



PROVIDER POLICIES & PROCEDURES

CONTINUOUS GLUCOSE MONITORS (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 continuous glucose monitors. 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.

Real-Time Continuous Glucose Monitors (rtCGM)

Real-time continuous glucose monitors (rtCGM) continuously monitor and record interstitial glucose levels, glycemic trends and may provide reactive or predictive glucose alerts. The receiver component of the CGM system must be a CGM enabled insulin pump or standalone CGM monitor. A CGM that uses a smart device (e.g., smart phone, tablet, personal computer) as a receiver is not classified as durable medical equipment and therefore, is not covered by Medicaid.

Intermittently Scanned CGM (isCGM)

Intermittently scanned continuous glucose monitors (isCGM) continuously monitor and record interstitial glucose levels but require the user to purposely scan the sensor to obtain information. An isCGM that uses a smart device (e.g., smart phone, tablet, personal computer) as a receiver is not classified as durable medical equipment and therefore, is not covered by Medicaid.

CLINICAL GUIDELINE

Coverage guidelines for 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 their 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 Coverage of Real-Time Continuous Glucose Monitors (rtCGM) – Children and Adolescents

Initial rtCGM may be considered medically necessary for individuals up to 21 years of age when there is documented evidence of:

- A. Current therapy is basal/prandial (3 or more doses of injected and/or inhaled insulin - insulin doses may be administered via syringe, pen or other equivalent device per day) or insulin pump therapy;

AND

- B. The individual is engaged in the recommended care and has health-care provider support for the safe and effective use of continuous glucose monitoring. The following elements must be adequately documented in the individual's clinical visit notes to determine if this element is met:
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.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

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Initial Coverage of Real-Time Continuous Glucose Monitors (rtCGM) - Adult

Initial rtCGM may be considered medically necessary for individuals over the age of 21 when there is documented evidence of:

A. **Any one** of the following clinical indicators:

1. Hypoglycemia unawareness; or
2. Hypoglycemia resulting in an inpatient stay or emergency department visit or the use of glucagon; or
3. Suboptimal glycemic control; or
4. Pregnancy or planning a pregnancy; or
5. 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.

AND

B. The individual is engaged in the recommended care and has health-care provider support for the safe and effective use of continuous glucose monitoring. The following elements must be adequately documented in the individual's clinical visit notes to determine if this element is met:

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

A. The individual and/or caregiver have the skills necessary for the safe and effective use of continuous glucose monitoring. 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. Insulin doses may be administered via syringe, pen or other equivalent device) or insulin pump therapy;

AND

2. Glucose monitoring a minimum of four (4) times per day during the preceding 15 days or current isCGM use.

Initial Coverage of Intermittently Scanned Continuous Glucose Monitors (isCGM)

Initial isCGM may be considered medically necessary for individuals when there is documented evidence of:

A. A medical diagnosis that would warrant the monitoring of glucose levels;

AND

B. The individual is engaged in the recommended care and has health-care provider support for the safe and effective use of continuous glucose monitoring. The following elements must be adequately documented in the individual's clinical visit notes to determine if this element is met:

1. A minimum of **one (1)** 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.

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Coverage of Continuous Glucose Monitor (CGM) Supplies Needed on an Ongoing Basis

The use of CGM supplies (rtCGM and isCGM) on an ongoing basis may be considered medically necessary when there is:

- A. Documentation from a recent diabetes-related visit showing maintained use of the CGM device or a recent CGM download;

AND

- B. A current prescription for the CGM supplies being requested.

Replacement Continuous Glucose Monitors (CGM)

Replacement of a rtCGM or isCGM may be considered medically necessary when there is documented evidence that the CGM 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 finger stick glucose monitoring.

Replacement of a rtCGM may be considered medically necessary when there is documented evidence of:

- A. Hypoglycemia resulting in an inpatient stay or emergency department visit or the use of glucagon while using current CGM;

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 while using current CGM;

Note: Persistent is defined as four or more episodes occurring within a two (2) week period of time.

AND

- C. The member's current CGM lacks predicative hypoglycemia alerts.

NOTE: If the member has previously used rtCGM or isCGM, has stopped and the ordering practitioner is requesting to restart CGM, then the request will be reviewed as an initial request and will require the documentation outlined for initial use.

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 continuous glucose monitors is required. Requests for coverage of 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 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 from the prescribing MD, PA or APRN;

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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 continuous glucose monitors for individuals covered under the HUSKY Health Program beginning March 1, 2017.

LIMITATIONS

N/A

CODES:

Code	Description
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 or isCGM systems (readers and sensors).

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

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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 pertaining 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.

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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	<p>Removed content related to Insulin Pump Therapy. New Policy created for Insulin Pump guidelines.</p> <p>Updated to reflect current 2019 ADA standards of care.</p> <p>Updated with definitions for continuous glucose monitoring. Criteria reformatted and broken out into categories to better align with current diabetes management technology. Breakouts by initial and replacement devices and age.</p> <p>Hypoglycemia defined using the American Diabetes Association criteria.</p> <p>Changes approved at the February 27, 2019 Medical Reviewer meeting.</p> <p><i>Added inhaled insulin and may be administered via syringe, pen or other equivalent device per day to Clinical Guideline section.</i></p> <p>Separated real time continuous glucose monitors and intermittently scanned continuous glucose monitors.</p> <p>Changes approved at the March 13, 2019 Medical Reviewer meeting.</p> <p>Changes approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019.</p> <p>Approved by DSS on March 27, 2019.</p>

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