



State of California—Health and Human Services Agency
Department of Health Care Services



MICHELLE BAASS
DIRECTOR

GAVIN NEWSOM
GOVERNOR

DATE: December 23, 2022

NL: 15-1222
Supersedes: NL: 14-0818
Index: Benefits

TO: All County California Children's Services Program Administrators, Medical Directors and Consultants, Genetically Handicapped Persons Program and Integrated Systems of Care Division Staff

SUBJECT: CONTINUOUS GLUCOSE MONITORING SYSTEMS AS A CALIFORNIA CHILDREN'S SERVICES PROGRAM AND GENETICALLY HANDICAPPED PERSONS PROGRAM BENEFIT

I. PURPOSE

The purpose of this California Children's Services (CCS) Numbered Letter (NL) is to modify policy for the CCS Program and the Genetically Handicapped Persons Program (GHPP) regarding authorization of continuous glucose monitoring (CGM) systems for CCS Program and GHPP clients.

The CCS Program publishes this NL under the program's authority to authorize services that are medically necessary to treat CCS-eligible conditions.^{1, 2, 3}

II. BACKGROUND

CGM systems are minimally invasive devices that measure subcutaneous interstitial fluid glucose. The availability of real-time CGM data allows the individual or caregiver to monitor glucose levels, receive alerts for dangerously high or low blood glucose levels, and adjust diet and medications to avert adverse hypoglycemic or hyperglycemic events.

The CGM systems are particularly beneficial for those with hypoglycemic unawareness, consistent hyperglycemia, nocturnal hypoglycemia, and fear of hypoglycemia resulting in hyperglycemia. The CGM system is comprised of up to three main components:

- A. **Sensor:** An adhesive device containing a small wire placed subcutaneously which measures interstitial glucose and remains in place for a various number days, depending on the CGM system used. For application site information, product specific information should be followed.
- B. **Transmitter:** A device that attaches to the top of the sensor and sends glucose levels via radio waves to the receiver and/or part of a combined system that

sends information to the receiver. With some systems, the sensor and transmitter are integrated.

- C. Receiver: A device that collects and tracks data so the client, caregiver, and/or healthcare provider can adjust diet and/or insulin regimen for improved diabetes management. Some receivers are equipped with an alarm that alerts the client or client's caregiver when an individual is at risk for hypoglycemia or hyperglycemia. Some CGM systems allow for the use of a compatible smart device instead of receiver.

Numerous insulin pumps now have the ability to integrate with specific CGM systems. This includes two recently Food and Drug Administration (FDA) approved integrated insulin pumps with an automatic low glucose suspend feature and one pump with auto-corrections. The American Diabetes Association states, "These devices may offer the opportunity to reduce severe hypoglycemia for those with a history of nocturnal hypoglycemia."⁵

In 2017, the FDA separated CGMs into therapeutic and non-therapeutic. Therapeutic CGM are FDA approved for non-adjunctive use and can be used for making diabetic treatment decisions while non-therapeutic CGM are for an adjunct use only. When using non-therapeutic CGMs, diabetic treatment decisions must be made using home blood glucose monitor testing. Both therapeutic CGMs, which currently include Dexcom and Abbott Libre models, and non-therapeutic CGMs are now covered as a pharmacy benefit through Medi-Cal Rx.

III. POLICY

Effective October 1, 2022, non-therapeutic CGMs are also processed through Medi-Cal Rx according to the Medi-Cal Rx integrated coverage policy. Prior Authorization is required on all CGM requests through Medi-Cal Rx.

1. Section 13.4 of the [Medi-Cal Rx Provider Manual](#)
2. Under Covered continuous Glucose Monitoring (CGM) Systems [Medi-Cal Providers | Forms and Information](#).

- A. Therapeutic and non-therapeutic CGMs may be prescribed by one of the following:
1. A CCS Program-paneeled endocrinologist affiliated with an Endocrine Special Care Center (SCC) or SCC nurse practitioner if the physician has ordered CGM for the client, as documented in the medical record.
 2. A CCS-paneeled community pediatric endocrinologist if the client meets all of the following:

- a. Is within the age approved by the FDA for the specific CGM.
 - b. Has had a multidisciplinary team visit by the Endocrine SCC in the past 12 months.
 - c. Plans to continue to follow up at an Endocrine SCC at least annually.
3. For GHPP clients, an adult endocrinologist at an approved Endocrine SCC or an adult endocrinologist or internal medicine specialist with an active Medi-Cal provider number treating the GHPP-eligible condition.
- B. The CCS Program or GHPP client must meet all of the following:
1. The client has a diagnosis of type 1 diabetes mellitus, cystic fibrosis (CF) related diabetes, insulin-dependent type 2 diabetes, or sequelae of a CCS Program-eligible condition that requires ongoing insulin use.
 2. The client requires glucose testing by finger stick or CGM at least three times per day.
 3. The client requires analog insulin injections at least three times per day or uses an insulin pump.
 4. The client's insulin regimen requires frequent adjustment on the basis of finger stick or CGM blood glucose readings.
- C. Documentation containing all of the following information must be submitted by the Endocrine SCC or provider to Medi-Cal Rx.
1. CGM is medically necessary based on the medical report from an approved Endocrine SCC.
 2. The client meets eligibility criteria described in Section III B.1-4 of this policy.
 3. The CCS Program client has been seen for a comprehensive team visit at an Endocrine SCC, including consultation with SCC endocrinologist, within the past 12 months.
 4. The client and/or caregiver agrees to use the CGM on most days.
 5. The client and/or caregiver demonstrate a high-level of motivation to achieve tighter glucose control and competency to accurately use the CGM system and comply with recommended use.

6. The client has completed at least one session of general diabetes education within the past 12 months.

D. Reauthorization:

A CGM system may be reauthorized for up to 12 months when documentation from the Endocrine SCC or the CCS Program-paneled provider demonstrates consistent uses.

E. Additional considerations for medical necessity determination:

For clients who do not meet the criteria described in policy Section III. A through D, providers may demonstrate medical necessity by submitting other clinical documentation and/or evidence that would support the medical necessity of the CGM system for the client. Providers should submit this documentation to Medi-Cal Rx for a PA approval.

F. Integrated Insulin Pumps - A CGM system integrated with insulin pump may be authorized if the client:

1. Meets criteria for an insulin pump, described in CCS NL 06-1120⁶ or CCS NL superseding CCS NL 06-1120, and does not have a pump or requires a new pump, and
2. Meets the criteria described above for CGM.

G. Disposable Insulin Delivery Devices (DIDD) are a Medi-Cal Rx benefit. All DIDD requests must be submitted to Medi-Cal Rx according to the Medi-Cal Rx integrated policy.

1. Section 13.3 of the [Medi-Cal Rx Provider Manual](#)
2. [Covered Disposable Insulin Delivery Devices.xls](#)

H. The following items related to CGM systems are non-benefits of the CCS Program and GHPP and are not reimbursable:

1. Smart/mobile phone, tablet, or computer for downloading glucose values.
2. Mobile phone plans, even if the CGM systems has a way to share downloaded values with client's healthcare provider.
3. Mobile applications or PC software related to CGM systems.
4. Professional or personal CGM systems when used intermittently.

I. Whole Child Model (WCM) Counties:

For CCS clients who are enrolled in a Medi-Cal managed care health plan (MCP) and reside in a WCM County, CGMs and DIDD may be covered through the MCP. The client's MCP is responsible for coordinating coverage, and authorizing these items and other CGM systems, which are billable by HCPCS code only.

IV. POLICY IMPLEMENTATION

A. The following must be verified prior to authorizing CGMs:

1. The request for the CGM is from a provider listed in Section III. A of this policy.
2. The request is accompanied by all necessary documentation and the client meets the full criteria as stated in Section III of this policy.

B. Reauthorization:

Reauthorization requires documentation that the client is meeting the recommended use guidelines and the CGM has contributed to improved diabetes management. A CGM system may be reauthorized for up to one year with a PA renewal along with a report from a CCS Program-approved Endocrine SCC. This can occur after the CGM was initiated, which contains or summarizes the following information:

1. Date CGM use was initiated.
2. Medical record documentation of:
 - a. Percent of time glucose is in target range or a statement in the medical record that the client used CGM most days.
3. Hemoglobin A1C level or equivalent assessment of glucose control within the last 180 days. A hemoglobin A1c level the same or lower than baseline, or use of an insulin pump or justification for continued use by endocrinology team, is required for reauthorization.

C. Medi-Cal RX is responsible for the review for CGM replacements.

ISCD will continue to monitor developments in the use of CGM systems and will update policy as appropriate.

If you have any questions regarding this NL, please send an email to the Medical Policy Team at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Cortney Maslyn
Division Chief
Integrated Systems of Care Division

¹ [22 CCR § 41515.1 et. seq. Determination of Medical Eligibility](#)

² [22 CCR § 41700 Availability](#)

³ [22 CCR § 41740 Eligibility for Treatment Services](#)

⁴ [Medi-Cal Rx Provider Manual](#)

⁵ Numerous insulin pumps have the ability to integrate with a CGM system. This includes two recently FDA-approved integrated insulin pumps with an automatic low glucose suspend feature. The American Diabetes Association states, "These devices may offer the opportunity to reduce severe hypoglycemia for those with a history of nocturnal hypoglycemia."

⁶ [CCS Numbered Letters](#)