PROVIDER POLICIES & PROCEDURES

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION PUMPS (CSII) AND CONTINUOUS GLUCOSE SENSORS (CGM)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program with the information needed to support a medical necessity determination for external insulin pumps and continuous glucose monitoring. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Insulin Pumps

A continuous subcutaneous insulin infusion pump is a programmable, battery-powered computerized device that's used to deliver a continuous subcutaneous insulin infusion into the body. Typically, these devices contain a 2-3 day supply of insulin connected to an infusion set or pod programmed to deliver basal amounts of insulin and user initiated meal and correction bolus doses. The purpose of the device is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control and to prevent the metabolic complications of hypoglycemia and hyperglycemia. Regular self-monitoring of blood glucose (SMBG) is nonetheless necessary in order to assure that appropriate doses of insulin are being delivered by the pumps. An external insulin pump is considered durable medical equipment (DME).

Continuous Glucose Monitors (CGM)

Continuous glucose monitoring (CGM) devices continuously monitor and record interstitial fluid glucose levels utilizing a disposable subcutaneous sensor, transmitter and receiver. The receiver can be a CGM enabled insulin pump, standalone CGM monitor or a compatible smart device. Glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using finger stick or alternate site blood samples, but are used in conjunction with SMBG. CGM provides real-time monitoring and notification of glucose levels that are trending above or below target levels.

Clinical Guideline

Coverage guidelines for insulin pumps and continuous glucose monitors for the treatment of diabetes are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only*. **Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:**

Standard External Insulin Pumps

Standard external insulin pumps are the usual and customary pump used in the management of diabetes. Pumps with enhanced features may be appropriate when there is a documented special need, such as: (a) a physical and/or sensory impairment that requires additional or enhanced pump features for successful use; (b) a documented failure to achieve adequate glycemic control with a standard pump; or (c) when age is a contributing factor.

The administration of insulin by an external continuous subcutaneous insulin infusion pump in an individual with diabetes mellitus requiring insulin therapy may be considered medically necessary when there is any one of the following:

Clinical Indicators

- Suboptimal glycemic control despite intensive insulin therapy:
  - 3 or more injections of basal and prandial insulin a day; and
  - Blood glucose monitoring a minimum of 4 or more times per day
- Glycemic variability
- Recurrent hypoglycemia
- Recurrent nocturnal hypoglycemia
  - Note: Sensor-augmented insulin pump therapy with the threshold suspend should be considered for individuals with nocturnal hypoglycemia per the 2016 American Diabetes Association (ADA) *Standards of Medical Care* as outlined below:
    - A large randomized trial in patients with type 1 diabetes with nocturnal hypoglycemia reported that sensor-augmented insulin pump therapy with the threshold suspend feature reduced nocturnal hypoglycemia, without increasing glycated hemoglobin values
      - Intensive management through pump therapy/continuous glucose monitoring and active patient/family participation should be strongly encouraged
- Hypoglycemia unawareness
- Dawn phenomenon
- Pregnancy and/or pre-pregnancy
  - Including gestational diabetes
- Gastroparesis

AND

Participation and Engagement in Care

The individual has adequate documentation of needed health care provider support for safe and effective use of insulin pump therapy. The following elements are used as guide to determine if this element is met.

- A minimum of two (2) diabetes care related visits occurring in the last twelve (12) months
- An endocrinologist or physician/PA/Nurse Practitioner who typically manages individuals with diabetes has prescribed the device and has a documented involvement in the ongoing management of the individual

AND

Individual and/or Caregiver Self-Management Skills

The individual has adequate documentation of needed self-management skills for safe and effective use of insulin pump therapy. The following elements are used as guide to determine if this element is met.

- Insulin Therapy
  - 3 or more injections of insulin a day
- Self-blood glucose monitoring (SMBG) minimum of four (4) times per day during the preceding 30 days.
- Understanding and willingness to carry out the following prior to beginning pump therapy:
  1. Skills needed to safely and effectively manage pump therapy
  2. Appropriate treatment of hypoglycemia;
  3. Appropriate treatment of hyperglycemia;
  4. Carbohydrate counting or its equivalent with the ability to calculate meal/snack boluses;

5. Use (when indicated) and maintain and a written backup plan to follow for use when pump malfunctions, including use of insulin injected by syringe or pen; and
6. Use (when indicated) and maintain a written plan for dealing with site and infusion set failure/occlusion or lack of needed insulin pump supplies, including use of insulin injected by syringe or pen.

Replacement Pumps
Replacement of an external insulin pump may be considered medically necessary have when there's documented evidence of **all** of the following:

1. The insulin pump is malfunctioning;
2. The pump Is no longer under manufacturer's original warranty; and
3. The individual can no longer use their pump because of the malfunction and has transitioned back to insulin injections or is using a loaner pump.

OR
Replacement of an external insulin pump may be considered medically necessary when there is sufficient documented evidence of all of the following:

- **Suboptimal glycemic control and/or hypoglycemia unawareness**
- **Current insulin pump lacks the any of following indicated features based on the individual clinical need:**

Feature	**May be considered medically necessary when there is sufficient t documented evidence of :**
Auto suspension of insulin delivery when CGM reache a preset/predetermined low interstitial glucose	Hypoglycemia unawareness or recurrent hypoglycemia
Suspend before a low interstitial glucose	Hypoglycemia unawareness or recurrent hypoglycemia
Auto adjustment of basal insulin delivery	Suboptimal glycemic control despite current pump therapy

Continuous Glucose Monitors (CGM)

Type 1 Diabetes

Continuous glucose sensors in an individual with Type 1 diabetes may be considered medically necessary when there is any one of the following:

Clinical Indicators
Documented evidence of any of the following:

- Hypoglycemia unawareness
- Recurrent hypoglycemia
- Recurrent nocturnal hypoglycemia
- Suboptimal glycemic control

AND
Participation and Engagement in Care
The individual has adequate documentation of needed health care provider support for safe and effective use continuous glucose monitoring. The following elements are used as guide to determine if this element is met.

- A minimum of two (2) diabetes care related visits occurring in the last twelve (12) months
- An endocrinologist or physician/PA/Nurse Practitioner who typically manages individuals with diabetes has prescribed the device and has a documented involvement in the ongoing management of the individual

AND
Individual and/or Caregiver Self-Management Skills

The individual has adequate documentation of needed self-management skills for safe and effective use of continuous glucose monitoring. The following elements are used as guide to determine if this element is met.

- 3 or more injection of insulin a day
- Self-blood glucose monitoring a minimum of four (4) times per day during the preceding 30 days.
- Understanding and willingness to carry out the following prior to beginning CGM:
    1. Self-monitoring of blood glucose (SMBG) as recommended with attention to:
        - Required CGM calibration
        - Benefits and risks of CGM as the sole source to monitor glucose levels
        - CGM readings must be confirmed by SMBG when making treatment decisions, if indicated ***based on CGM device used***.

OR

Type 2 Diabetes

Medically necessity of continuous glucose sensors in an individual s with insulin requiring Type 2 diabetes will be evaluated on a case-by-case basis when any one of the following:

Clinical Indicators
Documented evidence of any of the following:

- Hypoglycemia unawareness
- Recurrent hypoglycemia
- Recurrent nocturnal hypoglycemia
- Suboptimal glycemic control

AND
Participation and Engagement in Care
The individual has adequate documentation of needed health care provider support for safe and effective use continuous glucose monitoring. The following elements are used as guide to determine if this element is met.

- A minimum of two (2) diabetes care related visits occurring in the last twelve (12) months
- An endocrinologist or physician/PA/Nurse Practitioner who typically manages individuals with diabetes has prescribed the device and has a documented involvement in the ongoing management of the individual

AND
Individual and/or Caregiver Self-Management Skills

The individual has adequate documentation of needed self-management skills for safe and effective use of continuous glucose monitoring. The following elements are used as guide to determine if this element is met.

- 3 or more injection of insulin a day
- Self-blood glucose monitoring a minimum of four (4) times per day during the preceding 30 days.
- Understanding and willingness to carry out the following prior to beginning CGM:
    1. Self-monitoring of blood glucose (SMBG) as recommended with attention to:
        - Required CGM calibration
        - Benefits and risks of CGM as a the sole source to monitor glucose levels
        - CGM readings must be confirmed by SMBG when making treatment decisions, if indicated based on CGM device used.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of insulin pumps and continuous glucose sensors is required accompanied with clinical documentation and a prescription from the prescribing MD, PA or APRN. Requests for coverage of insulin pumps and continuous glucose monitors will be reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for insulin pumps and continuous glucose monitors:

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Valid prescription for the requested goods;
3. Documentation from the medical record supporting the medical necessity of the requested item; and
4. Appropriate pricing documentation as outlined in the MEDS pricing policy.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for external insulin pumps for individuals covered under the HUSKY Health Program beginning March 1, 2017.

LIMITATIONS
N/A

CODES:

Code	Description
E0784	External ambulatory infusion pump, insulin
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
A9999	Miscellaneous DME supply or accessory, not otherwise specified*

*Code A9999 should be submitted when requesting authorization for OmniPod® pods

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

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PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	December 2013	
Reviewed	December 2014	Clinical Quality Subcommittee Review. Reference updated. Update to introduction. Added statement concerning use of infusion pods and user Initiated meal and correction bolus doses. Updates to criteria. These changes approved at the December 16, 2014 Clinical Quality Sub-Committee meeting. These changes approved by DSS on December 17, 2014.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D programs at request of DSS.
Updated	June 2016	Updates to language in introductory paragraph pertaining to purpose of policy. Updates to Clinical Guideline section pertainin to definition of Medical Necessity . Updates throughout policy to reflect importance of person-centeredness when reviewing requests for insulin pumps and continuous glucose monitors. Added criteria continuous glucose monitoring. Added criteria for the appropriate management of those with a diabetes duration of less than six (6) months.
Updated	December 2106	Updated to current 2017 ADA evidence based guidelines and 2016 Endocrine Society guidelines. Added criteria related to hybrid insulin pump therapy. These changes approved at the November 9, 2016 Medical Policy Review Committee meeting. These changes approved at the December 19, 2016 Clinical Quality Sub-Committee meeting. These changes approved by DSS on February 15, 2017.