Local Coverage Determination (LCD)

Implantable Continuous Glucose Monitors (I-CGM)

L38617

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

LCD Information

Document Information

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Issue

Issue Description

This LCD modifies the coverage criteria for Implantable Continuous Glucose Monitors (I-CGMs) based on the current available evidence. This revision is in response to an inquiry from a stakeholder requesting that the LCD be updated in accordance with the recently revised Durable Medical Equipment (DME) Contractor's LCD, L33822, Glucose Monitors. Following review of the available evidence, a new indication has been added to address beneficiaries with problematic hypoglycemia and the other indications and limitations have been modified.

Issue - Explanation of Change Between Proposed LCD and Final LCD

N/A

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for Implantable Continuous Glucose Monitors (I-CGM). Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for Implantable Continuous Glucose Monitors (I-CGM) and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM 100-08, *Medicare Program Integrity Manual*,
    - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Diabetes mellitus (DM) is a chronic metabolic disease involving an underproduction or resistance to insulin, resulting in elevated blood glucose levels. The two most common types of diabetes are type 1 (T1DM) and type 2 (T2DM).[1] T1DM comprises approximately 5-10% of diabetes cases and describes an etiology in which an autoimmune response damages the insulin-producing beta cells of the pancreas, resulting in insufficient insulin production. Conversely, T2DM is characterized by insulin resistance.[1,2] In T2DM, an individual's insulin production fails to offset the deficit that is created by the resistance.[1] T2DM constitutes an estimated 90%-95% of diabetes cases.[2]

Approximately 11.3% of Americans have diagnosed diabetes, and an additional 3.4% of Americans are estimated to have undiagnosed diabetes. The prevalence of diabetes is known to increase with age. In Medicare-aged populations in the United States (≥ 65 years of age), 22.4% of the population has diagnosed diabetes, with an additional 4.7% estimated to have undiagnosed diabetes.[3] Economic evaluations have estimated that diabetes annually accounts for $237 billion in direct US medical expenditure, and an additional $90 billion in lost productivity.[4]

Acute complications of diabetes include hypoglycemia, hyperglycemia, diabetic coma, and nonketotic hyperosmolar coma. Chronic hyperglycemia, resulting from poorly controlled diabetes, may result in serious and life-threatening damage, including dysfunction and failure of the eyes, kidneys, nervous system and cardiovascular system. The complications of diabetes mellitus are far less common and less severe in people who have well-controlled blood sugar levels.[1]

To prevent and/or delay the development of both short- and long-term complications of diabetes, the American Diabetes Association (ADA) recommends person-centered care aimed at timely treatment decisions following evidence-based guidelines. Person-centered care goals include minimizing the progression of hyperglycemia with more intensive approaches for individuals at higher risk which include those with higher glucose levels (e.g., fasting blood glucose 110-125 mg/dL, 2-hour post-challenge glucose 173-199 mg/dL, A1C ≥ 6.0%).[5]

Diabetes treatment relies on diet, exercise, lifestyle modifications, and in many, medications in order to keep their blood sugar under a stable and controlled level. Close glucose monitoring either multiple times a day or continuously may be warranted in those diabetics that are having difficulty maintaining that level.[1,6]

Continuous glucose monitoring (CGM) devices measure glucose via interstitial fluid instead of blood. CGM systems traditionally rely on a multi-part system that often involves: 1.) a sensor that is inserted into subcutaneous tissue; 2.) a receiver/mobile application consisting of a display and interface; 3.) a transmitter component that is attached to the sensor and worn externally.[6,7] The sensors for these subcutaneous CGM systems need to be removed and replaced every 4 to 6 days depending upon the system.[6]

Despite the number of benefits that subcutaneous CGM offer in the DM management paradigm, some CGM studies have reported relatively high attrition rates that patients attributed to discomfort, contact dermatitis, issues changing the sensors, and physical interference with activities of daily living.[8] The rationale for implantable continuous glucose monitoring (I-CGM) seeks to circumvent these negative patient experiences. Unlike with subcutaneous CGM, I-CGM involves a sensor that is surgically implanted for longer spans of time between replacement, allowing for skin barrier closure, and less frequent manipulation.

Covered Indications

Therapeutic I-CGMs are considered medically reasonable and necessary by Medicare when all of the following coverage criteria (1-4) are met:

1. The beneficiary has diabetes mellitus; **and**,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; **and**,
3. The I-CGM is prescribed in accordance with its FDA indications for use; **and**,
4. The beneficiary for whom an I- CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
    - The beneficiary is insulin-treated; or,
    - The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
        - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL [3.0mmol/L]) that persists despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        - A history of one level 3 hypoglycemic event (glucose <54mg/dL [3.0mmol/L]) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

ICGM Continued Coverage

Every 6 months following the initial prescription of the I-CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their I-CGM regimen and diabetes treatment plan.

Limitations

I-CGM devices will be considered not medically reasonable and necessary for short-term (72 hours to 1 week) use.

Exception: Beneficiaries who have previously met the coverage criteria for a non-implantable therapeutic/non-adjunctive and non-therapeutic/adjunctive continuous glucose monitor through the Medicare DME benefit may subsequently choose to switch to the implantable device with a provider order. However, all other coverage criteria above must be fulfilled in order for Medicare payment.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

Introduction

The primary aim of this summary of evidence is to determine if I-CGM performs with equivalent clinical validity, efficacy, safety, and patient perceived benefit when compared with subcutaneous CGM devices. The secondary aim of this summary of evidence is to evaluate the expected magnitude of benefit across the aforementioned outcomes resulting from the inclusion of I-CGM into the diabetes management paradigm.

At the time of this review, the Eversense E3 is the only device that has received clearance for use by the United States Food and Drug Administration (FDA). However, it is this Medicare Administrative Contractor's expectation that additional devices are in the development and/or FDA approval process and soon may be publicly available. Hence, this policy is written to reflect coverage criteria and accompanying evidentiary review and analysis on I-CGM devices in an agnostic manner without the endorsement of any specific product.

Food and Drug Administration (FDA) Approvals

Eversense Continuous Glucose Monitoring System: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048A.pdf

Literature Analysis

Clinical Validity

The accuracy of CGM devices is most commonly assessed by evaluating mean absolute relative difference (MARD). The MARD value represents the average percent difference between glucose readings that are concurrently obtained at multiple timepoints via an index test (I-CGM in this instance) and via an established reference standard test. MARD is then reported as a percentage, with lower values signifying a higher degree of test accuracy.[9] For reference, one narrative review reported that the majority of CGM systems achieve an average MARD of between 9% to 14%, and that a MARD of < 10% had been discussed as a threshold for a CGM system that is accurate enough to inform insulin dosage decisions.[10] Thirteen of the studies (14 publications) identified by the literature search evaluated the accuracy of I-CGM with MARD.[11-24]

Four of these 13 studies performed comparative analyses analyzing the accuracy of I-CGM compared with subcutaneous CGM systems.[12,13,17,19]

Fokkert and colleagues conducted a multi-test diagnostic cohort study among 23 athletes with T1DM. All 23 participants utilized an Eversense device, Free Style Libre (FSL) Flash Glucose Monitoring (FGM) system (subcutaneous CGM), and Free Style Libre Precision NeoPro strips (diagnostic standard). During normal activity among this sample of patients, Eversense performed with a MARD of 13% ± 6%, and the FSL FGM system had a MARD of 12% ± 5%; differences in these MARD values were not statistically quantified.[17]

One study conducted a three-way MARD analysis, comparing the accuracy of Eversense, the FSL Pro system (subcutaneous CGM), and the Dexcom G5 system (DG5) in a head-to-head fashion, with the StatStrip Xpress meter serving as the diagnostic standard. In this trial, 23 adults with T1DM utilized all 4 glucose monitoring devices over a 6-week timespan. Over the course of this trial, the authors reported that the MARD of Eversense was 14.8% ± 14.8%; FSL Pro performed with a MARD of 16.3% ± 15.4%, and the MARD of Libre Pro was 18.0% ± 17.9%. Jafri et al, then performed a pairwise comparison between these three MARD values, and determined that in this study, DG5 was significantly more accurate (P=0.004) than FSL Pro, and Eversense was significantly more accurate than both DG5 (P=0.008) and FSL Pro (P<0.000).[19]

Boscari and colleagues performed 2 separate trials comparing the MARD of Eversense with that of DG5. In the first trial, 11 adults with T1DM and HbA1c > 10% at baseline were enrolled, and Yellow Spring Instruments (YSI) STAT plus 2300 was used as the reference standard. Over the 1-week follow-up, the MARD of I-CGM (11.4% [IQR: 5.04% to 18.54%]) was statistically significantly less accurate (signed-rank test P<0.05) compared with that of Dexcom G5 (DG5) (7.91% [IQR: 4.14% to 14.30%]).[12] The second trial was designed as a crossover RCT study, in which 16 adults with T1DM and HbA1c < 10% underwent 12 weeks of DG5 and 12 weeks of Eversense, with self-monitoring of blood glucose (SMBG) serving as the reference test. Among this sample of 16 participants, the MARD of Eversense (12.27% ± 11.55%) was significantly more accurate (P<0.001) when compared with the MARD of DG5 (13.14% ± 14.76%).[13]

Nine single-test diagnostic accuracy studies were also identified; these publications assessed the MARD of I-CGM compared against a diagnostic reference standard (YSI 2300 STAT Plus, SMBG, or venous blood laboratory measurements). Among these 9 studies, the average MARD of I-CGM ranged between 8.8% to 12.3%.[14-16, 18, 20-24]

Clinical Efficacy

Glycated hemoglobin (HbA1c) is a key measure used to evaluate diabetes risk and morbidity.[1] Although the ADA recognizes that individual HbA1c normal ranges may vary, they recognize 7% as the standard threshold which most adult diabetics try to stay below.[25] None of the 16 studies included in the literature review performed a comparative analysis of HbA1c change between I-CGM and subcutaneous CGM. However, 6 noncomparative studies meeting inclusion did assess HbA1c among patients using Eversense, including 3 that performed a pretest-posttest analysis. Among those 3 before-and-after trials, all 3 determined that mean HbA1c levels statistically significantly decreased between baseline (mean: 7.4% - 7.6%) and final study follow-up (mean: 6.9% - 7.19%).[15,20,26] No statistical analyses were performed in the other 3 studies evaluating HbA1c, but all 3 noted a trend of HbA1c reduction following management with I-CGM.[13,18,27]

Time in Range (TIR) is an often-utilized surrogate outcome, used to evaluate the efficacy of diabetes management. Time in Range measures the percentage of time that CGM readings fall within the target blood glucose range (commonly defined as between 70 – 180 mg/dL).[9,28] One study was identified that directly compared TIR between patients using I-CGM systems and those utilizing subcutaneous CGM systems. Boscari et al, 2022[13] conducted a crossover RCT trial in which patients underwent 12 weeks of management with Eversense I-CGM, and 12 weeks of management with the Dexcom G5 (DG5) system. Results of this study showed that on average, 71.14% ± 12.29% of the I-CGM group readings were in the target range, which was statistically significantly favored (P<0.028) when compared with the 66.99% ± 11.8% mean TIR exhibited by the DG5 group. Four additional studies also evaluated TIR, but only among patients managing DM with I-CGM.[22,23,26,27] One of these 4 studies performed a pretest-posttest statistical analysis among 100 adults with T1DM. Irace et al, found that diabetes management with Eversense was associated with a significant improvement of TIR compared with baseline.[26] For 3 of the 4 noncomparative trials evaluating mean TIR during management with Eversense, the mean TIR was between 62.3% - 69%[22,24,26]; the fourth study had multiple different cohorts based upon patient characteristics and could not be pooled.[27]

Patient Reported Outcome Metrics (PROMs)

Boscari et al, 2022 was the only publication that comparatively analyzed patient reported outcome metrics (PROMs) between I-CGM and subcutaneous CGM.[13] In this crossover trial, all 16 patients underwent 12 weeks of management with the Eversense system, and 12 weeks with the DG5. Patient quality of life (QOL) was measured with the validated 17-item Diabetes Distress Scale (DDS), which asks respondents to evaluate each item with a 6-point Likert Scale ranging from 1 (no problem) to 6 (serious problem). Eversense was statistically significantly favored compared with DG5 for the total DDS score (I-CGM, 2.1 ± 1.1; DG5, 2.6 ± 1.4; P=0.009) as well as for the emotional burden domain score (I-CGM, 2.1 ± 1.0; DG5, 2.7 ± 1.4; P=0.01), regimen-related distress domain score (I-CGM, 2.1 ± 1.1; DG5, 2.7 ± 1.3; P=0.007), and the interpersonal distress score (I-CGM, 2.0 ± 1.1; DG5, 2.6 ± 1.2; P=0.003). Only the physician-related distress domain score was not significantly different (P=0.12) between DG5 and Eversense groups. Patient satisfaction with CGM devices was measured with the Diabetes Treatment Satisfaction Questionnaire (DTSQ), which is an 8-item survey that patients are to score between 0 (not satisfied) and 6 (extremely satisfied). The average total DTSQ score provided by respondents using Eversense (31.2 ± 4.3) was not significantly different (P=0.96) when compared with the mean DTSQ respondent score for the Dexcom G5 system (31.3 ± 3.9).[13]

Two noncomparative studies (3 publications) evaluated patient perceived change in QOL following diabetes management with I-CGM.[11,20,27] Among the 3 publications, QOL was assessed with the 36-Item Short Form Health Survey (SF-36), 28-Item DDS, and the Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire. Only 1 of these 2 trials performed a before-and-after statistical analysis, and the authors concluded that no significant change in QOL was observed over time.[27] Three noncomparative studies evaluated patient satisfaction with varying PROMs.[11,15,27] One trial found that 84% of respondents would choose to be re-inserted with Eversense for implantation cycle if given the opportunity.[11] Christiansen and colleagues examined patient satisfaction with the validated CGM Satisfaction Scale Questionnaire, which asks patients to rate items on a Likert Scale ranging from 1 (lowest satisfaction/largest hassle) through 5 (most satisfaction/least hassle).[15] This study found that among the 35 respondents, the mean overall satisfaction score with I-CGM was 3.9 ± 0.6. Among the respondents, only 20% of I-CGM users indicated that they would be unwilling to use I-CGM again after the study concluded. A third study found that the median DTSQ score over 180 days changed between a median of 0-2 points, which was not statistically quantified.[27]

Safety

None of the 16 primary studies meeting inclusion for the evidentiary review performed a comparative safety analysis between I-CGM and subcutaneous CGM.

However, 10 noncomparative studies assessed the safety profile of I-CGM. Six of the 10 studies considered the incidence of serious adverse events (SAEs), with all 6 reporting that no SAEs occurred.[14,16,18,20,26,29] Additionally, 2 studies stated that no adverse events occurred at all during study follow-up.[12,13] For the remaining 8 studies, the heterogeneity of how adverse events were grouped together and reported precluded the pooling of event rates across studies. Generally, events were infrequent, and mostly consisted of transient skin irritation at the patch site, site infection, pain, and difficulty removing the sensor during first attempt.[14,15,18,20,22,26,27,29]

Professional Society Recommendations

While the ADA, American Association of Clinical Endocrinology (AACE), Diabetes Canada Clinical Practice Guidelines, and National Institute for Health and Care Excellence (NICE) all have position/guideline recommendations supporting CGM, none of these specifically discuss if and when I-CGM should be considered in the treatment paradigm.[5,30-32] The following position statements directly invoke I-CGM, but only discuss optimal patient selection criteria.

American Diabetes Association (ADA) – In the safety subheading of a 2022 clinical practice guideline published by the ADA Professional Practice Committee, the authors state that contact dermatitis has been associated with all CGM devices, often linked to isobornyl acrylate. In some patients who have sensitivities to the tape used with subcutaneous CGM patches, the authors comment that I-CGM may provide an alternative that could preclude dermatitis events.[33]

European Association for the Study of Diabetes (EASD) – A consensus report published jointly by the EASD and the ADA in 2021 states that I-CGM could be a clinical alternative for patients who have sensitivities to the adhesive that is required with subcutaneous CGM.[34]

American Association of Clinical Endocrinology (AACE) – In 2021, the AACE issued a Grade C recommendation that clinicians should ensure patients undergoing treatment with CGM do not ingest any substances that could interfere with reliable interstitial glucose readings.[35] In the evidence section that informs this recommendation, Grunberger et al, cite other CGM systems that are susceptible to inaccuracy when in the presence of acetaminophen, ascorbic acid, xylose, bilirubin, or uric acid. Conversely, this section reports that Eversense sensors are only vulnerable to inaccuracy in the presence of mannitol or tetracycline, consistent with the contraindications listed by the FDA packaging.[35]

Other Expert Opinion

Deiss et al, 2019 present a collection of consensus best practice recommendations by a panel of international clinicians who were involved with early Eversense clinical trials.[36] Among the best practices, the following considerations are mentioned in relation to optimal patient selection criteria:

- The authors note that the adhesive for Eversense does not contain isobornyl acrylate. Additionally, they also discuss how the daily changing of adhesive allows for regular skin care at the site. They conclude that both of these characteristics make I-CGM a viable alternative for patients with a history of skin reactions to adhesives.
- Deiss et al, suggest that I-CGM is an ideal alternative to subcutaneous CGM for people who have an ongoing environmental risk to continued permanent breach of the skin, such as dust exposure.
- Deiss and colleagues mention the need for mobile device compatibility with the app, as well as ability to navigate the app. They then comment that certain groups of patients may be unable to access or use this technology and would not be suitable candidates for I-CGM.

Analysis of Evidence (Rationale for Determination)

This updated evidentiary review was conducted to evaluate whether the published evidence base continues to support the equivalency of I-CGMs and traditional subcutaneous CGMs in the management of adult DM. The evidence suggests that for adult patients managing DM, I-CGM performs with little to no difference in diagnostic accuracy, patient-reported efficacy outcomes, objective efficacy measures, and device/procedure-related adverse event rate when compared to subcutaneous CGM. Furthermore, the evidence suggests that the optimal patient selection criteria for I-CGM and for subcutaneous CGM are largely overlapping. Although limited in quality, this evidence base is sufficient to determine noninferiority/equivalency between I-CGM and subcutaneous CGM.

Additionally, although no direct evidence was identified that assessed I-CGM utilization among non-insulin treated (NIT) patients with diabetes complicated by hypoglycemia, there is still adequate evidence to infer equivalence with subcutaneous CGM systems among this population based upon the totality of evidence. Firstly, among the approved indications for I-CGM, the US FDA has cleared Eversense to “provide glucose trend information”, and to “provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia)”.[37] Also, although outside of the scope of the main evidentiary review, 3 publications were identified via bibliographic cross-referencing that evaluated subcutaneous CGM benefit among this subgroup of patients. One of these 3 trials concluded that among NIT patients with DM complicated by hypoglycemia, subcutaneous CGM systems resulted in a significantly greater reduction in HbA1c than SMBG.[32] The other 2 studies suggested CGM systems were able to detect hypoglycemic events among non-insulin treated patients that were overwhelmingly undetectable by symptoms or SMBG.[38,39]

General Information

Associated Information

Please refer to the related Local Coverage Article: Billing and Coding Article: Implantable Continuous Glucose Monitors (I-CGM) (A58110) for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

N/A

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This bibliography presents those sources that were obtained during the development of this policy. The Contractor is not responsible for the continuing viability of Website addresses listed below.

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
08/11/2024	R3	LCD posted for notice on 06/27/2024 to become effective 08/11/2024. Proposed LCD posted for comment on 02/15/2024.	• Creation of Uniform LCDs Within a MAC Jurisdiction
04/21/2022	R2	LCD revised and published on 05/19/2022 effective for dates of service on and after 02/28/22 in response to the CMS final DME rule effective on February 28, 2022 that expanded coverage of CGMs to include both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs for patients on intensive insulin therapy meeting certain criteria. The following sections of the LCD have been revised in this regard: the first and second paragraphs in the 'Covered Indications' section, the second paragraph for 'Exception' in the 'Limitations' section, and the third paragraph in the 'Analysis of Evidence' section. Minor formatting changes have been made throughout.	• Other (Non-discretionary update to LCD in response to change in CMS coverage)
04/21/2022	R1	LCD revised and published on 4/21/2022 to update the FDA website link. Minor formatting changes were also made throughout the LCD.	• Other

Associated Documents

Attachments
N/A

Related Local Coverage Documents
Articles
A58110 - Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM)
A59832 - Response to Comments: Implantable Continuous Glucose Monitors (I-CGM)

Related National Coverage Documents
NCDs

280.1 - Durable Medical Equipment Reference List
40.2 - Home Blood Glucose Monitors
280.14 - Infusion Pumps

Public Versions

Updated On	Effective Dates	Status	
06/21/2024	08/11/2024 - N/A	Currently in Effect	You are here
05/13/2022	04/21/2022 - 08/10/2024	Superseded	View
04/14/2022	04/21/2022 - N/A	Superseded	View

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Keywords

N/A