Therapeutic Continuous Glucose Monitors to Become a Benefit of the CSHCN Services Program April 1, 2019

Information posted March 29, 2019

Effective for dates of service on or after April 1, 2019, therapeutic continuous glucose monitors (CGMs) will be a benefit of the Children with Special Health Care Needs (CSHCN) Services Program.

Procedure codes K0553 and K0554 will be a benefit in the home setting when services are provided by home health durable medical equipment (DME), medical supplier (DME), and custom DME providers.

The Centers for Medicare & Medicaid Services (CMS) ruling 1682R defines CGMs as therapeutic for clients with diabetes for home use.

Therapeutic CGM services will be a benefit when used as a replacement for self blood glucose monitoring (SBGM) for treatment decisions. Therapeutic CGMs (procedure code K0554) replace any home blood glucose monitor used for SBGM. Procedure code K0554 will be limited to one per three rolling years, any provider.

Other home glucose monitors (procedure codes E2100 and E2101) will be denied when submitted within three calendar years of procedure code K0554.

The supply allowance (procedure code K0553) for supplies used with the therapeutic CGM system encompasses all items necessary for the use of the device. The DME provider is responsible for delivering the appropriate items and quantities to the client for continuous usage of the therapeutic CGM.

Procedure code K0553 will be denied when submitted during the same calendar month by any provider as procedure code A4250, A4256, A9275, E2100, or E2101.

Prior Authorization

Prior authorization is required for a therapeutic CGM device (procedure code K0554), and associated supplies (procedure code K0553) that exceed the limit of one per calendar month. All prior authorization requests must be submitted on the CSHCN Services Program Prior Authorization Request for External Insulin Pump form.

Therapeutic CGM Device

An endocrinologist or an advanced-level provider working with an endocrinologist must prescribe a therapeutic CGM. The therapeutic CGM may be considered for prior authorization for clients with a documented diagnosis of type 1 diabetes and clinical documentation of the following criteria:

- The client uses SBGM and performs frequent testing (at least four times per day).

- The client injects insulin three or more times per day, or the client is on an insulin pump.
- The client has an insulin treatment regimen that requires frequent adjustment on the basis of SBGM or CGM testing results.
- The client demonstrates compliance with his or her insulin regimen and monitoring of his or her blood sugar, by finger sticks at a minimum of 4 times per day in a submitted glucose log of one month of recent results.
- If the client already owns a monitor, the client must also meet at least two of the following criteria for the initial order of the monitor and/or supplies:
    - Elevated glycosylated hemoglobin level (HbA1c) > 7.0 percent
    - History of dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
    - History of severe glycemic excursions with wide fluctuations in blood glucose
    - History of recurring hypoglycemia (less than 60 mg/dL) with or without hypoglycemic unawareness
    - History of diabetic ketoacidosis

The provider must submit the CSHCN Services Program Prior Authorization Request for External Insulin Pump form indicating the following:

- The client or caregiver possesses the following competencies:
    - The cognitive and physical abilities to use the CGM
    - An understanding of cause and effect
    - The ability to learn to use the device, and to hear and view CGM alerts and respond appropriately
    - The willingness to support the use of the CGM
- The prescribing provider has attested to the following:
    - A training/education plan will be completed prior to initiation of CGM therapy.
    - The client or caregiver will be given face-to-face education and instruction, and will be able to demonstrate proficiency in integrating CGM therapy with their current treatment regimen for glucose control.

The ordering provider should also verify that the client's medical condition meets the manufacturers' recommendations for appropriate age range, testing and calibration requirements, and any other manufacturer recommendations prior to prescribing the CGM device.

The initial prior authorization will be valid for six months. If the client complies with the use of the CGM and treatment plan, the physician may write an order and submit an updated PA request for an additional six

months. After the first year, an order for replacement sensors, transmitter, and receiver may be written for a 12-month period.

Associated Supplies

When a therapeutic CGM device (procedure code K0554) is approved, the related supplies (procedure code K0553) are also covered once per calendar month. Prior authorization for the related supplies is required only when extra supplies provided exceed the allowance of once per calendar month.

Prior authorization is also required for the related supplies (procedure code K0553) when the client already owns a CGM device, and the provider is not requesting a new CGM device. Clinical documentation of the following must be submitted with the prior authorization request:

- The client-owned device meets the CMS definition of a therapeutic CGM.
- A physician's statement verifying the client's current condition meets therapeutic CGM coverage criteria, to approve the initial once per calendar month allowance for the related supplies.

SBGM-related supplies (procedure codes A4233, A4234, A4235, A4236, A4253, and A4259) provided within the same calendar month as an approved therapeutic CGM device and related supplies, will require prior authorization and documentation of medical necessity. Providers must use modifier U9 for insulin-dependent clients.

Revised Prior Authorization Form

The CSHCN Services Program Prior Authorization Request for External Insulin Pump form will be updated to include the following:

- New sections for therapeutic CGM services
- New diabetes condition for rental of an external insulin pump

TMHP will accept the previous form for processing during a 30-day grace period. Effective May 1, 2019, prior authorization requests submitted on the old form will be returned to the providers with instructions to submit the request on the revised form.

Noncovered Services

The following services are not benefits of the CSHCN Services Program:

- Non-therapeutic CGM devices used as an adjunct to SBGM
- Smart devices (smart phones, tablets, personal computers, etc.) used as CGM monitors
- Non-medical items, even if the items may be used to serve a medical purpose

For more information, call the TMHP-CSHCN Services Program Contact Center at 1-800-568-2413.