Sentara Health Plans

Medicaid

Diabetes Management, Medical 352

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Coverage Policy	Medical 352
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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 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.

Description & Definitions:

Automated insulin delivery systems (AID) (also called Artificial Pancreas, close looped or 'combination device') is a wearable device which includes a continuous insulin infusion pump and continuous glucose monitor (CGM) using an algorithm to deliver insulin therapy to the individual based on blood glucose values obtained throughout the day.

Continuous glucose monitor (CGM) is a wearable device that tracks glucose levels in real-time updates, 24/7, using a small sensor inserted under the skin to reduce the need for muyltiple fingersticks daily.

Continuous subcutaneous insulin infusion (CSII) is a wearable device that provides a constant administration of insulin through an external insulin pump, delivered to the individual through tubing and cannula placed in subcutaneous tissue.

Insulin infusion pumps are wearable, programable devices that may be used independently or in conjunction with a continuous glucose monitoring system to administer multiple daily injections needed to sustain insulin needs . Insulin infusion pumps that are integrated with CGMs are called "Sensor-augmented insulin pumps" which may use information to manage real time blood glucose trends.

Integrated Self-monitoring of blood glucose (SMBG) device is a meter which combines test (cassettes/discs) and a built-in lancing device for blood sampling.

Needleless injection systems (also known as needle-free injectors) injecting medicine with the use of rapid, pressure-driven jet streams which are powered by springs or compressed gas to penetrate the skin without a conventional needle.

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:

Diabetes Management is medically necessary for **1 or more** of the following:

- **Continuous Glucose Monitoring Systems** (CGMs) may be indicated for **1 or more** of the following:
  - **Initial** (external, non-implanted) CGM device is indicated with **ALL** of the following:
    - Diagnosis of diabetes (Type 1 diabetes mellitus, Type 2 diabetes mellitus or gestational diabetes), and
    - Long-term continuous glucose monitoring needed, as indicated by **ALL** of the following:
      - Intensive insulin regimen (3 or more short acting insulin injections per day), or use of "**COMPATIBLE**" continuous subcutaneous insulin infusion pump
      - Individual consistently monitors blood glucose 3 or more times per day as documented on **ALL** of the following:
        - Medical record documentation
        - Personal blood glucose log showing consistent measurements over 2 weeks. Individual and/or caregiver is adherent, capable of using the devices safely (either by themselves or a caregiver), knowledgeable and able to follow a diabetic treatment plan, and participates in ongoing education and support.
  - **Initial** (Implanted, 0446T, 0447T, 0448T) CGM device, (e.g. Eversense®, Guardian™ 3, or Guardian™ 4) with **ALL** of the following:
    - **Send to Pharmacy**
  - **Replacement** of Continuous Glucose Monitoring System is indicated with **ALL** of the following:
    - Which limit the use of the current continuous glucose monitoring system is clearly identified (including misuse or abuse of the equipment)
    - Documentation that the current continuous glucose monitoring system is not under warranty, including the date of warranty expiration.
  - **Continued use** of a Continuous Glucose Monitoring System devices are considered medically necessary with **ALL** of the following:
    - Member continues to meet above coverage criteria.
    - Non-Adherence to treatment has been addressed and documentation supports continued use.
- **Continuous Subcutaneous Insulin Infusion (CSII)** device (also known as of an external insulin pumps or insulin pump therapy) 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:
    - Diagnosis of diabetes (Type 1 diabetes mellitus, Type 2 diabetes mellitus)
    - 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.
    - Difficulty or 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
    - 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)
        - 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
    - **Replacement** of external insulin pump for all individuals are considered medically necessary with **ALL** of the following:
        - 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.

  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.
- **Integrated Self-monitoring of blood glucose (SMBG)** is medically necessary for **1 or more** of the following:
    - Individual that is legally blind (best corrected visual acuity less than 20/200);
    - Individual with severe physical limitations to impair the use of other devices.
- **Needleless injection systems** are considered medically necessary with **1 or more** of the following:
    - Individual has documentation which includes **ALL** of the following:
        - Documented evidence that individual is unable to perform insulin injection/standard blood glucose monitoring with a traditional delivery device after adequate training and is unable to use the traditional device
        - Documented evidence of "sharps phobia" such as repeated episodes of vasovagal reaction to injection or standard blood glucose monitoring making puncture technique impossible
        - Documentation of contact with diabetes educator for training to ensure proper technique and instruction has been offered to individual using traditional device
    - Individuals with predispososition to prolonged hyperinsulinemia and subsequent hypoglycemia that demonstrates better glycemic control with the jet injector compared with conventional needle and syringe
    - Individuals who are predisposed to lipoatrophy since jet injections may be less likely to lead to this complication compared with needle injection
    - Individuals with gestational diabetes who experience postprandial hyperglycemia with needle injection since it may reduce the risk of neonatal macrosomia

There is insufficient scientific evidence to support the medical necessity any of the following as they are not shown to improve health outcomes upon technology review:

- Diabetes Management Software
- Hypoglycemic wristband alarm (e.g., Diabetes Sentry, GlucoWatch)
- Nesidioblastosis (primary islet cell hypertrophy), neonatal hypoglycemia, and for monitoring blood glucose in non-diabetic persons
- Personal Digital Assistant-Based Blood Glucose Monitor (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module)
- Remote glucose monitoring device (e.g., mySentry, MiniMed Connect, Dexcom SHARE)

Authorization request is limited to the following. Requests for equipment outside of recommended utilization must have supporting documentation:

- For Dexcom: 3 sensors per 30 days, 1 transmitter per 90 days
- For Freestyle: 2 sensors per 28 days
- Other FDA approved CGM system

Needleless injection systems are considered **not medically necessary** as the current role remains uncertain, based on review of existing evidence, for any use other than those indicated in clinical criteria, to include but not limited to:

- Insuflon
- Laser lancet devices

Continuous Glucose Monitoring Systems are considered **not medically necessary** for any use other than those indicated in clinical criteria.

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:

- 2026: May – Implementation date of September 1, 2026. Added criteria to new policy Diabetes Management, Medical 352

Reviewed Dates:

Origination Date: May 2026

Coding:

Medically necessary with criteria:

Coding	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
A4210	Needle-free injection device, each
A4222	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
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 sensing, per week
A4230	Infusion set for external insulin pump, nonneedle cannula type

A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
E2102	Adjunctive continuous glucose monitor or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge
K0552	Supplies for external drug infusion pump, syringe type cartridge, sterile, each
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)

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
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

Considered Not Medically Necessary:

Coding	Description
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
E0620	Skin piercing device for collection of capillary blood, laser, each

U.S. Food and Drug Administration (FDA) - approved only products only.

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: