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

SUBJECT: CONTINUOUS GLUCOSE MONITORING (CGM) AS A CCS/GHPP PROGRAM BENEFIT

I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to disseminate policy for the California Children's Services (CCS) Program and the Genetically Handicapped Persons Program (GHPP) regarding the process for the 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 one to five minutes. When used with self-monitoring of blood glucose (SMBG), 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 The CGM systems may be particularly beneficial for those with hypoglycemic unawareness, consistent hyperglycemia, and nocturnal hypoglycemia.

The CGM system is comprised of three main components:

- A. **Sensor:** An adhesive device containing a small wire placed subcutaneously in the abdomen, hip, or buttock, which measures interstitial glucose and remains in place for four to seven days.

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

- 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. Most receivers are equipped with an alarm that alerts the client or client's caregiver when an individual is at risk for hypoglycemia or hyperglycemia.

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. While numerous CGM models are FDA approved for use in children seven years and older, currently the FDA has approved a limited number of models for use in children as young as two years old. The use of a CGM system does not alleviate the need for daily self-monitoring blood glucose (SMBG) finger sticks, as the FDA requires results from SMBG finger sticks be used to calibrate the CGM system twice a day and to confirm CGM values prior to adjusting insulin dosage, except when the CGM is used with an automatic suspend insulin pump.

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.²

At the time of this N.L., numerous insulin pumps have the ability to integrate with a CGM system. Additionally, the FDA recently approved two CGM 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."¹

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 CCS Program benefit when:

- A. Prescribed by a CCS Program-paneeled endocrinologist for CCS Program clients or adult endocrinologist at an approved Metabolic/Endocrine Special Care Center

² 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.

(SCC) or specialist treating the GHPP eligible condition at the appropriate SCC for GHPP clients.

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 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 cystic fibrosis 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 cystic-fibrosis related diabetes, or sequelae of a GHPP eligible condition requiring chronic insulin use. Requests for CGM for clients' conditions other than T1D or cystic fibrosis related diabetes will be submitted to and reviewed by a county CCS Program 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 8 years old and <55 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 in 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. 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.
4. The client and/or caregiver agrees to use the CGM 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.
- E. Reauthorization –A CGM system may be reauthorized for six 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, 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 CCS Program-paneled endocrinologist at an approved Metabolic/Endocrine SCC.
 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. Each component of the CGM requires a **separate** SAR.
 - a. Receiver: One unit per year, code SAR for one year
 - b. Transmitter: The recommended number (units), currently one or two, per 6-month period depending on the specific CGM model. Code SAR for 6 months.
 - c. Sensors: Six-month supply of sensors - with monthly (31 day) dispensing. Specifically, sensor recommended use is one per week for Dexcom, one every 6 days for Medtronic/Enlite. Others as specified by manufacturer. A billing unit is “one” sensor. Maximum allowable is 30 sensors in a six-month period. Sensors are supplied in two, 4-packs or 5-packs depending on the manufacturer. Therefore, requested number must be a multiple of two or five. When program end date is less than six months away, calculate weekly supply (usually one per week) until program end date. See This Computes # 329 for additional information regarding determining units and quantity on SARs.
 4. Each SAR should be authorized using the EPSDT-SS Z5999 miscellaneous code. Information regarding the processing of Z5999 claims can be found in This Computes # 421.

5. 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.

The screenshot shows a web browser window with a menu bar (File, Edit, View, Favorites, Tools, Help) and a toolbar. Below the toolbar are two buttons: "Change Provider" and "Edit Provider". The main content area is a form titled "SAR INFORMATION".

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: [Dropdown Menu]

Primary Diagnosis*: []

Secondary Diagnosis: []

SERVICE CODE INFORMATION

Remove Service Code: []

SPECIAL INSTRUCTIONS

The dropdown menu for "Category" is open, showing a scrollable list of services. An arrow points to the "Continuous Glucose Monitoring System" at the bottom of the list.

- Diaphragmatic Pacer
- Eye Prosthesis which includes part of the face
- FM System/Assistive Listening Device
- Incontinent Supplies for children under age five
- Investigational Non-FDA Approved Drugs
- Medical Foods
- Medical Nutrition Therapy for Ketogenic Diet
- Medical Nutrition Therapy not covered by a SCC
- Miscellaneous non-benefit items
- New Treatment Modalities and Interventions
- Non-Benefit Diabetic Test Strips/Lancets
- Non-Benefit Dietary Supplements, Vitamins, Minerals, Amino Acids, APIs, Thickeners - Requires Co Approval
- Non-benefit DME - Requires County approval
- Non-benefit DME - Requires State approval
- Non-benefit Hearing Aid
- Non-benefit Hearing Aid Batteries
- Non-benefit Radiology Service
- Occupational Therapy beyond benefit limitation
- Other Audiology Surgically Implanted Devices
- Skilled Nursing Services other than IHO
- Skilled Nursing Services via Workaround (EVR & ISR) process
- Speech Pathology Service beyond benefit limitations
- Weight Management Program
- Wheelchair Lift
- Bone Anchored Hearing Aid - Softband
- Bone Anchored Hearing Aid - Surgery
- Non-Benefit Enteral Nutrition Product
- Miscellaneous Non-Benefit - Requires County Approval
- Physician Services - Requires County Approval
- Continuous Glucose Monitoring System

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. Claim Form CMS 1500 paper claiming.
2. Copy of the CCS Program 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 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 request for reauthorization.
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 90 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 Medical Consultant or a SCD Medical Officer prior to reauthorization.

The Systems of Care Division 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) 327-2108.

Sincerely,

ORIGINAL SIGNED BY PATRICIA MCCLELLAND

Patricia McClelland, Chief
Systems of Care Division