Chapter 8 Section 5.3

Continuous Glucose Monitoring System (CGMS) Devices

Issue Date: December 15, 2009
Authority: 32 CFR 199

1.0 CPT[1] PROCEDURE CODES

95250, 95251, 0446T-0448T

2.0 HCPCS CODES

A9276 - A9278, K0553, K0554

3.0 DESCRIPTION

A CGMS is a minimally-invasive medical device that provides ongoing, real-time monitoring and recording of blood glucose levels by continuous measurement of interstitial fluid. These devices consist of an external receiver, external transmitter, and a subcutaneously placed sensor. A CGMS can be used by the provider for diagnostic purposes or by the patient for self-monitoring of blood glucose levels. A CGMS is prescribed for patients with insulin-treated diabetes mellitus. A CGMS can be an adjunctive device to complement, not replace, standard fingerstick Blood Glucose Monitor (BGM) testing or it can be used as a non-adjunctive device intended to replace fingersticks called "therapeutic CGMS."

4.0 POLICY

U.S. Food and Drug Administration (FDA) approved CGMS devices may be cost-shared when used according to FDA approved indications and it is documented that prior to being prescribed the CGMS the recipient of the device has diabetes, and the TRICARE authorized provider has examined the beneficiary in person and evaluated the beneficiary's diabetes control within six months prior to ordering the CGMS, and a TRICARE authorized provider documents that ALL of the following criteria have been met:

4.1 Completion of a comprehensive diabetic education program; and

4.2 Treatment regimen including at least three insulin injections per day or insulin pump therapy, with frequent self-adjustment of insulin doses in the last three months (except for Type I diabetes, gestational diabetes, and rare forms of diabetes which have no time requirement for the self-adjustment of insulin); and

4.3 Documented blood glucose self-testing on average of at least four times per day;

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4.4 And ANY of the following:

4.4.1 Glycosylated hemoglobin level (HBA1c) is greater than 7.0% or less than 4.0%;

4.4.2 History of unexplained large fluctuations in daily glucose values before meals;

4.4.3 History of early morning fasting hyperglycemia ("dawn phenomenon");

4.4.4 History of severe glycemic excursions;

4.4.5 Hypoglycemic unawareness;

4.4.6 History of recurrent, unexplained, severe hypoglycemic events (i.e., blood glucose less than 50 mg/dl);

4.4.7 History of recurrent episodes of ketoacidosis;

4.4.8 Hospitalizations for uncontrolled glucose levels;

4.4.9 Frequent nocturnal hypoglycemia; or

4.4.10 The beneficiary is pregnant and has poorly controlled diabetes or gestational diabetes.

5.0 CGMS DEVICES AND SUPPLIES

5.1 Therapeutic CGMS is defined as a device that is approved by the FDA for non-adjunctive use (i.e., used as a replacement for fingerstick BGM testing). Therapeutic CGMS devices and all related supplies shall be reported using HCPCS codes K0553 – K0554.

5.2 Non-therapeutic CGMS is defined as a device that is approved by the FDA for use to complement, not replace, information obtained from fingerstick testing. Non-therapeutic CGMS devices and all related supplies shall be reported using the following HCPCS codes: A9276, A9277 and A9278.

5.3 Replacement of a CGMS receiver may be cost-shared when BOTH of the following criteria are met:

- There is documentation confirming that the monitor/component is malfunctioning, is no longer under warranty, and cannot be repaired. (See Section 2.1 for additional information on Durable Equipment); and
- Evidence of an evaluation by a TRICARE-authorized individual professional provider (e.g., physician, nurse practitioner, etc.) managing the diabetes within the last six months that includes a recommendation supporting the continued use of a CGMS.

5.4 Contractors shall ensure the provisions of 32 CFR 199.9 and the TRICARE Operations Manual (TOM), Chapter 13, are followed to prevent fraud and abuse.

6.0 REIMBURSEMENT CONSIDERATIONS

6.1 Consistent with TRICARE's requirement to reimburse like Medicare, therapeutic (non-adjunctive) CGMS and supplies shall be reported utilizing HCPCS codes K0553-K0554 (or subsequent codes if replaced or renumbered). Devices that are labeled for use as therapeutic (non-adjunctive), even if the patient continues to perform glucose self-testing (e.g., finger sticks), shall be reported utilizing these codes.

6.2 Adjunctive (non-therapeutic) CGMS and supplies should be reported with HCPCS codes A9276 - A9278 (or subsequent codes if replaced or renumbered), with providers reminded of the requirement to use the most appropriate code for the service rendered. Only those devices which are not labeled by the FDA for therapeutic use (i.e., adjunctive, or only labeled to complement but not replace standard blood glucose monitoring) may be reported utilizing these codes.

6.3 CGMS shall be reimbursed using the rate on the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule. If there is no DMEPOS fee schedule rate, the allowable charge shall be established in accordance with the TRICARE Reimbursement Manual (TRM), Chapter 1, Section 39; Chapter 3, Section 1; and Chapter 5.

6.4 When reimbursement is made in accordance with the TRM, Chapters 3 and 5, especially when the state prevailing or billed rate is used, the contractor shall ensure the provisions of 32 CFR 199.9(b)(2), (b)(7), (c)(11) and the TOM, Chapter 13, are followed to prevent fraud and abuse.

7.0 REFERENCES

7.1 See Chapter 8, Section 2.1 for durable equipment.

7.2 See Chapter 8, Section 6.1 for medical supplies and dressings.

7.3 See TRM, Chapters 1 and 5 for reimbursement.

8.0 EXCLUSIONS

8.1 Use of a CGMS device for any condition or indication NOT included above.

8.2 Use of a CGMS device that is NOT FDA approved or used outside of the FDA labeled indications.

8.3 Equipment that does not serve a primarily medical purpose and/or does not meet TRICARE's definition of Durable Medical Equipment (DME), for example, personal computers, smart phones, tablets, smart watches, even if such devices are able to receive data from the CGMS or other DME, and/or are marketed to assist with self-management of diabetes.

8.4 Combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus.

8.5 Remote glucose monitoring devices (i.e., additional devices that will alarm in a location away from the person wearing the CGMS).

8.6 Hypoglycemic wristband alarm (a noninvasive device that does not monitor glucose levels, but measures perspiration and skin temperature).

8.7 Equipment, including the CGMS or replacement supplies, which are not medically necessary (e.g., charges for replacement supplies which are not medically necessary or documented.)

9.0 EFFECTIVE DATES

9.1 December 1, 2008.

9.2 January 1, 2017, for CGMS (CPT[2] codes 0446T-0448T).

9.3 January 1, 2020 for coverage beyond Type 1 diabetes including eliminating the use of HCPCS codes S1030-S1031 in paragraphs 2.0 and 6.2; definitions of the types of CGMS in paragraph 3.0 policy and prescription requirements in paragraphs 4.0 - 4.4.10; devices and supplies in paragraphs 5.0 - 5.4; reimbursement considerations in paragraphs 6.1 - 6.4; and exclusions added to paragraphs 8.1 - 8.7.

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