Sentara Health Plans

Medicaid

External Insulin Infusion Pump, DME 11

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Effective Date	01/1994
Next Review Date	07/2025
Coverage Policy	DME 11
Version	7

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses External Insulin Infusion Pump and accessories.

Description & Definitions:

Continuous subcutaneous insulin infusion is the constant administration of insulin through an external insulin pump, delivered to the individual through a subcutaneous needle.

A 'combination device' is one that both, delivers the continuous insulin infusion and monitors the individual's blood glucose.

Criteria:

Continuous Subcutaneous Insulin Infusion is considered medically necessary for **1 or more of the following**:

- **Initial insulin infusion devices** are considered medically necessary for **all of the** following:
  - Insulin pump requested is FDA approved and is indicated by **1 or more** of the following:
    - External insulin pump
    - Hybrid closed-loop threshold-suspend (low-glucose-suspend) external insulin pump
    - Sensor-augmented external insulin pump
    - Threshold-suspend (low-glucose suspend) external insulin pump
  - Diagnosis of diabetes, as indicated by **1 or more** of the following:
    - Type 1 diabetes mellitus
    - Type 2 diabetes mellitus and **all of the following**:
      - Multiple daily injections
      - prescribed by their health care provider

- Failure of Multiple daily injection insulin administration, as indicated by **1 or more** of the following:
  - Abnormal early-morning increase in blood glucose ("dawn phenomenon"), unresponsive to management with long-acting insulin analogue (eg, insulin glargine, insulin detemir) regimens
  - Child for whom multiple daily insulin injections are impractical or inappropriate
  - Diabetes complications (eg, neuropathy, nephropathy, retinopathy), and need for more intensive management
  - Extreme insulin sensitivity
  - History of recurring hypoglycemia (less than 70 mg/dL)
  - Hypoglycemia with recurrent episodes, including unconsciousness, seizure, glucagon administration, and emergency attendance and/or admission to hospital and recurrent prolonged hospitalizations
  - Individual is pregnant or planning pregnancy
- Individual or caregiver is adherent, capable of using the devices safely (either by themselves or a caregiver), knowledgeable, and able to monitor blood glucose 3 or more times per day
- Provider team is experienced and expert in management and support of Individual with insulin infusion pump
- Evaluated by the treating physician at least once every 6 months.

- **Replacement insulin infusion devices** are considered medically necessary with ALL of the following:
  - The problem(s) which limit the use of the current insulin infusion device is clearly identified and the device cannot be refurbished.
  - There is documentation that the current insulin infusion device is not under warranty, including the date of warranty expiration

The following **do not meet the definition of medical necessity**, to include but not limited to:

- single-use disposable insulin infusion device (ie. V-Go).
- Continuous subcutaneous insulin infusion for uses other than those listed in the clinical indications for procedure section.

Coding:

Medically necessary with criteria:

Coding	Description
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose
A4230	Infusion set for external insulin pump, nonneedle cannula type
A4231	Infusion set for external insulin pump, needle type
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
K0552	Supplies for external drug infusion pump, syringe type cartridge, sterile, each

Considered Not Medically Necessary:

Coding	Description
	None

Document History:

Revised Dates:

- 2023: July

- 2022: July
- 2021: October
- 2020: September
- 2018: November
- 2015: February, March, May, October, December
- 2014: May, August, October
- 2013: April, May, June, October
- 2012: June, August
- 2011: May, September
- 2010: June
- 2009: May
- 2008: June
- 2007: August, October, December
- 2006: October
- 2005: August, December
- 2004: December
- 2000: October
- 1999: February, September, October
- 1996: May

Reviewed Dates:

- 2024: July – no changes references updated
- 2023: July
- 2018: July
- 2017: November
- 2016: June
- 2015: May
- 2014: May
- 2010: May
- 2006: May
- 2004: December
- 2003: May, October
- 2002: May
- 2001; June
- 1998: October

Effective Date:

- January 1994

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice,

although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

SHP Durable Medical Equipment 11, Continuous Subcutaneous Insulin Infusion, CSII, Insulin Infusion, External Infusion, Insulinopenia, External insulin infusion, endocrinologist, Type I diabetes, Type II diabetes, Dawn Phenomenon, Hypoglycemia, hyperglycemia, Microalbuminuria, Proteinuria, nephropathy, retinopathy, Combination devices, Fasting C-peptide levels