Sentara Health Plans

Medicaid

External Insulin Infusion Pump, DME 11

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Effective Date	9/1/2025
Next Review Date	6/2026
Coverage Policy	DME 11
Version	8

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.*.

Description & Definitions:

Automated insulin delivery systems (AID) (also called Artificial Pancreas, close looped or 'combination device') is a device that includes a continuous insulin infusion pump and continuous glucose monitor and use of an algorithm to deliver insulin based on blood glucose values.

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

Insulin infusion pumps may be used independently or in conjunction with a continuous glucose monitoring system. Insulin infusion pumps may use information from a glucose monitor to stop the insulin infusion (sensor-augmented pumps).

Other common names: continuous subcutaneous insulin infusion [CSII], AUTOMATED INSULIN DELIVERY SYSTEMS (AID), hybrid closed loop (HCL), CSII used in conjunction with a CBGM (CSII-CBGM)

Criteria:

- Continuous Subcutaneous Insulin Infusion devices (also known as of an external insulin pumps) are considered medically necessary for 1 or more of the following:
- Initial placement of an external insulin pump are considered medically necessary for All of the following:
- Age used in accordance with FDA approval or authorization (for example, age 2 years or older)
- Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control

- Multiple blood glucose tests are required daily or a continuous glucose monitor is being used.
- Diagnosis of diabetes, as indicated by 1 or more of the following:
- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- 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.
- Insulin pump requested is FDA approved and is indicated by 1 or more of the following:
- Standard External insulin pump/ continuous subcutaneous insulin infusion (CSII) therapy
- Automated insulin delivery systems (AID) (also called Artificial Pancreas, close looped or ‘combination device’) 1 or more of the following:
- Fully Closed-loop system (mostly hands-off; automated)
- Hybrid closed-loop system (semiautomated, requires some user input) Threshold-suspend (low-glucose suspend) external insulin pump
- Open-loop system (fully user controlled), also known as Sensor-augmented external insulin pump (SAP)
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- NOTE: AID systems are considered as an equally acceptable alternative to a standard insulin pump and CGM for members who meet medical necessity criteria for external insulin infusion pumps for diabetes.
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- Replacement of an external insulin pump for all individuals 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
- Replacement of an external insulin pump for pediatric individuals (under 18 years of age) who require a larger insulin reservoir will be considered on a case-by-case basis.
- See Pharmacy/benefits (DMAS approves)
- There is insufficient scientific evidence to support the medical necessity of Continuous subcutaneous insulin infusion for uses other than those listed in the clinical indications for procedure section.

Document History:

Revised Dates:

- 2025: June – Implementation date of September 1, 2025. Add codes and new criteria for artificial pancreas
- 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

Origination Date:

- January 1994

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
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices (Authorization required – effective 1/1/2025)
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system (Authorization required – effective 1/1/2025)
S1036	Transmitter; external, for use with artificial pancreas device system (Authorization required – effective 1/1/2025)
S1037	Receiver (monitor); external, for use with artificial pancreas device system (Authorization required – effective 1/1/2025)

Considered Not Medically Necessary:

Coding	Description
	None

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement.

Special Notes: *

- Coverage:
  - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products:
  - Policy is applicable to Sentara Health Plan Virginia Medicaid products.
- Authorization requirements:
  - Pre-certification by the Plan is required.
- Special Notes:
  - Medicaid
    - 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.

- Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

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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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