eversense®
Continuous Glucose Monitoring System

EVERSENSE E3 CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM REIMBURSEMENT RESOURCE

ASCENSIA
Diabetes Care

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This document provides a reference on billing for the Eversense E3 CGM System and related procedures.

EVERSENSE E3 CGM SYSTEM COVERAGE

The Eversense E3 CGM System is covered by a broad range of payers. Each has its own policy on how to reimburse for both the Eversense E3 CGM system as well as the corresponding procedures. This is a summary to help navigate the types of available coverage.

PRIVATE PAYER COVERAGE OF THE EVERSENSE CGM SYSTEM

Most private payers cover CGM for specific patient populations, based upon diagnosis code. Most major commercial health plans have written policies that offer explicit guidelines for coverage.

It is important to understand the specific coverage criteria for payers in each region, as each plan may have different criteria for patient selection and billing; ultimately it is dependent on the member benefit.

MEDICARE COVERAGE OF THE EVERSENSE CGM SYSTEM

There are Local Coverage Determinations (LCDs) in place that allow Medicare beneficiaries who meet medical criteria, to be able to access the Eversense E3 CGM System. Billing for Medicare beneficiaries follows the Global Payment pathway which is further discussed in the guide.

CLAIMS PROCESSING

Payers process provider claims for the Eversense E3 CGM System in a few different ways. The healthcare provider can either bill for the system and affiliated procedure at once or only bill for the procedure. The billing process is determined by the policy of the payer.

Eversense E3 Healthcare Provider Billing Process	Type of Insurance
Eversense E3 Sensor and Procedure	
Bundled Code / Global Payment Model	Medicare / Medicare Advantage / Select Commercial Plans
Procedure Only	
Processed Through DME Benefit	Commercial Plans
Processed Through Pharmacy	Commercial Plans
Non-Covered by Payer	Not Covered / Uninsured

BILLING FOR EVERSENSE E3 PROCEDURES ONLY

DME/Pharmacy Benefit or Uninsured/Self-Pay

DME/Pharmacy Benefit Model: The billing codes in the chart below are only applicable to the services provided by the health care provider, the procedure, and do not include the Eversense E3 Sensor.

In this scenario, the Eversense E3 System will be processed and distributed by an in-network durable medical equipment supplier or a specialty pharmacy and shipped to the healthcare provider to perform the procedure. Distribution depends on the payer. The shipment would come from a durable medical equipment supplier.

Uninsured/Self-Pay: If a patient does not have insurance to cover the Eversense E3 CGM System, they may choose to purchase the product out of pocket. The shipment would come from a durable medical equipment supplier. In order to cover the cost of the procedure, it is recommended to submit a prior authorization with medical justification for the appropriate code listed below. Otherwise, the provider may bill the patient directly for the cost of the procedure.

Billing Codes	Code Description
Eversense E3 Codes (procedure only)	
CPT® code **0446T**	Sensor placement and system activation
CPT® code **0447T**	Sensor removal
CPT® code **0448T**	Sensor removal, re-insertion, and system activation
Standard CGM Billing Codes	
E/M codes 99212-99215	Office visit for the evaluation and management of an established patient
CPT® code **95251**	CGM data interpretation

BILLING FOR BOTH EVERSENSE E3 SENSOR AND PROCEDURE

Bundled Code / Global Payment Model

The Global/Bundled Payment Model is a single billing code that is inclusive of the both the product and procedure. This simplifies reimbursement by allowing the provider to submit one claim to the payer.

In this model, the provider purchases Eversense E3 directly from a distributor pursuant to agreed-upon terms. Once the sensor procedure is completed, the provider files a claim with the payer and receives global reimbursement for both the Eversense E3 product and procedure. The following billing codes can be billed by Physicians, Physician Assistants and Nurse Practitioners. They are applicable in the global payment/ bundled code model:

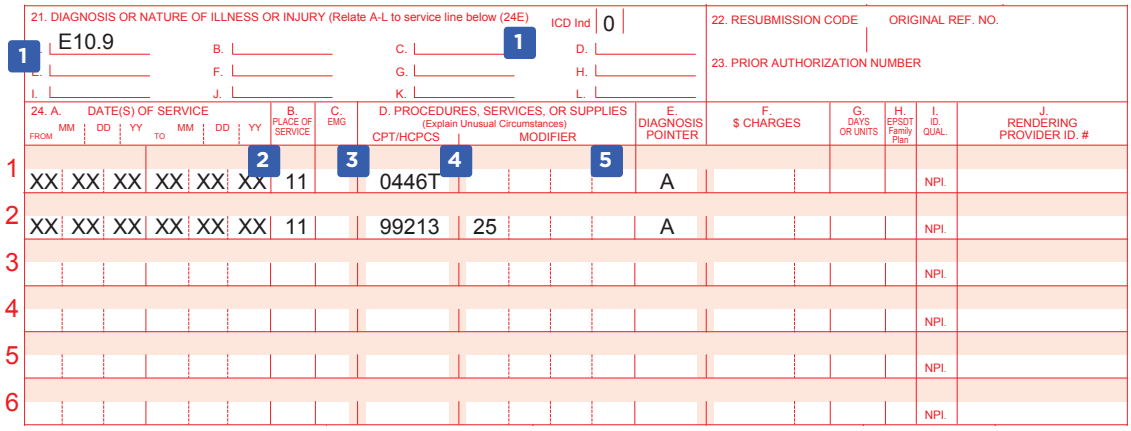
Billing Codes	Code Description
Eversense E3 Codes (bundled product and procedure)	
CPT® code **0446T**	Sensor placement and system activation **and supply**
CPT® code **0447T**	Sensor removal
CPT® code **0448T**	Sensor removal, re-insertion, and system activation **and supply**
Standard CGM Billing Codes	
E/M codes 99212-99215	Office visit for the evaluation and management of an established patient
CPT® code **95251**	CGM data interpretation

Medicare Resources

- **CMS Fee Schedule:** Confirm the contracted payment amount prior to purchasing Eversense E3 to understand reimbursement level. The appropriate reimbursement can be found at https://www.cms.gov/medicare/physician-fee-schedule/search
- **CMS guidance for Billing and Coding:** Implantable Continuous Glucose Monitors (I-CGM) can be found here: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58127
- **CMS-1500 Form:** Medicare billing is competed using CMS-1500 form (See sample below)*

SAMPLE CLAIM FORM

The following steps indicate the key information on the CMS-1500 claim form when billing for CGM-related services.*



21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) — ICD Ind: 0

1 E10.9 B. C. 1 D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE — ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

	24. A. DATE(S) OF SERVICE FROM MM DD YY TO MM DD YY	B. PLACE OF SERVICE (2)	C. EMG (3)	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS (4) MODIFIER (5)	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	XX XX XX XX XX XX	11		0446T	A				NPI.	
2	XX XX XX XX XX XX	11		99213 25	A				NPI.	
3									NPI.	
4									NPI.	
5									NPI.	
6									NPI.	

*Note: This example features a portion of a sample CMS-1500 claim form. This sample claim form is intended as a reference for CGM coding and billing and is not intended to be directive nor does the use of the recommended codes guarantee reimbursement. Providers should select coding that most accurately reflects their billing guidelines and services rendered. Source: APPROVED OMB-0938-1197 FORM CMS-1500 (02-12).

STEP 1

DIAGNOSIS CODES (Box 21)

- Document the primary diagnosis code and the appropriate ICD indicator.
- Example diagnosis code: E10.65 (Type 1 diabetes mellitus with hyperglycemia).

STEP 2

PLACE OF SERVICE (Box 24B)

- Specify the location where the service was performed.
- Examples: 11 = Office 22 = Outpatient Hospital

STEP 3

PROCEDURE CODES (Box 24D)

- Document the insertion and activation of the Eversense CGM System.
- Document CGM data interpretation with 95251.
- If relevant, enter the appropriate E/M code for separately identifiable visit(s) concurrent with CGM (e.g. for diagnosis and/ or therapy changes)

STEP 4

MODIFIERS AS NEEDED (Box 24D)

- Use the -25 modifier on an E/M code to distinguish a significant and separately identifiable E/M service, above and beyond the services associated with CGM, provided on the same day.

STEP 5

DIAGNOSIS POINTER (Box 24E)

- Specify the diagnosis code reference from Box 21 (1, 2, 3, or 4) that relates to the procedure code(s) listed in Box 24D.
- If only 1 diagnosis code is listed in Box 21, then list "A" in 24E.

PRIOR AUTHORIZATION FOR THE PROCEDURE

Private payers may have prior authorization requirements for CGMs. Since coverage varies by health plan, it is recommended to contact the payer to learn about their prior authorization process for the Eversense E3 CGM procedure. This is a recommended best practice for all commercially managed plans. If a plan indicates "No Prior Authorization Required," ensure that it is a valid billable code according to the plan.

For Medicare, a prior authorization is not required. For Medicare Advantage plans managed by private payers, it is still recommended to submit a prior authorization.

CLAIMS DENIALS AND APPEALS

A claim denial can occur for a wide variety of reasons. It is important to understand why the claim was denied and, as appropriate, know what options are available to resubmit or appeal the claim. Specific areas to verify are:

- Confirm the ICD-10-CM diagnosis codes are specific and valid for services provided
- Verify the specific CPT codes for the services covered within each health plan.
- Ensure that the submission frequency is within the specific insurance policy limits.
- Modifier -25 should be added to Evaluation and Management code (E/M) if billed on the same day as CPT code 95251. Modifier -25 verifies that the E/M service was separate and identifiable from the CGM service.
- For insurance plans requiring prior authorization, ensure that the authorization has been obtained prior to the service being performed.

If there are questions specific to the reconciliation of claims, it is recommended the office consult the Provider Handbook or contact a Provider Relations representative.

The following chart identifies additional steps to explore pending the reason for denial:

Reasons for Denial	Possible Action by HCP
No reason given or reason unclear	Contact payer to obtain clarifications: • Verify that the correct date(s) of service and provider number were included on the claim • Obtain additional details and/or reasoning about why the claim was denied • Inquire about appeal options available and documentation requirements • Verify that the claim was completed correctly
Payer may determine Eversense E3 is: — Experimental and Investigational — Not medically necessary for the diagnosis — Not included on the Medical Policy	File an appeal clearly explaining the reason that the Eversense CGM System is medically necessary for the patient.
Payer may require Prior Authorization	Verify which payers in your area require Prior Authorization, and always check if it is needed before providing the service.
Patient does not meet criteria established by the payer	Confirm that diagnosis codes are appropriate. Ensure that the submission frequency is within policy limits. Always verify that a patient meets the payer's coverage criteria before performing the service.
Exceeded frequency of submission limits	Always verify frequency limits before performing the service. If claims are denied due to frequency, you can still submit an appeal letter to demonstrate the medical necessity of the additional service.
Diagnosis code could flag the procedure as non-covered. For example, ICD-10-CM diagnosis codes E11.9 and E10.9 may be denied	Verify accuracy of ICD-10-CM diagnosis code, including ensuring that the highest level of specificity was used.

HOW TO APPEAL A DENIAL

Payers have documented appeals processes for reconsidering denials.

COMMERCIAL PAYERS

Appeals information for private payers is often found in the plan's provider manual, on the website or by contacting the insurer directly. If you need to appeal a prior authorization denial, providers may submit a letter of appeal. Appeal letters typically include similar information that may be submitted with prior authorization, including the following elements:

- Provide the rationale for filing an appeal (denial of coverage, medical necessity, etc.)
- Date of denial/denial letter
- Reference the denial reason and associated denial code, if applicable
- Detail the patient's diagnosis and course of treatment including recent laboratory reports (HbA1c results within 6 months of request) and recent hospitalization records (if available), as well as adverse outcomes or lack of improvement from prior therapies
- Describe the procedure in detail
- Description of the technology and rationale for its use (e.g., its benefits as they relate to the patient's condition) including a copy of the FDA approval letter
- Emphasize the advantages of the Eversense E3 CGM System as compared to another medical device or approach
- State the rationale and benefits of the technology and how its use can be expected to improve clinical outcomes and/or quality of life
- Discuss personal experiences and outcomes of similar cases using the Eversense E3 CGM System
- Provide a summary of the clinical evidence supporting the treatment plan, including comorbidities and copies of published literature supporting the safety and effectiveness
- Provide a contact name and phone number as well as the willingness to answer questions or provide additional information
- Request a specific timeframe for a response

DISCLAIMER

This is for informational purposes only and does not constitute legal advice or official guidance from payers. This resource is not intended to provide clinical practice guidelines or to increase or maximize reimbursement by any payer. The information provided is subject to change without notice as a result of changes in reimbursement laws, regulations, rules, policies, and payment amounts. While we have made effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Health care providers are ultimately responsible for verifying insurance coverage and billing policies and should contact the payer regarding the most recent billing, coding, and coverage policy information, as well as discuss any reimbursement inquiries.

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