Policy Key: Infusion Pumps and Continuous Glucose Monitoring Systems

TriWest Clinical Operations – TRICARE West

SCOPE

This Policy Key provides criteria to use during medical necessity review for using Continuous Glucose Monitoring Systems (CGMS), External and Implantable Infusion pumps (IIP), and Transdermal Insulin Delivery Systems (TIDS).

NOT COVERED [1,2]

- Using implantable infusion pumps in treating thromboembolic disease and diabetes.
- IIP use for contraindicated conditions.
- Using a CGMS device for any condition or indication **not** listed below.
- Using a CGMS device that is **not** FDA approved or used outside of the FDA labeled indications.
- Equipment that does not serve a primarily medical purpose and/or does not meet TRICARE's definition of durable medical equipment (DME), e.g., personal computers (PCs), smart phones, tablets, smart watches, even if the devices are able to receive data from the CGMS or other DME, and/or are marketed to assist with self-management of diabetes.
- Combination devices that include a home Blood Glucose Monitor (BGM) combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus.
- Remote glucose monitoring devices.
- Hypoglycemic wristband alarm.
- Equipment, including the CGMS or replacement supplies, which are not medically necessary.

COVERAGE CRITERIA

Continuous Glucose Monitor System

- **Initial Level of Review** may approve if meets the most current recommendations from the American Diabetes Association (ADA) standard of care in Diabetes or meets **all** of the following criteria: [1,3]
    - Diabetes diagnosis (type 1, type 2, gestational or other rare form) with documented in person examination and review of previous 6 months diabetes control by ordering provider
    - Completion of a diabetic education program including training on using the prescribed device(s)
    - Treatment regimen includes daily insulin injections or insulin pump therapy

CGMS Receiver Replacement [1]

- **Initial Level of Review** may approve if both of the following criteria are met:

- Documentation confirms the monitor/component is malfunctioning, is no longer under warranty, and cannot be repaired.
- Evidence of an evaluation by the provider (e.g., physician, nurse practitioner, etc.) managing the diabetes within the last six months that includes a recommendation supporting the continued use of a CGMS.

External Infusion Pump (EIP) [2]

- **Initial Level of Review** may approve for the following United States (U.S.) Food and Drug Administration (FDA)-approved EIPs for inpatient or outpatient use:
    - Cancer Chemotherapy agents
    - Morphine when used for intractable pain
    - Deferoxamine
    - Antibiotic therapy
    - Heparin therapy
    - Insulin with **one** or more of the following conditions (list is all-inclusive):
        - Insulin dependent Type 1 diabetes mellitus and there is documentation by the physician of poor diabetic control
        - Cystic Fibrosis-Related Diabetes (CFRD)
        - Type 2 diabetes mellitus when there is documentation by the physician of poor diabetic control **and** the patient has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy.
- **Initial Level of Review may approve:**
    - Medical supplies required in drug therapy administration performed in the home for an approved EIP

Implantable Infusion Pump (IIP) [2]

- **Initial Level of Review** may approve for ANY the following:
    - Treatment of primary liver cancer or metastatic colorectal liver cancer where the metastases are limited to the liver with continuous hepatic artery infusions of chemotherapeutic agents (e.g., floxuridine, doxorubicin hydrochloride, cisplatin, methotrexate, with bacteriostatic water or physiologic saline and/or heparin).
    - Treatment of osteomyelitis with administration of antibiotics
    - Treatment of chronic intractable pain of malignant or nonmalignant origin by administration of opioid drugs (e.g., morphine) intrathecally or epidurally in patients who have a life expectancy of at least three months and who have not responded to less invasive medical therapy. Must meet both of the following criteria:
        - Inadequate response to noninvasive methods of pain management such as systemic opioids, including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain.
        - A preliminary trial of intraspinal opioid with a temporary intrathecal/epidural catheter to evaluate pain relief, side effects, and patient acceptance.
    - Treatment of chronic intractable spasticity with administration of anti-spasmodic drugs (e.g., baclofen) in patients who have proven unresponsive to less invasive medical therapy. Must meet both of the following criteria:
        - Documentation of inadequate control of spasticity or intolerable side effects resulting

from at least a six-week trial of noninvasive methods of spasm control with drugs such as oral antispasmodics alone or combined with anticonvulsants (depending on the disease progression and the patient's symptoms.
        - Documentation of a favorable response to a trial intrathecal dose of the antispasmodic drug prior to pump implantation.
- All other IIP uses may be approved if **all** of the following criteria apply:
    - Not a TRICARE excluded indication.
    - The medication meets medical necessity.
    - The medical necessity and appropriateness of an IPP to deliver the drug is established.
    - The IPP use adheres to the FDA approved labeling for the pump and medication.
    - FDA-approved IIPs labeled for specific drugs and routes of administration, e.g., intravenous fluorouracil (5-FU), intra-arterial floxuridine, epidural morphine sulfate, and intrathecal baclofen.
- **Charges**
    - In-hospital implantation charges (pump, related equipment, supplies, and drugs) must be included in the hospital charges.
    - Outpatient office visit charges primarily for maintenance and refilling of infusion systems must be limited to maintenance and refilling services (no office visit charge).
- **Initial Level of Review may approve:**
    - Refilling, servicing, maintenance, and removal of the pump and/or accessories of a previously approved IPP device.

Transdermal Insulin Delivery System [2]

The Valeritas V-Go™ Insulin Delivery Device (V-Go) is FDA approved as a Class II, EIIP for the continuous subcutaneous delivery of insulin in preset basal rates with on-demand bolus dosing for adult patients requiring insulin. The V-Go is a fully mechanical device using a compressed spring and does not require electronics, batteries, or software. It is a patient fillable, single-use, completely disposable insulin infusion device with an integrated stainless steel subcutaneous needle. The device is used for the subcutaneous delivery of 24 hours of U-100 fast-acting insulin (i.e., Humalog® [insulin lispro] and Novolog® [insulin aspart]).

- **Initial Level of Review** may approve for **any** of the following:
    - Type 2 Diabetes
        - Beneficiary does not need more than 40 units of basal insulin daily and does not need more than 36 units of bolus insulin daily.
        - Beneficiary does not need less than two-unit increments of bolus dosing.
        - Beneficiary has been maintained on stable basal insulin for at least three months (at dosages of 20U, 30U, or 40U).
        - Beneficiary has been using prandial insulin for at least three months.

DEFINITIONS

Continuous Glucose Monitoring System (CGMS) is a minimally invasive medical device that provides ongoing, real-time monitoring and recording of blood glucose levels by continuous measurement of interstitial fluid. These devices consist of an external receiver, external transmitter,

and a subcutaneously placed sensor. A CGMS can be used by the provider for diagnostic purposes or by the patient for self-monitoring of blood glucose levels. A CGMS is prescribed for patients with insulin-treated diabetes mellitus. A CGMS can be an adjunctive device to complement, not replace, standard finger sticks Blood Glucose Monitor (BGM) testing, or it can be used as a device intended to replace finger sticks, also called “therapeutic CGMS.” [1]

External Infusion Pump (EIP) is a device designed to deliver measured amounts of a drug through injection over a period of time into a patient in a controlled manner. [2]

Implantable Infusion Pump System (IIP)–delivers therapeutic plasma levels of active drug to a target organ or body compartment for prolonged periods of time. The bulk flow of drug is generated either by fluorocarbon propellant (nonprogrammable IIP) or direct electromechanical action powered by a battery (programmable IIP). The pump is surgically implanted in a subcutaneous pocket and connects to a dedicated catheter that has been placed in the appropriate compartment. Constant or variable-rate infusions are possible over long periods of time (several weeks to years) with minimal human intervention (refilling or reprogramming) while retaining the capability for external control of rate and volume of primary and supplemental drug delivery. Besides the pump itself, dependent on the type of pump used, system components may include any of the following: reservoir, optional access port, connectors, various size catheters, micropore filter, hand-held programmer, and a variety of accessories. [2]

Transdermal Insulin Delivery System is a subset of the broader category of External Insulin Infusion Pumps (EIIPs). A patch filled with insulin is placed on the skin and skin penetration occurs by low-frequency ultrasound, use of an electrical charge (i.e., iontophoresis), or use of a microneedle. Some devices deliver a continuous low dose of basal insulin through the skin and/or deliver bolus insulin upon demand. Other than the device worn on the skin, there are no additional components or separate control devices that manage or monitor the insulin dosage. Additionally, these devices may be fully disposable. [2]

CODES

CPT 36260 - 36262, 36530 - 36535, 62350 - 62368, 96530

HCPCS A9247, A9276-A9278, E0780, E0784, K0553, K0554, Q0081, Q0084 - Q0085

REFERENCES

[1] TRICARE Policy Manual 6010.63-M, April 2021, Change 26, (December 6, 2024), Chapter 8, Section 5.3, Continuous Glucose Monitoring System (CGMS) Devices, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-12-06/AsOf/TPT5/C8S5_3.html

[2] [2] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 8, Section 2.3, External and Implantable Infusion Pumps, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S2_3.html

[3] MCD Medicare Coverage Database, Local Coverage Determination (LCD), Glucose Monitors, Retrieved July 22, 2024, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822