



JENNIFER KENT
Director

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



EDMOND G. BROWN JR
Governor

DATE: August 29, 2018

N.L.: 14-0818
Supersedes: NL: 03-0317
Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM
ADMINISTRATORS, MEDICAL CONSULTANTS, STATEWIDE
CONSULTANTS AND INTEGRATED SYSTEMS OF CARE DIVISION (ISCD)
STAFF

SUBJECT: CONTINUOUS GLUCOSE MONITORING (CGM) AS A CCS/GHPP
PROGRAM BENEFIT- REVISED WITH ATTACHMENT

I. PURPOSE

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

II. BACKGROUND

The CGM systems are minimally invasive devices that measure subcutaneous interstitial fluid glucose every five minutes. The availability of real-time CGM data allows the individual or caregiver to be aware of dangerously high or low blood glucose levels and adjust diet and medications to avert adverse hypoglycemic or hyperglycemic events. In 2016, the American Diabetes Association (ADA) stated, "For some patients, CGM are essential tools to assess therapy and detect incipient hypoglycemia."¹ In 2018, the ADA modified its recommended age range for prescribing CGM from 25 years of age to starting at age 18 years.² The CGM systems may be particularly beneficial for those with hypoglycemic unawareness, consistent hyperglycemia, and nocturnal hypoglycemia. The CGM system is comprised of up to three main components:

¹ American Diabetes Association Professional Practice Group. Standards of medical care in diabetes – 2016. Diabetes Care.2016; 39 (Suppl1).

² American Diabetes Association Professional Practice Group. Standards of medical care in diabetes – 2018. Diabetes Care.2018 January; 41 (Suppl1).

- A. Sensor: An adhesive device containing a small wire placed subcutaneously in the abdomen, arm, hip, or buttock, which measures interstitial glucose and remains in place for four to ten days, depending on the CGM system used.
- B. Transmitter: A device that attaches to the top of the sensor and sends glucose levels via radio waves to the receiver.
- 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 use of compatible smart device instead of receiver.

The U. S. Food and Drug Administration (FDA) has approved a number of CGM systems for use in children and adults to monitor real-time glucose levels, including a limited number of models for use in children as young as two years old.

Users of some CGM systems still are required to do self-monitoring blood glucose (SMBG) finger sticks for CGM calibration and to confirm blood glucose values prior to insulin dosing.

Other CGM systems have received FDA approval to allow for replacement of SMBG finger sticks prior to making a diabetes treatment decision. These systems are classified by Center for Medicare and Medicaid as "therapeutic" CGMs. Currently, two of the "therapeutic" CGM systems allow replacement of SMBG finger sticks for calibration, as well.

Current recommendations from the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) support the use of CGMs in individuals with type 1 diabetes. The International Society for Pediatric and Adolescent Diabetes (ISPAD) supports CGM use in children and adolescents, especially in children with hypoglycemic unawareness and consistent hyperglycemia. ISPAD also states that CGMs may be helpful in the management of hyperglycemia in patients with cystic-fibrosis related diabetes.³

³ Rewers, M.J., Pillay, K. de Beaufort, C., etc. ISPAD Clinical Practice Consensus Guidelines 2014 Compendium: Assessment and monitoring of glycemic control in children and adolescents with diabetes. *Pediatric Diabetes*. 2014; 15 (suppl. 20): 102 – 114.

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."⁴

III. POLICY

A CGM system may be authorized at the county level for a CCS Program client or a GHPP client for six months provided all requirements stated in this policy are met. Effective the date of this letter, CGM systems are a program benefit when:

A. Prescribed by:

1. A CCS Program-paneled endocrinologist for CCS Program clients.
2. An adult endocrinologist at an approved Metabolic/Endocrine Special Care Center (SCC).
3. A specialist treating the GHPP eligible condition at the appropriate SCC for GHPP clients.
4. A CCS paneled community pediatric endocrinologist if:
 - a. The client is over eight years old,
 - b. Has been seen by the endocrine SCC in the past 12 months; and
 - c. Will continue to follow up at that SCC at least annually.

B. The CCS Program or GHPP client meets the following medical eligibility criteria:

1. The CCS Program client has a diagnosis of type 1 diabetes mellitus (T1D), cystic-fibrosis (cf) related diabetes, or sequelae of a CCS Program eligible condition that requires chronic insulin use. Requests for CGM for clients with conditions other than T1D or cf related diabetes will be submitted to and reviewed by a county CCS Program Medical Consultant on a case-by-case basis.
2. The GHPP client has cf related diabetes, or sequelae of a GHPP eligible condition requiring chronic insulin use. Requests for CGM for clients' conditions other than cf

⁴ 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

- related diabetes will be submitted to and reviewed by a GHPP Medical Consultant on a case-by-case basis.
3. The client requires analog insulin injections at least three times per day or uses an insulin pump.
- C. The CCS Program or GHPP client has **at least one** of the following additional documented medical criteria:
1. History of hypoglycemia (blood glucose <65 mg/dl for children under eight years old or <55 mg/dl for all other clients), including recurrent hypoglycemia or nocturnal hypoglycemia, as documented in a SCC physician report.
 2. History of hyperglycemia due to client/caretaker fear of hypoglycemia, as documented in a SCC physician report.
 3. Hypoglycemic unawareness as documented in a SCC physician report.
- D. The CCS Program County Nurse case manager or designated staff has received documentation from the Metabolic/Endocrine SCC which confirm **all** of the following:
1. CGM is medically necessary based on the medical report from an approved Metabolic/Endocrine SCC report.
 2. The client meets eligibility criteria described in III-B and III-C above.
 3. The CCS Program client has been seen by a CCS Program-paneled endocrinologist from a Metabolic/Endocrine SCC at least 2 times in the last six months to optimize glucose control.
 4. When provider capacity to see patients is severely impacted, such that the provider can only see the client once every six months, one of the two required visits may be conducted by a CCS Program-paneled SCC non-physician provider (nurse practitioner or diabetes educator) trained or certified in diabetes management or by a CCS Program-paneled community endocrinologist.
 5. The client and/or caregiver agrees to use the CGM most days.
 6. 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.
- E. Reauthorization - A CGM system may be reauthorized for up to 12 months provided documentation from the Metabolic/Endocrine SCC or the CCS Program-paneled

community endocrinologist demonstrates the client is meeting recommended use guidelines and the CGM has contributed to improved diabetes management. (See section IV-D for reauthorization requirements.)

- 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 NL 11-1017, and does not have a pump or requires a new pump, and
 2. Meets the criteria described above for CGM.
- G. 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.

IV. Policy Implementation

- A. The CCS Program or GHPP Nurse Case Manager or designated staff shall ensure that the following are verified prior to authorizing:
1. The request for the CGM is from a provider listed in Section III-A.
 2. The request is accompanied by all necessary documentation as stated in Section III of this policy.
- B. If the request is determined to be medically appropriate, the authorizations are to be processed by the Nurse Case Manager or designated staff as follows:
1. For full-scope Medi-Cal, no share of cost clients, the request is to be processed as an Early Periodic Screening, Diagnosis, and Treatment – Supplemental Service (EPSDT-SS) (91) Service Authorization Request (SAR). Instructions for completing the EPSDT-SS (91) SAR can be found in Section 12.3 of the CMS Net SAR/Web Manual. These instructions can be accessed at <http://www.dhcs.ca.gov/services/ccs/cmsnet/Pages/WebManual.aspx>.

2. For the CCS Program-only and Medi-Cal Share of Cost clients, the request is to be processed using the 97 SAR prefix.
3. For therapeutic CGMs:
 - a) Review attachment for information on FDA approved “therapeutic” CGMs and coding for receiver and supplies.
 - b) **Note:** there are new HCPCS codes (K0553 and K0554) for authorizing “therapeutic” CGM services.
4. For “non-therapeutic” CGMs, each component of the CGM requires a **separate** SAR.
 - a. Receiver: One unit every three years. Exceptions will be evaluated on a case-by-case basis.
 - b. Transmitter: The recommended number (units), currently one or two, per six-month period depending on the specific CGM model. Code SAR for six- months. For some CGM systems, there is no transmitter.
 - c. Sensors: Six-month supply of sensors - with monthly (31 day) dispensing for initials authorization and 12-month supply for reauthorization. Lifespan of each sensor varies by manufacturer. Consult product literature for how long a sensor can be used before replacement. The billing unit is “one” sensor. Also, sensor packaging varies by manufacturer. Consult product literature for number of sensors per package.
5. For “non-therapeutic” CGMs, each SAR should be authorized using the EPSDT-SS Z5999 miscellaneous code, until a permanent HCPCS becomes available. Information regarding the processing of Z5999 claims can be found in This Computes # 421.
6. For “non-therapeutic” CGMs, each SAR is to be processed by using the “Category” drop-down list and choosing “Continuous Glucose Monitoring System” on the SAR form. See picture below.

Change Provider Edit Provider

SAR INFORMATION

SAR Number SAR Status

Service Begin Date * Service End Date

Patient not discharged

Service Request Date * Number of Days

EPSDT-SS State Approved Yes No

Category

Primary Diagnosis*

Secondary Diagnosis

SERVICE CODE INFORMATION

Remove Service Code

SPECIAL INSTRUCTIONS

Quantity Negotiated Price

- C. Pharmacy and durable medical equipment providers must submit claims for EPSDT-SS services on a separate claim form without other Medi-Cal items or services. The following items must be submitted in order for Z5999 claims to be processed:
1. On CMS-1500 Claim Form, for paper claiming.
 2. Copy of the CCS Program or GHPP authorization.
 3. Manufacturer's purchase invoice for billed services.
 4. Copy of the MSRP (Manufacturer's Suggested Retail Price) from a catalog published on or before the date of service. The copy must show the published date and include a description of the item, the model number, and the MSRP.
- D. Reauthorization - Reauthorization requires documentation that the client is meeting recommended use guidelines and the CGM has contributed to improved diabetes management. A CGM system may be reauthorized for up to 1 year once the CCS Program County or GHPP Nurse Case Manager or designated staff has received a

report from a CCS Program approved Metabolic/Endocrine SCC after the CGM was initiated that contains or summarizes the following information:

1. Date CGM use was initiated.
 2. Dates of data download – A two-week download of CGM data within the last 90 days is required prior to initial request for reauthorization and for clients with poor glucose control while on CGM. CGM data download may be within 180 days for clients who have had good glucose control on CGM.
 3. Medical record documentation of:
 - a. Average days per week CGM is used.
 - b. Percent of time glucose is in target range or a statement in the medical record that the client used CGM most days.
 4. HbA1c level within the last 180 days. A level the same or lower than baseline is required, without an increase in hypoglycemia episodes, is required for reauthorization unless SCC staff member describes reason for continuing medical necessity despite no documented clinical improvement is in the medical report.
- E. All requests to replace a lost or damaged CGM component will be reviewed and approved by a CCS Program County or GHPP Medical Consultant or by an ISCD Medical Officer prior to reauthorization.

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

If you have any questions regarding this N.L., please contact Dr. Jill Abramson via e-mail at Jill.Abramson@dhcs.ca.gov or by telephone at (916) 713-8388.

Sincerely,

ORIGINAL SIGNED BY

Sarah Eberhardt-Rios, Chief
Integrated Systems of Care Division

Attachment

On January 12, 2017, the Centers for Medicare & Medicaid Services issued a ruling that certain Continuous Glucose Monitoring (CGMs) systems, called “therapeutic” CGMs, to be a durable medical equipment benefit service when:

1. Equipment is U.S. Food and Drug Administration (FDA) approved for use in place of a blood glucose monitor for making diabetic treatment decisions (“non-adjunctive” use).
2. Generally not useful to the individual in the absence of an illness or injury.
3. Appropriate for home use.
4. Considered durable, lifespan of at least 3 years with repeated use.

CGM devices not having FDA designation as a therapeutic CGM are considered “non-therapeutic” CGMs and are considered as an “adjunct use” to blood glucose monitor testing. Diabetic treatment decisions must still be made using a home blood glucose monitor test.

On December 20, 2016, the FDA expanded its approval of the Dexcom’s G5 Mobile CGM System to allow for replacement of the blood glucose monitor finger stick. As a result, use of a Dexcom G5 Mobile CGM System for treatment decisions can be made without confirmation with a finger stick glucose test. The FDA considers these systems as “non-adjunctive” use. However, daily calibration with finger stick glucose readings are still required. This device is approved for adults and pediatric patients two years of age and older.

On September 27, 2017, the FDA approved Abbott’s Free Style Libre Flash CGM without need for finger stick calibration and for making diabetic treatment decisions. This device is approved for adults only, aged 18 years or older.

March 27, 2018, Dexcom’s G6 was FDA approved as an iCGM, a new category to integrate with automated insulin dosing systems). No calibration is needed and diabetes treatment decision can be made without need for finger sticks, so it is considered to be a “therapeutic CGM”. In addition, the sensor will now last ten-days. The G6 may be used as a standalone CGM or integrated into an automated insulin dosing system, for ages two years and older.

The Medi-Cal Program will consider coverage of “therapeutic” CGMs on a case-by-case basis while “non-therapeutic” CGMs remain a Medi-Cal non-benefit service.

Two new HCPCS codes were implemented, effective retroactively back to dates of service July 1, 2017:

1. K0553: Supply allowance for therapeutic CGM, includes all supplies and accessories, 1 unit of service = 1 month's supply.

2. Supplies and accessories include the following: CGM sensor, CGM transmitter, home blood glucose monitor, related blood glucose monitor supplies (test strips, lancets, lancing device, and calibration solutions), and batteries. When Provider bills K0553, these items are considered included in the payment, therefore no longer separately payable.
3. K0554: Receiver (Monitor), dedicated, for use with therapeutic continuous glucose monitor system.

Beginning with the date of this new revised number letter with attachment, CCS County/Special Populations Authorization Unit, and GHPP Service Authorization Request (SAR) processing should proceed as follows:

1. If the CGM system is, FDA approved and considered “therapeutic”, HCPCS code K0554 must be used for the receiver.
2. If the CGM system is, FDA approved and considered “therapeutic”, HCPCS code K0553 must be used for all supplies and accessories.
3. If K0553 is authorized, the provider is no longer eligible to separately bill for any supplies listed as included in the monthly allowance for K0553. Any current SARs for these supplies and accessories should be end-dated. Future SARs for these supplies and accessories will not be separately authorized, so long as the client continues to use a therapeutic CGM and should bill K0553 monthly.
4. If the CGM system is deemed “non-therapeutic”, continue to use Early Periodic Screening, Diagnosis, and Treatment – Supplemental Service EPSDT-SS code, Z5999, as instructed in this numbered letter, for all “non-therapeutic” CGM sensors, transmitters, receiver. Use of Z5999 for authorizing “non-therapeutic” CGM systems will continue until this code is cross-walked to another HCPCS code.
5. If the client is approved for a therapeutic CGM, K0553 replaces the following but not limited to these HCPCS codes:
 - a. E0607
 - b. E2100
 - c. E2101
 - d. A4233-A4236
 - e. A4244-A4247
 - f. A4250

- g. A4253
- h. A4255-A4259
- i. NDCs for contracted diabetic test strips and lancets
- j. Z5999 for non-contracted diabetic test strips and lancets

Currently, the following systems are FDA approved “therapeutic” CGM Systems:

1. Dexcom G5 Mobile CGM System.
2. Abbott FreeStyle Libre Flash Glucose Monitoring System.
3. Dexcom G6 CGM System, pending.