTION
E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3291	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E13.3292	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E13.3293	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3299	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3391	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E13.3392	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E13.3393	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3399	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy

ICD-10 CODE	DESCRIPTION
	with macular edema, left eye
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3491	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E13.3492	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E13.3493	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3499	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E13.3521	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E13.3522	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E13.3523	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E13.3529	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E13.3531	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E13.3532	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E13.3533	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E13.3539	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye

ICD-10 CODE	DESCRIPTION
E13.3541	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E13.3542	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E13.3543	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E13.3549	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E13.3551	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E13.3552	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E13.3553	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E13.3559	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E13.3591	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E13.3592	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E13.3593	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E13.3599	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E13.36	Other specified diabetes mellitus with diabetic cataract
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
ICD-10 CODE	DESCRIPTION
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following

ICD-10 CODE	DESCRIPTION
	treatment, unspecified eye
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.51	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
E13.59	Other specified diabetes mellitus with other circulatory complications
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy
E13.618	Other specified diabetes mellitus with other diabetic arthropathy
E13.620	Other specified diabetes mellitus with diabetic dermatitis
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
E13.628	Other specified diabetes mellitus with other skin complications
E13.630	Other specified diabetes mellitus with periodontal disease
E13.638	Other specified diabetes mellitus with other oral complications
E13.641	Other specified diabetes mellitus with hypoglycemia with coma
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia
E13.69	Other specified diabetes mellitus with other specified complication
E13.8	Other specified diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs

Group 2 Paragraph:

For HCPCS code J1457:

Group 2 Codes:

ICD-10 CODE	DESCRIPTION
E83.52	Hypercalcemia

Group 3 Paragraph:

For HCPCS codes J1555, J1558, J1559, J1561, J1562, J1569, J1575 and J7799 (Cutaquig):

Group 3 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

ICD-10 CODE	DESCRIPTION
G11.3	Cerebellar ataxia with defective DNA repair

Group 4 Paragraph:

For HCPCS code for J7340:

Group 4 Codes:

ICD-10 CODE	DESCRIPTION
G20	Parkinson's disease

Group 5 Paragraph:

For HCPCS code for J9039:

Group 5 Codes:

ICD-10 CODE	DESCRIPTION
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

For the specific HCPCS codes indicated above, all ICD-10 codes that are not specified in the previous section.

For all other HCPCS codes, ICD-10 codes are not specified.

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
09/15/2020	R17	**Revision Effective Date: 09/15/2020** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: Information related to HCPCS code E0787, which is invalid for Medicare submission for DOS on or after 09/15/2020 MODIFIERS: Removed: HCPCS code E0787 CODING GUIDELINES: Removed: Guidelines for HCPCS codes E0787 and A4226 Added: Coding guidelines for insulin infusion pumps with integrated continuous glucose sensing capabilities ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Removed: HCPCS code E0787 from Group 1 Paragraph *09/17/2020: 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.*
09/06/2020	R16	**Revision Effective Date: 09/06/2020** MODIFIERS: Added: J1558 and J7799 (Cutaquig) to the JB modifier requirements CODING GUIDELINES: Added: Billing instructions for Xembify based on DOS Added: UOS billing instruction for J7799 (Cutaquig) ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: J1558 and J7799 (Cutaquig) to the Group 3 paragraph *07/23/2020: 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.*

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
05/31/2020	R15	**Revision Effective Date: 05/31/2020** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: "physician's" to "practitioner's" Removed: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g) section 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 DME INFORMATION FORM (DIF): Revised: "physician" to "practitioner" MODIFIERS: Added: J7799 (Xembify®) to the JB modifier requirements CODING GUIDELINES: Revised: 'detailed order' to 'standard written order' Added: UOS billing instruction for J7799 (Xembify®) ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: J7799 (Xembify®) to the Group 3 paragraph *04/16/2020: 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.*
01/01/2020	R14	**Revision Effective Date: 01/01/2020** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES Added: PDAC approval requirement for HCPCS code E0787 KX, GA, GY and GZ MODIFIERS: Added: HCPCS code E0787 CODING GUIDELINES: Added: Coding information for E0787 and A4226 Added: All-inclusive statement to A4224 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" Added: E0787 to Group 1 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" *12/19/2019: 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.*
08/13/2019	R13	**Revision Effective Date: 08/13/2019** ICD-10 CODES THAT ARE COVERED: Added: Codes D80.2, D80.3, D80.4, D80.6, D80.7, D81.5, D82.1, D82.4, and

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		G11.3 to Group 3 per update to Medicare Benefit Policy Manual, Chapter 15, section 50.6 *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.*
01/01/2019	R12	**Revision History Effective Date: 01/01/2019** CODING GUIDELINES: Added: Professional services description ICD-10 CODES THAT ARE COVERED: Added: All diagnosis codes formerly listed in the LCD ICD-10 CODES THAT ARE NOT COVERED: Added: Notation excluding all unlisted diagnosis codes from coverage *02/14/2019: 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.*
01/01/2018	R11	**Revision Effective Date: 01/01/2018** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: Clarified claims adjudication of pumps when an infusion is started in the physician's office *06/07/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.*
01/01/2018	R10	**Revision Effective Date: 01/01/2018** CODING GUIDELINES: Added: Treprostinil to K0455 Added: HCPCS code J9039 Updated: Levodopa-Carbidopa UOS Removed: Coding instructions for HCPCS Q9977 for DOS between July 01, 2015 through December 31, 2015 *04/19/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.*
07/11/2017	R9	Revision Effective Date: 07/11/2017 CODING GUIDELINES: Revised: Clarified blinatumomab UOS, and added instructions for a 7-day

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		infusion protocol Revised: Added HCPCS code J1555 for CUVITRU effective for claims on or after 01/01/2018 11/30/2017: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.
01/01/2017	R8	Revision Effective Date: 01/01/2017 CODING GUIDELINES: Revised: A4221 descriptor to include subcutaneous infusion catheter Revised: Typographical error K0522 to correct code of K0552 Added: Coding guidelines for Cuvitru (J7799) - effective 9/13/2016
01/01/2017	R7	Revision Effective Date: 01/01/2017 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Replaced: A4221 with A4224 when using catheter insertion devices POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: 42 CFR 410.38(g), DIF and Modifiers requirements CODING GUIDELINES: Added: Billing instructions for A4224 and A4225 RELATED LOCAL COVERAGE DOCUMENTS: Added: The LCD-related Standard Documentation Requirements Language Article
07/01/2016	R6	Revision Effective Date: 07/01/2016 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Language regarding payment rules for infusion drugs started in a physician’s office or hospital outpatient department. – Effective 4/25/2016
07/01/2016	R5	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
01/01/2016	R4	Revision Effective Date: 01/01/2016 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/5/2015) CODING GUIDELINES: Updated: HCPCS Code Q9977 cross-walked to J7999 Added: J1575, J7340, J9039 (previously J7799)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Updated: Billing instructions, by HCPCS code, based on dates of service.
12/01/2015	R3	Revision Effective Date: 12/01/2015 Draft Policy Article promoted to final CODING GUIDELINES: Added: Q9977 (Compounded drug NOC)
10/01/2015	R2	Revision Effective Date: 01/01/2015 (March 2015 Publication) CODING GUIDELINES: Revised: Units of service for blinatumomab Added: Instructions for least wastage of blinatumomab; inadvertently omitted from previous publication
10/01/2015	R1	Revision Effective Date: 10/01/2015 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: “When required by state law” from ACA new prescription requirements Revised: Face-to-Face Requirements for treating practitioner CODING GUIDELINES: Added: Coding requirements for lithium batteries Deleted: References to codes J2271 and J2275 Added: Levodopa-Carbidopa enteral suspension (effective for dates of service on or after 01/09/2015) Added: Blinatumomab (effective for dates of service on or after 12/03/2014)

Associated Documents

Related Local Coverage Document(s)

Article(s)
A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs
LCD(s)
L33794 - External Infusion Pumps

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)

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