

External Insulin Infusion Pumps

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

An external insulin infusion pump is used to deliver insulin into patients with diabetes, and several insulin pump systems include a built-in CGM component.

MEDICARE ADVANTAGE POLICY CRITERIA

| | |
|---|---|
| CMS Coverage Manuals* | None |
| National Coverage Determinations (NCDs)* | For general coverage criteria (including non-coverage of an implantable infusion pump for diabetes) (<i>the LCD below supplements this NCD, providing the same coverage criteria, as well as providing further clarifying details</i>): <ul style="list-style-type: none"> ✓ Infusion Pumps (280.14) (Criterion 1.e) |

**Noridian Healthcare
Solutions (Noridian) Local
Coverage Determinations
(LCDs) and Articles (LCAs)***

For **additional guidance for coverage** (for the HCPCS code combination of E0784 + K0554, see below):

- ✓ External Infusion Pumps ([L33794](#)) (See criterion IV A-D within the LCD, and the requirements for continued coverage of an external insulin pump.)

The LCA for External Infusion Pumps - Policy Article (A52507) provides coding guidance and can be accessed directly from the LCD. According to A52507, “Use code J1817 for insulin administered through an external insulin pump (E0784).” According to L33794, if criteria are not met “the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.” Therefore, J1817 would only be allowed if the coverage criteria for the insulin pump is met. If the coverage criteria are not met, the insulin for the pump would not be allowed as a “related” item or service.

Additional criteria for the HCPCS code combination E0784 + K0554:

“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 Monitor policy (LCD L33822)....” (LCD L33794)

- ✓ Glucose Monitors ([L33822](#)) (See this LCD **and** the LCD L33794 above)

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Either C-peptide test levels or Beta cell autoantibody test results; and,
- One of the following:
 - Documentation of a completed a diabetes education program, multiple daily injections of insulin with frequent self-adjustments for at least 6 months prior to insulin pump use, and has documented glucose self-testing an average of at least 4 times/day during the 2 months prior to pump use, and meets one or more of the following while on multiple injection regimen:
 - 1. HbA1C > 7%
 - 2. History of recurring hypoglycemia
 - 3. Wide fluctuations in blood glucose before mealtime
 - 4. Dawn phenomenon with fasting blood sugars frequently > 200 mg/dL
 - 5. History of severe glycemic excursions; or
 - If the beneficiary was on an external insulin infusion pump prior to enrollment in Medicare, documentation must support frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.
- Device name.

REGULATORY STATUS

As of the date this medical policy was is reviewed and published, as of September 15, 2020, HCPCS code E0787 is invalid for Medicare use. The t:slim X2 Insulin Pump (Tandem Diabetes Care) was approved by the U.S. Food and Drug Administrative (FDA) in 2018 and is reported with HCPCS code E0784 plus K0554. Other devices reported with HCPCS code E0784 include the MiniMed 530G, MiniMed 670G and the Real-Time Revel (Medtronic).

CROSS REFERENCES

None

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, [§110.1 - Definition of Durable Medical Equipment, C. Replacement](#)
2. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, [§110.1 - Definition of Durable Medical Equipment, B and B.2](#)
3. U.S. Food and Drug Administration (FDA) website; Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180008A.pdf [Last Cited 04/17/2020]

CODING

| Codes | Number | Description |
|-------|--------|--|
| CPT | None | |
| HCPCS | E0784 | External Ambulatory Infusion Pump, Insulin |

| Codes | Number | Description |
|--------------|---------------|--|
| | E0787 | External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing <i>(Not valid for Medicare purposes)</i> |

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.