CMS Rulings **Department of Health and Human Services**

Centers for Medicare & Medicaid Services

Ruling No.: CMS-1738-R Date: May 13, 2022

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This Ruling provides notice of the CMS Administrator's determination to rescind a January 17, 2017 CMS Ruling (CMS-1682-R) (hereinafter referred to as the January 2017 Ruling), and instead apply the terms of the December 28, 2021 final rule (86 FR 73860 through 73902) (hereinafter referred to as the December 2021 final rule), and this Ruling, to Medicare Part B and Part C claims for payment for continuous glucose monitors (CGMs). February 28, 2022 is the effective date of the December 2021 final rule, and claims for payment for a CGM monitor or receiver and/or its necessary supplies and accessories furnished to a Medicare beneficiary on or after February 28, 2022 shall be classified, covered, and paid in accordance with the December 2021 final rule. As for CGMs furnished before February 28, 2022, this Ruling provides that the substantive CGM classification, coverage, and payment policies

established by the December 2021 final rule shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where either: (1) a valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM claim or file a valid CGM appeal had not expired as of February 28, 2022.

M**EDICARE PROGRAM**

SUPPLEMENTARY MEDICAL INSURANCE (PART B) AND MEDICARE ADVANTAGE PROGRAM (PART C)

CLASSIFICATION, COVERAGE, AND PAYMENT FOR CONTINUOUS GLUCOSE MONITORS AS DURABLE MEDICAL EQUIPMENT

CITATIONS: Sections 1861(n) and 1852 of the Social Security Act (42 U.S.C. 1395x(n) and 42 U.S.C. 1395w-22) and 42 CFR 414.202 and 42 CFR 422.101.

BACKGROUND

1. Medicare Classification, Coverage, and Payment for Continuous Glucose Monitors as Durable Medical Equipment

Medicare Part B provides for coverage and payment of certain durable medical equipment (DME). DME is a benefit category under Medicare Part B, defined at section 1861(n) of the Act. The term durable medical equipment is further defined and addressed in regulation and program instructions (see 42 CFR 414.202 and section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02), respectively).

Under § 414.202, durable medical equipment means equipment which

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;

- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME under Medicare Part B. Also, Medicare coverage generally requires that the item or service was reasonable and necessary for the diagnosis or treatment of illness or injury. Section 1862(a)(1)(A) of the Act (42 U.S.C. 1395y(a)(1)(A)); 42 CFR 411.15(k)(1).

Under Medicare Part C, Medicare Advantage organizations (MAOs) must provide Medicare Advantage (MA) plan enrollees, either directly or through contracts with providers, with certain basic benefits consisting of all covered benefits under Medicare Parts A and B (except for hospice care or coverage for organ acquisitions for kidney transplants), and generally offer at least one plan option that covers benefits under Part D. Section 1852(a)(1) of the Act (42 U.S.C. 1395w-22(a)(1)); 42 CFR 422.100(a) and (c)(1) and 422.101. DME covered under Part B is among the basic benefits that MAOs must provide under Part C (42 CFR 422.100(l)).

CGMs are systems that use disposable glucose sensors to monitor a patient's interstitial fluid glucose levels on a continuous basis. The interstitial fluid glucose level is a reflection of the patient's blood glucose level, which is then displayed by the CGM monitor or receiver. A "therapeutic" or "non-adjunctive" CGM provides such monitoring without requiring the use of another device such as a blood glucose monitor for verifying the patient's blood glucose level. A "non-therapeutic" or "adjunctive" CGM requires an additional blood glucose determination using a device like a blood glucose monitor to verify the accuracy of the CGM's measurement. Additionally, certain insulin pumps can also function as a CGM monitor or receiver.

The January 2017 Ruling was issued on January 12, 2017, and is entitled Classification of Therapeutic Continuous Glucose Monitors as "Durable Medical Equipment" Under Part B. The January 2017 Ruling classified therapeutic or non-adjunctive CGMs as DME. If a certain therapeutic or non-adjunctive CGM met the criteria for DME, then it would be covered if the specific CGM was reasonable and necessary for treatment of illness or injury for the Medicare beneficiary. The January 2017 Ruling also addressed the calculation of fee schedule payment amounts for therapeutic or non-adjunctive CGMs under section 1834(a) of the Act (42 U.S.C. 1395m(a)) and 42 CFR part 414, subpart D.

However, the January 2017 Ruling rejected classification of non-therapeutic or adjunctive CGMs as DME because such CGMs require an additional device like a blood glucose monitor to verify blood glucose levels. Also, the January 2017 Ruling did not specifically address DME classification of insulin pumps that also function as a CGM monitor or receiver.

Final agency decisions denying coverage of non-therapeutic or adjunctive CGMs based on the January 2017 CMS Ruling were challenged in several lawsuits. In each case to reach the merits, the court concluded that Medicare should cover non-therapeutic or adjunctive CGMs. (*See Olsen v. Cochran*, No. 2:20-cv-00374-SMJ, 2021 WL 711469 at *3-4 (E.D. Wash. February 23, 2021) (summarizing cases).)

Informed in part by this line of judicial precedent, CMS engaged in notice and comment rulemaking regarding classification, coverage, and payment for CGMs. The result was the previously referenced December 2021 final rule, which established the same classification and coverage policies for all three types of CGMs: therapeutic or non-adjunctive CGMs; non-therapeutic or adjunctive CGMs; and insulin pumps that also function as a CGM monitor or receiver. The December 2021 final rule provides that disposable supplies and accessories

essential for the use of CGMs can be covered under the DME benefit regardless of which of these three types of CGMs is used. Because smartphones, tablets, or other similar devices that can also function as a CGM monitor or receiver are also useful to an individual in the absence of an illness or injury, such smartphones, tablets, or other similar devices are not classified as DME. However, if a Medicare beneficiary uses a smartphone or other similar non-DME device to display their glucose readings in conjunction with one of the three types of CGMs which they use as their primary display device, Medicare will cover disposable supplies and accessories pursuant to the December 2021 final rule because the beneficiary is using their covered CGM device as their primary display device for their glucose readings. In the case of an insulin pump that doubles as a CGM receiver, it must be determined that both the insulin pump and CGM are reasonable and necessary for the treatment of illness or injury for the beneficiary in order for the insulin pump/CGM receiver combination and related supplies and accessories for this equipment to be covered. The December 2021 final rule also addressed payment policies for the different types of CGMs.

As noted previously, February 28, 2022 is the effective date of the December 2021 final rule. Thus, claims for a CGM monitor or receiver and/or its necessary supplies and accessories furnished to a Medicare beneficiary on or after February 28, 2022 must be classified, covered, and paid as DME in accordance with the December 2021 final rule.

CMS addressed CGMs furnished before February 28, 2022 in its Technical Direction Letter-220257 (February 25, 2022) ("the 2022 TDL"). The 2022 TDL provides that, for CGMs furnished before February 28, 2022, the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule must also be applied to claims for payment for a CGM monitor or receiver and/or its necessary supplies and accessories where either (1) a

valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM claim or file a valid CGM appeal had not expired as of February 28, 2022. As set forth later in this section, this Ruling reiterates and effectively replaces the essential terms of the 2022 TDL.

The December 2021 final rule replaced the 2017 CMS Ruling, CMS-1682-R, for CGMs furnished on or after February 28, 2022. Taken together, the December 2021 final rule and this Ruling prohibit further application of the January 2017 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or non-adjunctive CGMs, non-therapeutic or adjunctive CGMs and insulin pumps that also function as a CGM monitor or receiver can also meet the definition of DME at 42 CFR 414.202. As set forth later in this section, this Ruling rescinds the January 2017 Ruling and applies the CGM classification, coverage, and payment provisions of the December 2021 final rule to valid CGM claims and valid CGM appeals for CGM monitors or receivers and/or necessary supplies and accessories furnished before February 28, 2022 under certain conditions. By rescinding the January 2017 Ruling, this Ruling will avoid the expenditure of administrative resources on further application of the January 2017 Ruling on CGMs and additional appeals challenging application of the January 2017 Ruling.

Like the 2022 TDL, the purpose of this Ruling is to bring an orderly conclusion to pending (and potentially forthcoming) administrative claims and appeals relating to the requirements for classification, coverage, and payment of CGM claims under Parts B and C. In accordance with section 1871(b)(2)(C) of the Act (42 U.S.C. 1395hh(b)(2)(C)) and the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), there is good cause to issue and apply this Ruling without further public notice-and-comment rulemaking procedures because such procedures are impracticable, unnecessary, and contrary to the public interest in the orderly processing of CGM claims and

administrative appeals under Parts B and C, particularly because the substantive CGM classification, coverage, and payment policies adopted in this Ruling were already subject to notice-and-comment rulemaking in connection with the December 2021 final rule. Moreover, in accordance with section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii)), the issuance and retroactive application of this Ruling is necessary to serve the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C.

2. Administrative and Judicial Review

Upon receipt of a valid Part B DME claim by a claimant (that is, the patient-beneficiary or their supplier-assignee), the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) issues an initial determination addressing coverage of the item or service and determining any payment due. Section 1869(a)(1), (2) of the Act (42 U.S.C. 1395ff(a)(1) and (2)); 42 CFR 405.904 and 405.920. The claimant then may pursue a multi-level process for administrative and judicial review. First, the appellant (a claimant who has filed an appeal) may request a redetermination by the DME MAC. Section 1869(a)(3) of the Act (42 U.S.C. 1395ff(a)(3)); 42 CFR 405.940. Then the appellant may seek reconsideration by a qualified independent contractor (QIC). Section 1869(b)(1)(A), (c) of the Act (42 U.S.C. 1395ff(b)(1)(A) and (c)); 42 CFR 405.960. Next the appellant may request a hearing before an Administrative Law Judge (ALJ). Sections 205(b) and 1869(b)(1(A) of the Act (42 U.S.C. 405(b) and 1395ff(b)(1)(A)); 42 CFR 405.1002. Then the appellant may request review by the Medicare Appeals Council (the Appeals Council) within the Departmental Appeals Board. Section 1869(d)(2) of the Act (42 U.S.C. 1395ff(d)(2)); 42 CFR 405.1100. The Appeals Council's final decision is subject to judicial review in accordance with sections 205(g) and 1869(b)(1)(A) of the Act (42 U.S.C. 405(g), 1395ff(b)(1)(A)) and 42 CFR 405.1130. If an

appellant does not timely pursue administrative review at any level, then the non-appealed determination or decision becomes final and binding (42 CFR 405.928, 405.958, 405.978, 405.1048, and 405.1130). Final and binding determinations and decisions on Part B claims are subject to reopening if certain criteria are met (42 CFR 405.980).

A similar administrative and judicial review process applies to Part C claims. Upon receipt of a pre-service request for coverage or a valid Part C claim for payment by a claimant (that is, the MA plan enrollee or the provider of the item or service in question), the MAO issues an organization determination addressing coverage of the item or service and determining any payment due. Section 1852(g)(1) of the Act (42 U.S.C. 1395w-22(g)(1)); 42 CFR 422.566(b)(2) and 422.568. The claimant then may pursue a multi-level process for administrative and judicial review if the request is denied or partially denied. To start, the appellant (a claimant who has filed an appeal) may request a reconsideration by the MAO. Section 1852(g)(2) of the Act (42 U.S.C. 1395w-22(g)(2)); 42 CFR 422.578. If the MAO does not rule fully in favor of the appellant in the reconsideration process, it is required to forward the request to an independent entity contracted by CMS for reconsideration. Section 1852(g)(4) of the Act (42 U.S.C. 1395w-22(g)(4)); 42 CFR 422.590 and 422.592. If the independent entity does not rule fully in favor of the appellant, then the appellant may request a hearing before an ALJ. Sections 205(b) and 1852(g)(5)) of the Act (42 U.S.C. 405(b) and 1395w-22(g)(5)); 42 CFR 422.600 and 422.602. The MAO has the right to be a party to this ALJ proceeding (42 CFR 422.602(c)). Next the appellant or, if a party to the ALJ proceeding, the MAO, may request review of the ALJ's decision or dismissal by the Appeals Council (42 CFR 422.608). The Appeals Council's final decision is subject to judicial review in accordance with sections 205(g) and 1852(g)(5) of the Act (42 U.S.C. 405(g) and 1395w-22(g)(5)) and 42 CFR 422.612. Any party to the Appeals

Council's final decision, including the MAO, may request judicial review. *Id.* If an appellant does not timely pursue administrative review at any level, then the non-appealed determination or decision becomes final and binding (42 CFR 422.576 and 422.596). Final and binding organization determinations and decisions on Part C organization determinations are subject to reopening if certain criteria are met (42 CFR 422.616).

IMPLEMENTATION

Implementation of this Ruling involves the following four requirements.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary on or after the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, then such claim shall be processed in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule. If an enrollee in an MA plan seeks, on or after February 28, 2022, approval of coverage of a CGM prior to receipt of the benefit, then the Part C organization determination shall be decided in accordance with the substantive CGM classification, coverage, and payment policies established in the December 2021 final rule.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, then the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling shall be applied to claims for a CGM monitor or receiver and/or its necessary supplies and accessories where either: (1) a valid CGM claim or valid CGM appeal was pending as of February 28, 2022; or (2) the right to submit a valid CGM

claim or file a valid CGM appeal had not expired as of February 28, 2022. If an enrollee in an MA plan falls in category (1) or (2) of the prior sentence and seeks, before February 28, 2022, approval of coverage of a CGM prior to receipt of the benefit, then any Part C organization determination shall be decided in accordance with the substantive CGM classification, coverage, and payment policies established in the December 2021 final rule and adopted in this Ruling.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, and a non-favorable determination or decision regarding the claim was issued but had not yet become final and binding as of February 28, 2022 (that is, the time to appeal the determination or decision had not yet expired as of February 28, 2022), then such non-final and non-favorable determination or decision shall be reopened for application of the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

- If a CGM monitor or receiver and/or its necessary supplies and accessories has been furnished to a Medicare beneficiary before the February 28, 2022 effective date of the December 2021 final rule and payment for the CGM is claimed under Part B or Part C, as applicable, and as of February 28, 2022 there was a final and binding determination or decision for such CGM claim and the time to file a valid CGM appeal had expired, then such final and binding determination or decision shall not be reopened for application of the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

RULING

First, it is CMS's Ruling that the January 12, 2017 Ruling, CMS-1682-R, is hereby rescinded and shall not be applied to any additional CGM claims under Part B or Part C, as applicable, or to any further administrative appeals of CGM claims.

Second, it is further CMS's Ruling that claims for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B and CGM requests for coverage and claims under Part C, as applicable, shall be controlled by the December 2021 final rule or this Ruling, as applicable, and in any event the following types of CGMs shall be classified as DME: therapeutic or non-adjunctive CGMs; non-therapeutic or adjunctive CGMs; and insulin pumps that also function as a CGM monitor or receiver. However, because smartphones, tablets, or other similar devices that can also function as a CGM monitor or receiver are also useful to an individual in the absence of an illness or injury, and therefore do not meet the definition of DME, such smartphones, tablets, or other similar devices are not classified as DME.

Third, it is also CMS's Ruling that a specific claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or a CGM request for coverage under Part C, as applicable, that is classified as DME under the December 2021 final rule or this Ruling, shall be covered under Part B or Part C, as applicable, provided that the specific CGM is determined to be reasonable and necessary for diagnosis or treatment of illness or injury for the Medicare patient-beneficiary. If a Medicare beneficiary is using a smartphone or other similar non-DME device to display their glucose readings in conjunction with the DME item, then the disposable items (but not the smartphone or other similar non-DME item) shall be covered under Part B or Part C, as applicable, because the beneficiary is using the DME item as the primary device to display their glucose readings, again provided that the specific DME item is determined to be

reasonable and necessary for diagnosis or treatment of illness or injury for the Medicare beneficiary.

Fourth, it is further CMS's Ruling that if a specific CGM monitor or receiver and/or its necessary supplies and accessories qualifies for coverage under Part B or Part C, as applicable, under the December 2021 final rule or this Ruling, then the pertinent claim shall be paid in accordance with the fee schedule payment policies addressed in the December 2021 final rule and adopted in this Ruling.

Fifth, it is also CMS's Ruling that if a non-final, non-binding, and non-favorable determination or decision on a claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, was pending in a valid administrative appeal as of February 28, 2022, then the pertinent administrative appeal tribunal shall issue a determination or decision based on this Ruling. Effectuation of such determination or decision shall be performed by the DME MAC (for Part B claims) or the MAO (for Part C claims), as applicable, and the underlying claims shall be adjusted in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

Sixth, it is further CMS's Ruling that if, as of February 28, 2022, a non-final, non-binding, and non-favorable determination or decision on a claim for a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, has not yet been appealed but the period for filing a valid appeal had not yet expired as of February 28, 2022, then whomever rendered such determination or decision shall reopen its determination or decision and issue a new determination or decision based on this Ruling. Effectuation of the new determination or decision shall be performed by the DME MAC (for Part B claims) or the MAO

(for Part C claims), as applicable, and the underlying claims shall be adjusted in accordance with the substantive CGM classification, coverage, and payment policies established by the December 2021 final rule and adopted in this Ruling.

Seventh, it is also CMS's Ruling that, consistent with 42 CFR 405.986(b) and 422.616(a), this Ruling is not an appropriate basis for the reopening of any payment determination or decision regarding a CGM monitor or receiver and/or its necessary supplies and accessories under Part B or Part C, as applicable, except as set forth in the third bulleted paragraph of the Implementation section of this Ruling, and directly above in the sixth paragraph of this Ruling section.

Eighth, it is further CMS's Ruling that in accordance with section 1871(b)(2)(C) of the Act (42 U.S.C. 1395hh(b)(2)(C)) and the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), there is good cause to issue and apply this Ruling without further public notice-and-comment rulemaking procedures because such procedures are impracticable, unnecessary, and contrary to the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C. CMS notes that the substantive CGM classification, coverage, and payment policies underlying this Ruling were already subject to notice-and-comment rulemaking in connection with the December 2021 final rule, and CMS is adopting those policies here for similar reasons as those described in the December 2021 final rule.

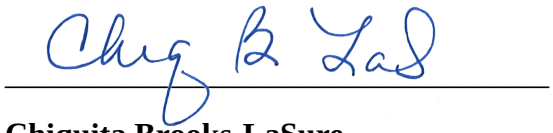
Ninth, it is also CMS's Ruling that in accordance with section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii)), the issuance and retroactive application of this Ruling is necessary to serve the public interest in the orderly processing of CGM claims and administrative appeals under Part B and Part C.

Tenth, it is also CMS's Ruling that this Ruling shall be implemented in accordance with the four requirements set forth in the Implementation section of this Ruling.

EFFECTIVE DATE

This Ruling is effective May 13, 2022. **[Insert date]**

Dated: May 13, 2022 **[Insert date]**



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