

1 (A) in subparagraph (EE), by striking
2 “and” at the end;

3 (B) in subparagraph (FF), by adding
4 “and”; and

5 (C) by adding at the end the following new
6 subparagraph:

7 “(GG) continuous glucose monitoring devices
8 (as defined in subsection (iii)(1)) furnished to a
9 CGM qualified individual (as defined in subsection
10 (iii)(2));” and

11 (2) by adding at the end the following new sub-
12 section:

13 “Continuous Glucose Monitoring Device; CGM Qualified
14 Individual

15 “(iii)(1)(A) The term ‘continuous glucose monitoring
16 device’ means a class III medical device approved by the
17 Food and Drug Administration that continuously mon-
18 itors and trends glucose levels in body fluid.

19 “(B) Such term applies to such medical device—

20 “(i) as a stand-alone product;

21 “(ii) when integrated with an insulin pump; or

22 “(iii) as an integral component of any other
23 medical device cleared or approved by the Food and
24 Drug Administration, such as artificial pancreas de-
25 vice systems.

1 “(C) With respect to a continuous glucose monitoring
2 device that is described in clause (ii) or (iii) of subpara-
3 graph (B), the Secretary shall treat an insulin pump or
4 other medical device that has a continuous glucose moni-
5 toring device as an integrated or integral component as
6 a single medical device.

7 “(D) Such term includes components, accessories,
8 and supplies that are necessary and related to the oper-
9 ation of the class III medical device, such as sensors,
10 transmitters, receivers, and requisite software.

11 “(2) The term ‘CGM qualified individual’ means any
12 of the following:

13 “(A) An individual with Type I diabetes—

14 “(i) who is following an intensive insulin
15 treatment regimen that consists of 3 or more
16 insulin injections per day or the use of a sub-
17 cutaneous insulin infusion pump;

18 “(ii) subject to paragraph (3), whose at-
19 tending physician certifies that the individual’s
20 condition cannot be safely and effectively man-
21 aged with self-monitoring of blood glucose; and

22 “(iii) who—

23 “(I) has been unable to achieve opti-
24 mum glycemic control in accordance with
25 evidence-based guidelines; or

1 “(II) has experienced hypoglycemia
2 unawareness or frequent hypoglycemic epi-
3 sodes.

4 “(B) An individual not described in subpara-
5 graph (A) who meets such other medical criteria as
6 the Secretary may specify for the furnishing of a
7 continuous glucose monitoring device based on avail-
8 able medical evidence and taking into account any
9 anticipated pathway to the development of artificial
10 pancreas device systems.

11 “(C) An individual with diabetes who has been
12 regularly using a continuous glucose monitoring de-
13 vice before becoming entitled to, or enrolling in, part
14 A, or enrolling in part B, or both.

15 “(3) For purposes of a certification by an attending
16 physician described in paragraph (2)(A)(ii), such certifi-
17 cation shall not be required more frequently than once
18 every 3 years.”.

19 (b) PAYMENT.—

20 (1) IN GENERAL.—Section 1833(a)(1) of the
21 Social Security Act (42 U.S.C. 1395l(a)(1)) is
22 amended—

23 (A) by striking “and” before “(Z)”; and

24 (B) by inserting before the semicolon at
25 the end the following: “, and (AA) with respect

1 to continuous glucose monitoring devices under
2 section 1861(s)(2)(GG)), the amount paid shall
3 be an amount equal to 80 percent of the
4 amount determined under the fee schedule es-
5 tablished under section 1834(p)”.

6 (2) CONFORMING AMENDMENT.—Section 1834
7 of the Social Security Act (42 U.S.C. 1395m) is
8 amended by adding at the end the following new
9 subsection:

10 “(p) FEE SCHEDULE FOR CONTINUOUS GLUCOSE
11 MONITORING DEVICES.—

12 “(1) ESTABLISHMENT.—

13 “(A) IN GENERAL.—With respect to con-
14 tinuous glucose monitoring devices (as defined
15 in section 1861(iii)(1)) furnished during a year,
16 the amount of payment under this part for such
17 devices shall be determined under a fee schedule
18 established by the Secretary in accordance with
19 this subsection.

20 “(B) CLARIFICATION OF APPLICATION OF
21 FEE SCHEDULE TO DEVICES HAVING CGM AS AN
22 INTEGRAL COMPONENT.—Payment shall be cal-
23 culated and made under the fee schedule estab-
24 lished under this subsection for any insulin
25 pump or other medical device that has a contin-

1 uous glucose monitoring device as an integrated
2 or integral component.

3 “(2) INITIAL PAYMENT RATE.—

4 “(A) IN GENERAL.—With respect to each
5 distinct type of continuous glucose monitoring
6 device, the Secretary shall establish an initial
7 payment rate under the fee schedule established
8 under this subsection for the first year, which
9 may be a partial year, during which payment
10 may be made for such continuous glucose moni-
11 toring device under this part.

12 “(B) DATA.—With respect to a continuous
13 glucose monitoring device, the initial payment
14 rate under subparagraph (A) shall—

15 “(i) reflect market rates for such de-
16 vice; and

17 “(ii) take into account the most recent
18 available data on prices for such device.

19 “(C) ACCOUNTING FOR DIFFERENCES IN
20 FUNCTIONALITIES AMONG VARIOUS CGM DE-
21 VICES.—For purposes of the initial payment
22 rates established under subparagraph (A), the
23 Secretary shall establish a new HCPCS code for
24 each distinct type of class III medical device
25 cleared or approved by the Food and Drug Ad-

1 ministration that includes a continuous glucose
2 monitoring device, such as a medical device de-
3 scribed in clause (ii) or (iii) of section
4 1861(iii)(1)(B). Such HCPCS codes shall dis-
5 tinguish among the different functionalities of
6 such devices in a manner that reflects the clas-
7 sifications of the Food and Drug Administra-
8 tion in clearing or approving such devices.

9 “(3) UPDATES TO PAYMENT RATES.—With re-
10 spect to each year beginning after the year, or par-
11 tial year, referred to in paragraph (2)(A) during
12 which an initial payment rate is established for a
13 distinct continuous glucose monitoring device, the
14 Secretary shall provide for annual updates to the
15 payment rate under the fee schedule established
16 under this subsection for each such device for the
17 preceding year by the percentage increase in the
18 consumer price index for all urban consumers
19 (United States city average) for the 12-month period
20 ending with June of the preceding year.

21 “(4) ADJUSTMENT FOR GEOGRAPHIC VARI-
22 ATIONS.—The Secretary shall provide for adjust-
23 ments to the payment rates under the fee schedule
24 established under this subsection to take into ac-

1 count geographic variations in the prices of contin-
2 uous glucose monitoring devices.”.

3 (c) ENSURING BENEFICIARY ACCESS TO APPRO-
4 PRIATE COMPONENTS.—Section 1847(a) of the Social Se-
5 curity Act (42 U.S.C. 1395w–3(a)) is amended by adding
6 at the end the following new paragraph:

7 “(8) ENSURING BENEFICIARY ACCESS TO AP-
8 PROPRIATE COMPONENTS.—

9 “(A) IN GENERAL.—In carrying out the
10 programs under this section with respect to glu-
11 cose meters required for continuous glucose
12 monitoring devices (as defined in section
13 1861(iii)(1)) that are furnished to CGM quali-
14 fied individuals (as defined in section
15 1861(iii)(2)), the Secretary shall ensure that
16 such CGM qualified individuals are furnished
17 the brand of diabetic testing supplies (as de-
18 fined in subparagraph (B)) that function with
19 such continuous glucose monitoring devices,
20 such as in the case where there is only one
21 brand of glucose meter that is compatible with
22 a particular continuous glucose monitoring de-
23 vice.

1 “(B) DEFINITION.—In this paragraph, the
2 term ‘diabetic testing supplies’ means glucose
3 meters and diabetic testing strips.”.

4 (d) EFFECTIVE DATE; RULEMAKING.—

5 (1) EFFECTIVE DATE.—The amendments made
6 by this section shall apply to items and services fur-
7 nished on or after January 1, 2015.

8 (2) RULEMAKING.—

9 (A) IN GENERAL.—The Secretary of
10 Health and Human Services (in this paragraph
11 referred to as the “Secretary”) shall implement
12 the amendments made by this section through
13 notice and comment rulemaking.

14 (B) CONSULTATION.—As part of the rule-
15 making process under subparagraph (A), the
16 Secretary shall consult with national organiza-
17 tions representing individuals with diabetes,
18 physicians with relevant clinical expertise in en-
19 docrinology, and other relevant stakeholders to
20 develop clinical criteria for the determination of
21 whether an individual qualifies as having Type
22 I diabetes under section 1861(iii)(2)(A) of the
23 Social Security Act, as added by subsection
24 (a)(2). Not later than 60 days after the date of
25 enactment of this Act, the Secretary shall con-

1 vene a meeting of those stakeholders to develop
2 consensus recommendations for such clinical
3 criteria. The Secretary shall take such rec-
4 ommendations into account in implementing the
5 amendments made by this section.

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