MN.027.A External Infusion Pump, Insulin

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Thank you for being a valued provider for members in one or more of our health plans: Jefferson Health Plans Medicare Advantage, Jefferson Health Plans Individual and Family Plans, Jefferson Health Plans CHIP, and/or Jefferson Health Plans EverWell (our Medicaid plan).

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans lines of business unless noted below.

☒ Jefferson Health Plans Medicare Variation.

Please reference the Medicare LCD L33794 for Jefferson Health Plans Medicare Variations for Guidelines:
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794

POLICY STATEMENT

External insulin infusion pumps are deemed medically necessary when the criteria outlined in InterQual® are met, along with the additional clinical criteria listed below:

1. The member has documented Diabetes mellitus(DM) type 1 or 2 requiring intensive insulin therapy(insulin administration at least 3 times per day):

    - History of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL); ***or***

- Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL); ***or***
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; ***or***
- History of severe glycemic excursions.

2. Member or caregiver have demonstrated ability and commitment to comply with a regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise. Member or caregiver has completed diabetic education and is comfortable with carbohydrate counting and diabetic meal planning; ***and***

3. Member or caregiver can manage device technology, ***and***

4. The pump is ordered by and the follow-up care of the member is managed by qualified practitioners as appropriate according to federal and state MA policy (See 42 CFR §440.70 a) with experience in managing persons with insulin infusion pumps (such as an endocrinologist) and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of insulin infusion pumps.

Documentation of continued medical necessity of the external insulin infusion pump requires that member is seen and evaluated by the treating physician at least once every 6 months and that the benefits from the insulin pump use are included in the record (such as improved diabetes control-HBA1C). If the member's condition does not show improvement and there is evidence of noncompliance, extension of approval is not considered medically necessary.

A replacement of an external insulin infusion pump is considered medically necessary:

1. For children who require a larger insulin reservoir.
2. The pump is out of warranty, malfunctioning, and cannot be refurbished.
3. Personal Diabetes Monitor (PDM) for Omnipod System is out of warranty, malfunctioning, and cannot be refurbished.4. Replacement of a functioning insulin pump with a newer model(an upgrade-sole member's preference, or convenience)

POLICY GUIDELINES

InterQual Criteria (IQ) for external insulin infusion pumps can be available upon request when needed. *If you have an IQ license, you can also access the criteria here:* InterQual log in (license required).

Medical necessity criteria for external infusion insulin pumps for diabetes are consistent with the most recent edition of InterQual (Durable Medical equipment module , Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology subset) which in terms have adopted most recent recommendations from the leading professional groups in Diabetes Management, such as American Diabetic Association , American Association of Clinical Endocrinologists and CMS's Coverage Issues Manual Section 60-14.

To support the medical necessity of an insulin pump, comprehensive clinical documentation must be submitted, including relevant medical records that demonstrate the member's clinical need for insulin pump therapy. Proper patient selection is critical; therefore, documentation must also reflect that the member meets established clinical criteria and is capable of appropriately managing insulin pump therapy.

Some external insulin infusion pumps (e.g., Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System, Animas OneTouch PING, Animas VIBE) are able to take results of the blood glucose reading, calculate the appropriate insulin infusion rate, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. These insulin pump features, when present, are considered integral to the external insulin infusion pump and blood glucose monitor.

Most insulin pumps currently available are designed to integrate with continuous glucose monitors (CGMs), enabling automated insulin delivery adjustments based on real-time glucose readings. Coverage for CGM-related components is contingent upon the member meeting all applicable CGM coverage criteria.

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code

that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT® is a registered trademark of the American Medical Association.

CPT Code	Description
N/A	

HCPCS Code	Description
E0784	External ambulatory infusion pump, insulin

ICD-10 Codes	Description
N/A	

BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the members' benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the Member's applicable benefit contract on the date the service was rendered. Services determined by the Plan to be investigational or experimental, cosmetic, or not medically necessary are excluded from coverage for all lines of business.

DESCRIPTION OF SERVICES

An external insulin pump is a portable, programmable medical device designed to deliver a continuous subcutaneous infusion of rapid-acting insulin for the management of diabetes mellitus. The device delivers a predetermined basal rate of insulin throughout the day and allows the user to administer bolus doses at mealtimes or to correct hyperglycemia. The pump system typically includes an insulin reservoir, infusion set (cannula and tubing), and control unit worn

externally on the body. Many devices are capable of integrating with continuous glucose monitoring (CGM) systems to support more precise glycemic control. External insulin pumps are an alternative to multiple daily injection (MDI) therapy for individuals requiring intensive insulin management.

CLINICAL EVIDENCE

Continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, has been shown to improve glycemic control and reduce glycemic variability in individuals with type 1 diabetes, and in selected patients with type 2 diabetes who are unable to achieve adequate control with multiple daily injections (MDI). Clinical trials and meta-analyses have demonstrated that CSII is associated with significant reductions in HbA1c levels and fewer episodes of severe hypoglycemia compared to MDI.

The American Diabetes Association (ADA) Standards of Care in Diabetes—2025 recommend the use of insulin pump therapy for individuals with type 1 diabetes who are motivated and capable of managing the device, and when it is expected to improve glycemic outcomes. Similarly, the Endocrine Society guidelines support CSII in individuals who experience frequent hypoglycemia, high glycemic variability, or suboptimal control despite intensive MDI.

DEFINITIONS

An external insulin pump is a battery-operated, computerized device designed to deliver insulin subcutaneously in a programmed and controlled manner. It eliminates the need for multiple daily insulin injections by providing continuous insulin infusion. The primary objective of insulin pump therapy is to maintain near-normal blood glucose levels, thereby reducing the risk of both acute and chronic complications associated with diabetes.

Continuous Glucose Monitor (CGM) is a device that continually monitor[s] your blood glucose (blood sugar), giving you real-time updates through a device that is attached to your body.

Glycated hemoglobin (HbA1c) is a form of hemoglobin—the iron-containing protein in red blood cells that transports oxygen and imparts the red color to blood. Over the typical 120-day lifespan of a red blood cell, glucose molecules in the bloodstream bind irreversibly to hemoglobin, forming glycated hemoglobin. In individuals with diabetes, elevated blood glucose levels lead to increased formation of HbA1c, which serves as an important marker for long-term glycemic control.

Hypoglycemia is generally defined as a blood glucose level low enough to cause symptoms and potentially harm, typically **below 70 mg/dL (3.9 mmol/L)**.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Jefferson Health Plans EverWell and Jefferson Health Plans CHIP products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2026 Annual Review. No revisions. Reference updated.	A	09/18/2025
New Policy.	A	09/18/2025

REFERENCES

1. American Diabetes Association: Insulin Pumps: Relief and Choice: https://diabetes.org/about-diabetes/devices-technology/insulin-pumps-relief-and-choice

2. Centers for Medicaid and Medicare Services (CMS): Local Coverage determination:
LCD L33794: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794

3. Cleveland Clinic Insulin pumps:

https://my.clevelandclinic.org/health/articles/insulin-pumps

4. American Diabetes Association. *Standards of Care in Diabetes—2025*. Diabetes Care. 2025;48(Suppl 1): S1–S300

   https://diabetes.org/newsroom/press-releases/american-diabetes-association-releases-standards-care-diabetes-2025

5. Endocrine Society- High Risk for Hypoglycemia Guideline Resources:

   https://www.endocrine.org/clinical-practice-guidelines/high-risk-for-hypoglycemia