CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3751	**Date: April 21, 2017**
	Change Request 10013

SUBJECT: Two New "K" Codes for Therapeutic Continuous Glucose Monitors

I. SUMMARY OF CHANGES: To facilitate implementation of the CMS Ruling (CMS 1682-R) which was issued on January 12, 2017, the following two codes for therapeutic continuous glucose monitors will be added to the HCPCS code set effective July 1, 2017. The addition of the codes will allow the DME MACs to correctly adjudicate claims. The attached Recurring Update Notification applies to Chapter 23, section 20.

EFFECTIVE DATE: July 1, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 3, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3751	Date: April 21, 2017	Change Request: 10013

SUBJECT: Two New "K" Codes for Therapeutic Continuous Glucose Monitors

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I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) issued a Ruling (CMS-1682-R) on January 12, 2017, concluding that certain CGMs, referred to as therapeutic CGMs, that are approved by the Food and Drug Administration (FDA) for use in making diabetes treatment decisions are considered durable medical equipment (DME). The Ruling is effective on or after January 12, 2017, for CGM products covered by the Ruling.

Continuous glucose monitoring systems are considered therapeutic CGMs that meet the definition of DME at section 1861(n) of the Act and 42 CFR 414.202 if the equipment:

- Is approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
- Generally is not useful to the individual in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

  If a CGM system meets all of these criteria, it can be considered DME. The durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements is the base DME item.

B. Policy: To facilitate implementation of the CMS Ruling, the following two codes will be added to the HCPCS code set effective July 1, 2017:

K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, *1 month supply = 1 unit of service*

K0554 Receiver (Monitor), dedicated, for use with therapeutic continuous glucose monitor system

The billing jurisdiction for both of these codes will be DME MAC.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10013.1	Contractors shall add the following codes to the system for processing: K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, *1 month supply = 1 unit of service* P=34 B=D1E C=D TOS=9 K0554 Receiver (Monitor), dedicated, for use with therapeutic continuous glucose monitor system P=32 B=D1E C=D TOS= A,P,R		X		X			X	X	
10013.2	CWF shall add the codes to the CWF categories specified below on the HCPI file in HIMR in CWF: K0553 (16 ,60) K0554 (04 ,60)				X				X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10013.3	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X		X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information: N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr, Wendy.Knarr@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0