# Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38659)

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# Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|---|---|---|---|---|
| Noridian Healthcare Solutions, LLC | A and B MAC | 02101 - MAC A | J - F | Alaska |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02102 - MAC B | J - F | Alaska |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02201 - MAC A | J - F | Idaho |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02202 - MAC B | J - F | Idaho |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02301 - MAC A | J - F | Oregon |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02302 - MAC B | J - F | Oregon |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02401 - MAC A | J - F | Washington |
| Noridian Healthcare Solutions, LLC | A and B MAC | 02402 - MAC B | J - F | Washington |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03101 - MAC A | J - F | Arizona |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03102 - MAC B | J - F | Arizona |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03201 - MAC A | J - F | Montana |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03202 - MAC B | J - F | Montana |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03301 - MAC A | J - F | North Dakota |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03302 - MAC B | J - F | North Dakota |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03401 - MAC A | J - F | South Dakota |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03402 - MAC B | J - F | South Dakota |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03501 - MAC A | J - F | Utah |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03502 - MAC B | J - F | Utah |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03601 - MAC A | J - F | Wyoming |
| Noridian Healthcare Solutions, LLC | A and B MAC | 03602 - MAC B | J - F | Wyoming |

# LCD Information

# Document Information

**LCD ID**
L38659

**LCD Title**
Implantable Continuous Glucose Monitors (I-CGM)

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
DL38659

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**


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**Retirement Date**
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or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

## 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 shall 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 policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The two common types of diabetes are type 1 and type 2. Type 1 diabetes, known as insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin. Insulin is a hormone needed to allow sugar (glucose) to enter cells to produce energy. Type 2 diabetes is the most common form of diabetes, in which your body doesn't use insulin properly.

According to the American Diabetes Association, 34.2 million Americans have diabetes. Of the 34.2 million Americans, 14.3 million are seniors aged 65 and older.(1)

The complications of diabetes mellitus are far less common and less severe in people who have well-controlled blood sugar levels.(1) Acute complications 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.

As of March 1, 2020, there is only one Food and Drug Administration (FDA) approved implantable therapeutic

continuous glucose monitoring system (I-CGM). The Eversense Continuous Glucose Monitoring System was approved by the FDA in June 2018, with expanded indications in June, 2019.(2) Please refer to the FDA June 2019 approval information located at https://www.fda.gov/medical-devices/recently-approved-devices/eversense-continuous-glucose-monitoring-system-p160048s006. This implantable CGM is a prescription device that provides real-time glucose monitoring every five minutes for up to 90 days at a time for people with diabetes. The system consists of an implantable fluorescence-based sensor, a smart transmitter, and a mobile application for displaying glucose values, trends and alerts on the patient's compatible mobile device. It is designed to replace fingerstick blood glucose testing for diabetes treatment decisions as indicated in the FDA 2019 approval. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The FDA requires the specific training or experience practitioners need in order to use the device and insofar as the sale and distribution of the device are restricted to practitioners who are enrolled in, undergoing, or have completed the specific training identified in the labeling (2).

Covered Indications

I-CGMs are class III medical devices that require premarket approval by the FDA. In order to be considered reasonable and necessary, the FDA approved indication must include use as a therapeutic CGM.(3) The FDA recently approved expanding the indications of an implantable CGM product to replace fingerstick blood glucose measurements for diabetes treatment decisions.

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

1. The beneficiary has diabetes mellitus (Refer to the related Billing and Coding Article (A58138) for applicable diagnoses); and,
2. The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and,
3. The beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM (blood glucose monitor) or CGM testing results; and,
4. Within six (6) months prior to ordering the I-CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met.

Limitations

I-CGM devices will not be considered reasonable and necessary for the following:

1. Individuals that do not require insulin therapy.
2. Short-term I-CGM (72 hours to 1 week) for diagnostic use.

Exception: For those beneficiaries who have previously met the coverage criteria for a non-implantable therapeutic continuous glucose monitor through the Medicare DME benefit and subsequently choose to switch to the implantable device, they may do so 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 policy, 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.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

**Summary of Evidence**

## Introduction

This evidence review focuses on evidence for FDA approved implantable therapeutic continuous glucose monitors and whether this evidence is adequate to draw conclusions about health outcomes for the Medicare population. Health outcomes of interest include mortality, patient morbidity as a result of diabetes, harm from treatments, and patient quality of life and function. Additionally, proven intermediate outcomes in the causal pathway of health outcomes are of interest. The current clinical evidence based on trial data for I-CGMs includes one pivotal European trial, two pivotal U.S. clinical trials under one investigational device exemption (IDE), two post-market registry studies, and guideline and consensus statements.

## Internal Technology Assessment

Pubmed was searched for clinical studies that included "implantable continuous glucose monitor" or "Eversense" (the only FDA approved implantable CGM as of March 1, 2020). Literature was reviewed for inclusion if it met these criteria, and all abstracts were reviewed. Studies must be published in English language and specific to the human population. Only devices approved by the FDA as of March 1, 2020 were included in this review.

### Pivotal clinical studies U.S.

Christiansen M, et.al reported on two studies conducted under IDE #G150165, the PRECISE II and PRECISION studies. Data from both studies are included in the FDA summary of safety and effectiveness data (SSED). PRECISE II was a non-randomized, blinded, prospective single-arm study at 8 U.S. sites evaluating 90 patients with type 1 and type 2 diabetes in 2016.(6) The I-CGM glucose values and all glucose-related alerts were blinded to patients and investigators. Management decisions were based on self-monitored blood glucose. Of the initial 90 patients, 82 completed the 90 day visit with data. The primary endpoint was the Mean Absolute Relative Difference (MARD) between paired Eversense and Yellow Springs Instrument (YSI) reference measurements through 90 days for reference glucose values from 40 to 400 mg/dL.(6) The prospective, unblinded, multicenter PRECISION study evaluated 35 patients, with enrollment starting in July 2017 and subject completion in February 2018.(7) Study outcome measurement was similar to PRECISE II. In PRECISION, the glucose calculation algorithm was updated. Inclusion and exclusion criteria, follow-up schedules, and accountability of patients are included in the respective articles. The demographics of both trials are listed in Table 8 of the 2018 SSED.(13p15) The mean age of PRECISE II was 45 years (SD:16 years, minimum age: 18, maximum age: 77) and 52 years (SD: 16 years, minimum age: 18, maximum age: 75) for PRECISION. Table 9 of the SSED has diabetic history, with PRECISE II having 28.6% type II patients and PRECISION having 32.2% type II patients.(13p17) Types of insulin therapies for PRECISE II included: 14.3% none, 31.4% multiple daily injections, 54.3% continuous insulin infusion pump; PRECISION: 22.2% none, 26.7% multiple daily injections, 47.8% continuous insulin infusion pump. Safety endpoints for both studies are in Table 10 in the SSED and Table 11 reports the adverse events related or possibly related to the device or procedure, with most related to dermatological issues.(13p18) There were no infections in either study. Effectiveness results are tabulated in Tables 13 – 26 of the SSED.(13p20-35) In PRECISE II, the overall reported MARD value against reference glucose values was 8.8% (95% CI: 8.1 – 9.3%), which was lower than the performance goal of 20%. The system identified 93% of hypoglycemic events and 96% of hyperglycemic events per YSI. In PRECISION, the MARD value against reference was 9.6% (95% CI 8.9 – 10.4). Precision measurement results that compare data from two separate sensors from the same subject are available for both studies (Tables 27 and 28) as is alert performance (Tables 29 – 36).(13p36-39)

### Pivotal Clinical Studies Outside the US

The Eversense implantable CGM study by Kropff J, et.al, studied 71 patients in a 180-day prospective trial at seven clinical sites in Europe November 2014 to November 2015. Baseline patient characteristics are reported in Table 1

and include 66 type 1 and 5 type 2 patients with diabetes.[7p65] Average age was 41.7 years (SD 12.6 years). The sensor accuracy compared to venous plasma glucose samples using YSI 2300 STAT PLUS glucose and lactate analyzer (YSI, Yellow Springs, OH) over the range of 2.2 – 22 mmol/L or 40 – 400 mg/dL is reported in Table 2.[7p66] The MARD compared to reference venous glucose values (>4.2mmol/L) was 11.1% (95% CI 10.5, 11.7).[7] Table 3 reports the accuracy of the sensor for glycemic ranges and for rates of change.[7p66] In particular, in the range of <75 mg/dL, the MARD was 21.7%, SD 21.5 and 95% CI 20.4, 23.0.[7] No device related serious adverse events occurred. Two cases of incision site infection were reported; one received antibiotic treatment. The authors note, "Results from the questionnaire data indicated high participant acceptance of the system but did not register improved perceived generic quality of life, as assessed per SF-36 questionnaire."[7p66]

**Post-Market Registry Studies**

A study by Sanchez P et.al included deidentified data from the first 205 patients to reach a 90-day wear period in the Eversense Data Management System (DMS).[8]This data was analyzed for mean sensor glucose (SG), median interquartile range, coefficient of variation, glucose measurement index, and percent and time across glucose ranges for various time periods. Data was collected from August 1, 2018 to May 11, 2019. Patients were identified as either type 1 (129), type 2 (18), or unreported (58). Only limited demographic data was obtained. SG data and "patient-entered inputs such as meals, exercise, and insulin are automatically uploaded" into the DMS through smartphone connection. Results are listed in Table 1.[8p3] The MARD compared to home blood glucose meters was 11.2% (SD 11.3%).[8] Patients chose to have the sensor reinserted 78.5% of the time after the completion of the first sensor wear.[8] The transmitter wear time median was 83.6%. No serious adverse events were reported with 2% of patients reporting mild infection at the insertion site (3 treated with oral antibiotics), 1.5% reporting hypoglycemia that was self-treated, and 2% reporting failure to remove the sensor on first attempt. The authors state, "In conclusion, the 90-day implanted Eversense I-CGM system appears to be a valuable and safe tool for management of diabetes with patients reinserting and using the device the majority of the time."[8p4]

Deiss D et.al reports on the post-market clinical follow-up (PMCF) registry in 534 centers in Europe and South Africa from June 2016 to August 2018.[9] The initial device approval in Europe occurred in May 2016 for the 90-day sensor and September 2017 for the 180-day sensor. All patients with implanted sensors were enrolled prospectively, a total of 3,023 patients.[9] Patient inclusion/exclusion criteria were consistent with the device label. A total of 969 patients had used the system for at least 6 months and 173 patients had used the system for a minimum of 1 year. Adverse events were defined as, "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in patients, users, or other persons, whether or not related to the medical device.[9] A serious adverse event (SAE) was defined as an AE that led to death, led to serious deterioration in the health of the patient requiring medical assistance including emergency medical services and/or hospitalization, or led to fetal distress, fetal death, or a congenital abnormality or birth defect. AEs were recorded at each visit and also between visits by patient report. Events were adjudicated by a medical monitor. The primary safety endpoint was the rate of SAEs through 4 sensor cycles. No SAEs were reported. The discontinuation rate was 11% (337 patients), with the most common reason listed as unknown and next most common listed as lack of medical reimbursement. Sensor location site infection was reported at a rate of 0.96% and inability to remove the sensor upon first attempt at 0.76%.[9] Sensor life was 91% for 90-day sensors and 75% for 180-day sensors. The authors conclude, "The PMCF registry provides real-world evidence that the Eversense I-CGM system is safe over multiple cycles of use."[9p2]

**Evidence-Based Guidelines**

According to information from 2019 Chamberlain JJ et.al, the American Diabetes Association (ADA) added this section on diabetes technology to the Standards of Medical Care in Diabetes. The Professional Practice Committee of the ADA who developed this guideline is comprised of an expert committee whose appointment is based on excellence in research or clinical care. For these recommendations, members systematically search the literature. The recommendations are rated as A, B, C, or E.[10] Those with an A rating are based on large, well-designed

clinical trials or high-quality meta-analyses. Recommendations with a B rating are based on well-conducted cohort studies, while uncontrolled studies are given a C rating. An E rating is assigned when there is no evidence from clinical trials, clinical trials might be impractical, or evidence is conflicting. "The ADA funds development of the standards from its general revenues, with no industry involvement or support."[10]

Recommendations for self-monitoring of blood glucose, continuous glucose monitors, and automated insulin delivery are included in this document. Several of the recommendations are listed below:

**Continuous Glucose Monitors**

"Sensor-augmented pump therapy can be considered for children, adolescents, and adults to improve glycemic control without increasing overall or severe hypoglycemia. Benefits correlate with ongoing consistent use of the device. (Grade A recommendation)"[10p74]

**Real-Time Continuous Glucose Monitor Use in Adults**

"When used properly, real-time CGM in conjunction with intensive insulin regimens is a useful tool to lower HbA1C levels in adults with type 1 diabetes who are not meeting glycemic targets. (Grade A recommendation)."[10p76]

"Real-time CGM may be a useful tool in those with hypoglycemia unawareness or frequent hypoglycemic episodes. (Grade B recommendation)"

**Professional Society Recommendations/Consensus Statements/Other Expert Opinion**

In 2016, the American Association of Clinical Endocrinologists and the American College of Endocrinology convened a conference to review available CGM data. They felt the evidence supported the use of CGM in patients with type 1 diabetes and the benefits are likely to apply, whenever, intensive insulin therapy is used, whether the patients has type 1 or type 2. Fonseca V et.al reported findings from this conference, and felt that patients older than 65 years with comorbidities and/or risk for severe hypoglycemia may have significant benefits, though at that time, additional studies were needed. "[11] The primary purpose of CGM is to identify glucose patterns, hypoglycemia, and hyperglycemia."[11] The goal of management is to maximize time in the desired glucose range. The authors concluded, CGM improves glycemic control, reduces hypoglycemia, and may reduce overall costs of diabetes management. Expanding CGM coverage and utilization is likely to improve the health outcomes of people with diabetes."

The Advanced Technologies and Treatments for Diabetes Congress convened an international panel of experts in CGM technologies to make recommendations on the use on CGMs. Danne T et.al indicated the panel made recommendations on these topics: limitations of HbA1c; use of glucose monitoring methodologies to guide management and assess outcomes in different patient populations; minimum requirements for CGM performance; definition and assessment of hypoglycemia in clinical studies; assessment of glycemic variability; time in range; and visualization, analysis, and documentation of key CGM metrics.[12]

**Analysis of Evidence**
**(Rationale for Determination)**

In examination of this diabetes management technology, the findings of the 2019 ADA clinical guideline are noted: "Use of self-monitoring of blood glucose (SMBG) or CGM is most important for insulin-treated patients because it enables them to adjust therapy to minimize hypoglycemia and manage hyperglycemia."(10) Reduction of hypoglycemia and hyperglycemia are accepted health outcomes in the management of diabetes. SMBG involves finger-sticks to obtain capillary blood samples at a single point in time. With certain CGMs, patients can receive real-time data, trending information, and alert notification of hypoglycemia or hyperglycemia. Additionally, the need for finger-sticks is reduced, thus reducing patient burden. CGMs measure interstitial glucose, which correlates well with plasma (venous) glucose.(10) In June 2019, the FDA approved an implantable CGM system for the expanded indication of replacement of finger-stick blood glucose testing for diabetes treatment decisions ( https://www.fda.gov/medical-devices/recently-approved-devices/eversense-continuous-glucose-monitoring-system-p160048s006).

CGMs can provide a significant amount of patient data, such as time in hypoglycemia range, time in target range, and time in hyperglycemia range, that allows patients to see how medications, meals, and exercise affect blood glucose and if necessary help patients make behavioral changes. Alerts to notify patients of hypoglycemia and hyperglycemia are available, which is particularly helpful if patients have hypoglycemia unawareness. For optimal management of glucose, accuracy of the device is important. Furthermore, CGMs should be used consistently. "Real-time CGM should be used as close to daily as possible for maximal benefit (Grade A recommendation).(10)

Medicare covers therapeutic CGMs for patients on intensive insulin therapy meeting certain criteria. Adjunctive CGMs are not covered. By analogy, if implantable CGMs are shown to produce similar results to the current FDA approved non-implantable therapeutic CGMs, then implantable CGMs will similarly improve health outcomes for these Medicare patients with diabetes on insulin. The available clinical studies for implantable CGMs include pivotal trials from the U.S. and Europe, and post-market registry data. The available studies are all sponsor supported however bias in the objective data has not been previously noted. Data submitted to the FDA from the sponsor is additionally available for review in the SSED. Both the pre-market and real-world post-market data support patient benefit with MARD and other relevant data in the acceptable range. In the U.S. pivotal trials, most patients had type 1 diabetes, though a little less than 1/3 had type II. Few patients appeared to be in the Medicare aged population, but age does not influence the current CGM coverage criteria. Thus, the results of the trials for this implantable device should be applicable to the Medicare population. The risk of the device appears minimal based on reported adverse events to date. The accuracy of the device over various ranges, in particular lower glucose ranges where there are also limitations with external sensor devices, has improved over time, as demonstrated in the PRECISE II trial in comparison to the PRECISION trial.

Objective criteria of this implantable device is similar to external sensor therapeutic CGMs. Therefore, coverage of this device will be in line with current CGM criteria.

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# General Information

**Associated Information**

Please refer to the related Billing and Coding Article: Implantable Continuous Glucose Monitors (I-CGM) (A58138) for documentation and utilization requirements as applicable.

**Sources of Information**

N/A

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# Revision History Information

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# Associated Documents

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)

A58138 - Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM)

A58399 - Response to Comments: Implantable Continuous Glucose Monitors (I-CGM)

LCD(s)

DL38659 - Implantable Continuous Glucose Monitors (I-CGM)

**Related National Coverage Documents**

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