Sentara® Health Plans

Commercial

# External Insulin Infusion Pump, DME 11

**Table of Content**


Purpose
Description & Definitions
Criteria
Coding
Document History
References
Special Notes
Keywords


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

**Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.**

## 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: 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).

Code of Federal Regulations. Title 21. Chapter 1, Subchapter H, Part 862, Subpart B, § 862.1358 Insulin therapy adjustment device. 11.1.2018. Retrieved 6.12.2024. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-862/subpart-B/section-862.1358

U.S. Food and Drug Administration. Class II Special Controls. 6.14.2022. Retrieved 6.13.2024. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents

Hayes. A symplr company. Health Technology Assessment. Annual Review: Mar 20, 2023. Continuous Subcutaneous Insulin Infusion with OmniPod Insulin Management System (Insulet Corporation) for Management of Diabetes Mellitus. Retrieved 6.13.2024. https://evidence.hayesinc.com/report/htb.omnipod962

Hayes. A symplr company. 2. Evidence Analysis Research Brief. Mar 22, 2024. V-Go (MannKind Corp.) Disposable Insulin Delivery Device For The Management Of Type 1 Or Type 2 Diabetes Mellitus. Retrieved 6.13.2024. https://evidence.hayesinc.com/report/earb.vgo2634

Centers for Medicare and Medicaid Services. CMS.gov. Local Coverage Determination (LCD). External Infusion Pumps. L33794. 1.1.2024. Retrieved 6.12.2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794

Centers for Medicare and Medicaid Services. CMS.gov. National Coverage Determination (NCD). Infusion Pumps. 280.14. 2.18.2005. Retrieved 6.12.2024. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=223&ncdver=2

Commonwealth of Virgina. Department of Medical Assistance Services. Provider Manual Title: Durable Medical Equipment (DME) , Chapter IV: Covered Services and Limitations . Revision date 1.4.2024. Retrieved 6.12.2024. https://vamedicaid.dmas.virginia.gov/sites/default/files/2024-01/DME%20Chapter%20IV%20%28updated%201.4.24%29_Final.pdf

National Comprehensive Cancer Network. Retrieved 6.12.2024. https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=insulin%20pump

Carelon. Clinical Appropriateness Guidelines. Retrieved 6.12.2024. https://guidelines.carelonmedicalbenefitsmanagement.com/new-and-emerging-interventions-01-01-21/

American Diabetes Association, 2024 Standards of Care. January 2024. Retrieved 6.12.2024. https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in

Freckmann, G., Buck, S., Waldenmaier, D., Kulzer, B., Schnell, O., Gelchsheimer, U., Ziegler, R., & Heinemann, L. (2021). Insulin Pump Therapy for Patients With Type 2 Diabetes Mellitus: Evidence, Current Barriers, and New Technologies. Journal of diabetes science and technology, 15(4), 901–915. Retrieved 6.12.2024. https://doi.org/10.1177/1932296820928100

MCG Informed Care Strategies: Insulin Infusion Pump. ACG: A-0339 (AC). Ambulatory Care 28th Edition. Retrieved 6.12.2024. https://careweb.careguidelines.com/ed28/index.html

## Special Notes: *

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.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

MUST SEE MEMBER BENEFIT FOR DETERMINATION.
We only cover DME that is Medically Necessary and prescribed by an appropriate Provider. We also cover colostomy, ileostomy, and tracheostomy supplies, and suction and urinary catheters. We do not cover DME used primarily for the comfort and wellbeing of a Member. We will not cover DME if We deem it useful, but not absolutely necessary for Your care. We will not cover DME if there are similar items available at a lower cost that will provide essentially the same results as the more expensive items.

Pre-Authorization is Required for All Rental Items.

Pre-Authorization is Required for All Repair and Replacement.

## 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