PROVIDER POLICIES & PROCEDURES

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION PUMPS (CSII)

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. 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.

A continuous subcutaneous insulin infusion pump is a programmable, computerized device that is 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 bolus doses. The purpose of the device is to provide an accurate, continuous, controlled delivery of insulin to achieve improved glycemic control and to minimize and/or prevent acute and chronic complications. An external insulin pump is considered durable medical equipment (DME).

CLINICAL GUIDELINE

Coverage guidelines for insulin pumps 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:**

Initial Insulin Pump Therapy

Initial Pump Therapy without Continuous Glucose Monitoring (CGM) Integration

The administration of insulin by an external continuous subcutaneous insulin infusion pump in an individual with diabetes requiring insulin therapy may be considered medically necessary when:

A. There is adequate documentation that the individual is engaged in the recommended care and has health-care provider support for the safe and effective use of insulin pump therapy as demonstrated by:
    1. A minimum of **two (2)** diabetes care related visits occurring in the prior 12 months; and
    2. An endocrinologist or physician, physician assistant or 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

B. There is adequate documentation that the individual and/or caregiver have the skills necessary for the safe and effective use of insulin pump therapy. The following elements must be adequately documented in the individual's clinical visit notes to determine if this element is met:
    1. Basal/prandial insulin therapy - three (3) or more doses of injected and/or inhaled insulin a day. (Insulin doses may be administered via syringe, pen or other equivalent device); and
    2. Glucose monitoring a minimum of four (4) times per day during the preceding 15 days or

current rtCGM or isCGM use.

Initial Pump Therapy with Real-Time Continuous Glucose Monitoring (rtCGM) Integration

The administration of insulin by an external continuous subcutaneous insulin infusion pump with rtCGM integration in an individual with diabetes requiring insulin therapy may be considered medically necessary when:

A. There is documentation of the initiation of insulin pump therapy;

AND

B. The insulin pump, when used with rtCGM contains one of the following features:
    1. Predictive low-glucose suspend; or
    2. Hybrid closed-loop; or
    3. Reactive low-glucose suspend.

AND

C. There is adequate documentation that the individual is engaged in the recommended care and has health-care provider support for the safe and effective use of insulin pump therapy as demonstrated by:
    1. A minimum of **two (2)** diabetes care related visits occurring in the prior 12 months; and
    2. An endocrinologist or physician, physician assistant or 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

D. There is adequate documentation that the individual and/or caregiver have the skills necessary for the safe and effective use of insulin pump therapy. The following elements must be adequately documented in the individual's clinical visit notes to determine if this element is met:
    1. Basal/bolus insulin therapy - three (3) or more doses of injected and/or inhaled insulin a day. (Insulin doses may be administered via syringe, pen or other equivalent device); and
    2. Glucose monitoring a minimum of four (4) times per day during the preceding 15 days or current rtCGM or isCGM use.

Replacement Insulin Pumps

I. Replacement of an external insulin pump may be considered medically necessary when the insulin pump is malfunctioning, is no longer under the original manufacturer's warranty and cannot be used due to the malfunction and the individual has transitioned back to insulin injections or is loaning an insulin pump.

II.Replacement of an external insulin pump may be considered medically necessary when:

A. There is suboptimal glycemic control within the last three (3) months while using their current insulin pump indicated by **any one** of the following:
    1. Time in target glucose range is consistently below 50% despite treatment and/or self-care adjustments; or
    2. Greater than 3% of CGM values are < 70 mg/dL; or
    3. Episode(s) of hypoglycemia resulting in any of the following:
        a. Inpatient or emergency department utilization; or
        b. The use of glucagon; or
    4. Persistent episodes of level 1 (glucose <70 and > 54 mg/dL) or level 2 (glucose < 54 mg/dL) hypoglycemia despite treatment and/or self-care adjustments within the last three (3) months. Note: Persistent is defined as four or more episodes occurring within a two (2) week period of time.

AND

B. The individual's current insulin pump lacks a medically necessary feature including:
    1. Predictive low-glucose technology. Predictive low-glucose technology may be considered medically necessary for individuals with:
        a. Hypoglycemia resulting in an inpatient stay or emergency department visit or the use of glucagon; or
        b. Persistent episodes of level 1 (glucose <70 and > 54 mg/dL) or level 2 (glucose < 54 mg/dL) hypoglycemia despite treatment and/or self-care adjustments. Note: Persistent is defined as four or more episodes occurring within a two (2) week period of time.
    2. Hybrid closed-loop technology. Hybrid closed-loop technology may be considered medically necessary for individuals:
        a. Whose time in the target glucose range is consistently below 50% despite treatment and/or self-care adjustments; or
        b. With hypoglycemia resulting in an inpatient stay or emergency department visit or the use of glucagon; or
        c. With persistent episodes of level 1 or level 2 hypoglycemia despite treatment and/or self-care adjustments.

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 is required. Requests for coverage of insulin pumps 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:

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 from the prescribing MD, PA or APRN;
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

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:

1. Professional Practice Committee: *Standards of Medical Care in Diabetes—2019.* Diabetes Care Jan 2019, 42 (Supplement 1) S3; **DOI:** 10.2337/dc19-SppC01
2. Steven V. Edelman, Nicholas B. Argento, Jeremy Pettus, Irl B. Hirsch; Clinical Implications of Real-time and Intermittently Scanned Continuous Glucose Monitoring. Diabetes Care Nov 2018, 41 (11) 2265-2274; DOI: 10.2337/dc18-1150

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 refle importance of person-centeredness when reviewing requests for insulin pumps and continuous glucose monitors. Added criteria for 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.
Updated	April 2018	Updated to reflect 2018 ADA standards of care. Language modified in Continuous Glucose Monitoring (CGM) sections to reflect diagnostic use, changes in guidelines relating to confirmatory finger stick blood glucose checks, self-management skills, reinforcement of need for office notes to reflect all required clinical elements, addition of CGM as alternate to self-blood glucose monitoring (SBGM) and reduction of numbers of SBGM from 30 to 15 days. Approved by CHNCT Medical Policy Review Committee on February 14, 2018. Approved by CHNCT Clinical Quality Subcommittee on March 19, 2018. Approved by DSS on April 5, 2018.

Updated	February 2019	Removed content related to CGM. New policy created for CGM coverage guidelines. Updated to reflect current 2019 ADA standards of care. Removed clinical indicators for insulin pumps to better align with current standards of care. Hypoglycemia defined using the American Diabetes Association criteria. Defined suboptimal control for replacement pumps as: Time in target glucose range is consistently below 50% despite treatment and/or self-care adjustments; or greater than 3% of CGM values are < 70 mg/dL or episode(s) of hypoglycemia resulting in any of the following: inpatient or emergency department utilization; or the use of glucagon; or persistent episodes of level 1 (glucose <70 and > 54 mg/dL) or level 2 (glucose < 54 mg/dL) hypoglycemia despite treatment and/or self-care adjustments within the last three (3) months. Changes approved at the February 27, 2019 Medical Reviewer Meeting. Added *inhaled insulin* and *Insulin doses may be administered via syringe, pen or other equivalent device* to the Clinical Guideline section. Changes approved at the March 13, 2019 Medical Reviewer Meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019. Approved by DSS on March 27, 2019.