FreeStyle Libre Pro
FLASH GLUCOSE MONITORING SYSTEM

Professional Continuous Glucose Monitoring

Billing and Reimbursement Guide

See Indications and Important Safety Information on back.

Abbott

As a courtesy to its customers, Abbott Diabetes Care provides the most accurate and up-to-date information available, but it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott Diabetes Care does not guarantee third-party coverage or payment for our products or reimburse customers for claims that are denied by third-party payers.

Table of Contents

1. American Medical Association (AMA). CPT Code Book 2016.

1. Professional Continuous Glucose Monitoring with the FreeStyle Libre Pro Flash Glucose Monitoring System

1.1 Indications

- The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The System is intended for use by health care professionals and requires a prescription. Readings from the FreeStyle Libre Pro Sensor are only made available to patients through consultation with a health care professional. The System does not require user calibration with blood glucose values.
- The FreeStyle Libre Pro System aids in the detection of glucose level excursions above or below the desired range, facilitating therapy adjustments. Interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should be based on the trends and patterns analyzed through time using the reports available.

  IMPORTANT: The device may inaccurately indicate hypoglycemia. The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81-160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use.

1.2 Using this FreeStyle Libre Pro Reimbursement Guide

- This FreeStyle Libre Pro Reimbursement Guide provides HCPs, billing specialists, and other practice administrators and staff with an overview of insurance coding, coverage, and payment related to the professional CGM procedure and data interpretation.
- This FreeStyle Libre Pro Reimbursement Guide includes general coding, payer coverage, prior authorization information, claims denial, and appeal information.
- This guide only covers use of professional continuous glucose monitoring (CGM); it is not intended for use with personal CGM, which is owned and used by the patient.

2. Coding for the FreeStyle Libre Pro System

2.1 CPT® Codes for Reporting of Professional Continuous Glucose Monitoring (CGM)[1]

I. Technical set-up and interaction with the device

95250: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.

II. HCP review and interpretation of data

95251: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report.

2.2 Limitations and Restrictions for CPT Codes 95250 and 95251

2.2.1 Minimum sensor time

CPT codes 95250 and 95251 are defined as a minimum of 72 hours; neither code can be assigned or billed if CGM of less than 72 hours is provided.

2.2.2 Limit to reporting frequency

CPT codes 95250 and 95251 cannot be reported more than once per month per patient regardless of the duration of professional CGM or the number of times CGM is provided in a single month.[2]

1. American Medical Association (AMA). CPT Code Book 2016. CPT is a registered trademark of the American Medical Association.
2. American Medical Association (AMA). CPT Changes 2009: An Insider's View. Chicago, IL: AMA; 2009.

Professional CGM Workflow & Associated Billing Codes

STEP 1

Pre-Work

Patient Selection
HCP prescribes pro-CGM
Patient in office*

Verify Insurance Benefits
(Submit prior authorization, if required)

Schedule Visit

STEP 2

Procedure
CPT 95250

- Performed by physician or office staff under supervision, per state scope of practice

Begin Assessment
- Insert sensor
- Educate patient

Patient in office*

Data Collection

(Must collect at least 72 hours of device data to bill CPT 95250)

Assessment Complete
- Remove sensor
- Download data
- Generate reports

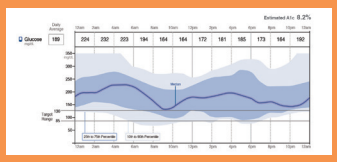
Patient in office*

STEP 3

Interpretation
CPT 95251

- Performed by physician or office staff under supervision, per state scope of practice

HCP Interprets & Reports
With/without patient in office*



STEP 4

Informed Decision-Making

HCP Treatment Recommendation & Patient Consultation
- Share evaluation results
- Discuss therapy options

Patient in office*

*Billing of CPT 95250 and 95251 does not preclude the use of Evaluation and Management codes. Add modifier "-25" to the E/M code if a separate face-to-face office visit above and beyond the CGM service is performed, medically necessary, and documented.

NOTES
- 95250 and 95251 can only be reported once monthly per patient and require a minimum of 72 hours of data. Payers are not obligated to cover monthly.
- E/M can only be billed separately on the same day when a significant and separately identifiable service took place above and beyond the services associated with CGM.
- Use modifier "-25" with E/M code when billing 95250 and 95251 on the same day.

Individual plans vary. Always verify coverage and frequency limits directly with the payer. It is the physician's responsibility to ensure appropriate code selection.

Abbott Diabetes Care Customer Support
www.FreeStyleLibrePro.us/reimbursement
877-549-9181
Hours of operation: 8am – 8pm EST

CPT code definitions sourced from AMA CPT Code Book 2016.

2.2.3 Payer policies and coverage vary

I. CPT codes only represent the service delivered; they do not define the actual coverage. Payers determine coverage based on the specific criteria set forth by their individual organization, and they are not obligated to extend coverage for professional CGM.

II. Payers may set additional limits to the frequency of reporting, so HCPs and billing professionals should confirm these policies with the patient's specific payer.

2.2.4 Who can perform and bill CPT code 95250

I. CPT code 95250 is for placing the sensor, hook-up, monitor calibration, patient training, removing the sensor, and printing out the recording.

II. The services described by CPT code 95250 can generally be performed by any qualified healthcare professional, including physicians, physicians assistants, nurse practitioners, certified diabetes educators (CDEs), registered and licensed practical nurses, registered dieticians (RDs), medical assistants (MAs) or laboratory technicians, consistent with each state's applicable scope of practice laws. In certain states and under some payer coverage requirements, non-physician clinicians performing the 95250 service must be working under a physician's supervision. Therefore, HCPs should always verify specific criteria directly with each payer.

III. HCP offices bill CPT code 95250 on a CMS-1500 claim form. Hospital outpatient departments bill 95250 on a standard UB-04 claim form for institutions.

2.2.5 Who can perform and bill CPT code 95251

I. Physicians or advanced practice HCPs may bill under CPT code 95251. Many payers will not consider payment for CPT code 95251 from a registered dietician. This varies both by payer and by state laws. Medicare defines 95251 as a "professional component code," meaning that it is restricted to use by physicians or advanced practice HCPs. Facilities provide technical services only and are not payable under code 95251.

II. The healthcare professional does not need to be face to face with the patient to assign and bill CPT code 95251. Analysis of data obtained remotely is the same as analysis of data obtained during an in-person encounter.

III. Medicare defines 95251 as a "professional component code," meaning that it is restricted to use by physicians or advanced practice HCPs. Facilities provide technical services only and are not payable under code 95251.

IV. Analysis and interpretation should be clearly documented in the patient's chart. It is useful to print professional CGM reports and include them in the patient's medical record.

Note: Definition of an "advanced practice HCP": In additions physicians (MDs and DOs), there are advanced practice HCPs which include nurse practitioners (NP), and physician assistants (PA). This varies by each state's applicable scope of practice laws.

WHO CAN BILL FOR CPT CODES 95250 AND 95251

CPT Code	Descriptor	Who bills
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; **sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording**	Physician, Advanced Practice HCP OR Institution (hospital outpatient department under OPPS)
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; **interpretation and report**	Physician or Advanced Practice HCP

2.3 Evaluation and Management (E/M) Codes

2.3.1 Billing of E/M codes

Billing of CPT 95250 and 95251 does not preclude the use of Evaluation and Management codes. Add modifier "-25" to the E/M code if a separate face-to-face office visit above and beyond the CGM service is performed, medically necessary, and documented.

2.3.2 Definition: Modifier "-25"

Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other service.[3]

2.4 ICD-10-CM Diagnosis Codes

2.4.1 Using ICD-10-CM codes

Since ICD-10-CM diagnosis codes indicate why a service or procedure was performed, the appropriate diagnosis code(s) must be included on health care claims. Payers reference the ICD-10-CM diagnosis codes in considering whether the billed service is medically necessary, meets coverage criteria, and thus, is eligible for reimbursement.

2.4.2 ICD-10-CM diagnosis codes for diabetes

For CGM, the ICD-10-CM diagnosis codes for diabetes are typically billed.

Be sure that CGM billing codes, modifiers, and diagnosis codes are included on the internal charge ticket or similar charge capture process.

3. American Medical Association (AMA). CPT Code Book 2016.

Common ICD-10 Code Descriptions

E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13.8	Other diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications

For a complete listing of ICD-10 Code descriptions related to Type 1 and Type 2 diabetes mellitus, please refer to page 14.

https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx

3. Payer Coverage for the FreeStyle Libre Pro System

Because payer benefits change regularly, providers are responsible for confirming coverage, coding, and payment with respective payers, as well as ensuring accuracy of service claim forms and supportive documentation sent to payers.

3.1 Commercial Payer Coverage for Professional CGM

I. Commercial payers may include private insurance companies or private employer groups that provide coverage and reimbursement. A patient's benefits will vary based on plan type and provider site of service.

II. Most private payers cover Professional CGM for specific patient populations, often based on type of diabetes and level of control.

III. HCPs should review payer coverage policies for professional CGM on a quarterly basis to maintain the latest information and identify any coverage changes. Call 877-549-9181 for assistance.

3.2 Medicare Coverage for Professional CGM

I. Currently, Medicare pays for professional CGM billed under CPT codes 95250 and 95251 in all 50 states.

II. Local policies dictate coverage and these policies could change.

3.3 Medicaid Coverage for Professional CGM

Visit **http://www.medicaid.gov** to access your state's Medicaid policies regarding professional CGM.

Refer to the Healthcare Practice Workflow for Coding and Billing on pg. 5 for a diagram of the key steps for FreeStyle Libre Pro system and respective coding information.

3.4 Prior Authorization

3.4.1 When to request a prior authorization:

If any additional documentation is necessary, it should be identified at the time of benefits verification. This may require submission of written documentation to the payer.

3.4.2 Examples of documentation:

Payer requirements vary and may include:

- Documented glycemic control problems
- Description of patient treatment plan
- Record of patient's adherence to plan
- Physician progress notes
- Evaluations and consultations related to the diagnosis
- Laboratory reports, including HbA1c
- Blood glucose logs
- Physician report with interpretation and findings based on information obtained during monitoring

3.4.3 Abbott Diabetes Care Customer Support can provide assistance, including:

- General guidance about submitting prior authorizations
- Providing phone and fax numbers for the payer's prior authorization department

3.5 Claims, Denials, and Appeals

If a claim for professional continuous glucose monitoring is denied, consider the following general guidelines regarding how to review the denial, resubmit the claim form, and appeal the denial:

Step 1: Review the denial

- Review the payer's explanation of benefits (EOB) and the payer's coverage policies to identify reason for the claim denial. Refer to the following chart for common reasons for denial:

COMMON REASONS FOR DENIALS

Submission errors	Payer-specific policies
Incomplete information	Payer does not have formal coverage policy for professional CGM services
Missing or wrong CPT code or -25 modifier Used ICD-9 instead of ICD-10 codes	Submission goes beyond payer's approved number of submissions for professional CGM services
Misspelled patient name	Payer-required prior authorization was not submitted/received
Missing physician signature	

Step 2: Research claim and payer requirements

- Verify that the initial claim form was complete; it did not have missing information.
- Research payer requirements for reopening/redetermination/appeal.

Step 3: Resubmit the corrected claim form

- Resubmit complete or corrected information.
- Verify that the patient meets the payer's coverage criteria.
- Verify correct ICD-10 codes are used.
- Submit letter of appeal along with proper documentation, such as that required for medical necessity.

4. Payment for the FreeStyle Libre Pro System

4.1 Payment by Site of Service

4.1.1 Physician practice

Typically paid under the physician fee schedule set by Medicare and commercial payers, which assigns a specific payment to each CPT code. Other payments by commercial payers can include capitated fees or billed charges.

I. **Hospital-based outpatient diabetes center:** If 95250 is billed by a hospital-based outpatient diabetes center, the facility will be reimbursed under the payer's outpatient hospital payment system.

II. Medicare and some private payers pay for hospital outpatient services based on Ambulatory Payment Classifications (APCs), which assign services to payment categories. Other commercial payers utilize billed charges or fee schedules for payment of hospital outpatient services.

III. For specific payment questions, contact the payer's provider relations team.

4.2 Medicare National Average Payments

Reimbursement for professional CGM services billed under CPT codes 95250 and 95251 will vary depending on the type of provider and place of service.

4.2.1 Physician fee schedule

Refer to the chart on the next page for the 2016 Medicare Physician Fee Schedule (MPFS) current national Medicare allowable for both physician and outpatient payment amounts. Actual rates will vary by geography and do not reflect payment impact from 2% sequestration.

4.2.2 Fee based on role of healthcare professional

The physician fee schedule payments shown are paid to HCPs when they personally render the professional CGM service, or when, as permitted, it is rendered by auxiliary staff "incident to" the physician's service. If the professional CGM service is rendered by other healthcare providers such as a PA or NP who are billing separately under their own provider numbers, payment is typically made at 85% of the physician amount.

4.2.3 To confirm local policies

View **https://www.cms.gov/medicare-coverage-database/** for a complete list of local carriers and their websites. Visit **https://www.cms.gov/Medicare/Medicare.html** for link to CMS Physician Fee Schedule Look-Up tool.

4.2.4 The Medicare physician fee schedule payment structure can also be found at **www.FreeStyleLibrePro.us/reimbursement**

2016 NATIONAL PAYMENTS FOR CPT CODES 95250 AND 95251

Definition	Medicare Physician Fee Schedule[1,2]	Private Payer[3]
	Medicare Allowable	Median Billed
95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (Do not repeat more than once per month)	$159.69	$303
95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	$44.04	$87

Medicare rates are not geographically adjusted and do not show the impact of the 2% sequestration.
Physician fee schedule rates represent the non-facility allowed rates.

*Individual plan coverage may vary. Please verify coverage criteria and frequency directly with the health plans and local Medicare contractors

1. Determining Medicare Payments PPRRVU16_V0122.xlsx https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/
2. January 2016 Web Addendum B.12.14.15.xlsx https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/
3. PMIC Medical Fees in the United States 2016. Numbers provided are 50th percentile of the Usual and Customary (UCR) charges.
Note: These are charges and not actual reimbursed amounts. Private payer paid rates are confidential.

5. Frequently Asked Questions

The information below is intended for reference only. Please contact health plans directly with specific questions related to coverage, coding, and reimbursement, as coverage and policies vary by plan.

1. How do I find out if my patient's insurance company covers professional continuous glucose monitoring (CGM) with services billed under CPT codes 95250 and 95251?

While some exceptions exist, most commercial insurance plans have written coverage policies for professional CGM. For a detailed list of coverage from your top regional payers, please refer to **www.FreeStyleLibrePro.us/reimbursement**. As always, verify coding and reimbursement requirements with patients' health plans prior to rendering services.

2. Does billing CPT 95250/95251 preclude me from billing for E/M?

No, you can bill both if services were performed/billed on the same day. If an Evaluation and Management code (E/M) is billed on the same day as 95250 and 95251, then add the modifier -25 to indicate that the E/M service is separate and identifiable from the CGM service.

3. What if my practice receives a denied claim for services billed under CPT codes 95250 and 95251?

Claim denials can occur for a wide variety of reasons. It is important to understand why the claim was denied and know what options are available to re-submit or appeal the claim.

For common reasons for claims denials, refer to page 9.

To appeal to a commercial payer, please refer to the payer's website for appeals requirements or contact their provider relations team.

To file an appeal as a Medicare-enrolled professional (EP), contact your local Medicare carrier.

4. When should I utilize a -25 modifier code?

It should be added to the Evaluation and Management code (E/M) if billed on the same day as 95250 and 95251. Modifier -25 verifies that the E/M service was separate and identifiable from the CGM service.

5. Do I need to submit a prior authorization form?

Policies vary. Not all payers require prior authorization. Refer to the payer's coverage policy on the plan's website to determine if prior authorization is needed.

Abbott Diabetes Care Customer Support at **www.FreeStyleLibrePro.us/reimbursement** is available to healthcare professionals to provide information about prior authorization requirements. Or, you can contact Abbott Diabetes Care Customer Support at 877-549-9181.

6. How many times can I bill per patient for continuous glucose monitoring?

Payer policies vary on the frequency of billing for professional CGM under CPT codes 95250 and 95251. These services can only be performed as a medical necessity. CPT codes 95250 and 95251 cannot be billed more than once per month per patient. Payers are not obligated to cover CGM once per month, and set their own criteria for frequency limits. Please contact the payer's coverage policies on the plan's website for details.

Should you be denied based on frequency of service, you have the ability to appeal the denial based on medical necessity. It is important to provide the documentation and reporting that best describes the patient's medical necessity for more frequent monitoring.

7. Does Medicare cover the HCP's cost for the continuous glucose monitoring device?

Reimbursement under CPT code 95250 provides payment for the technical portion of the service, including the sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording. The practice expense inputs underlying the valuation of 95250 include the cost for use of a glucose continuous monitoring system for 72 hours.*

*CMS-1631-FC_PUF_Equip.xlsb

8. Where can I find the state and local Medicare fee schedules?

The Centers for Medicare and Medicaid Services (CMS) has a search engine that you can use to find state and local fee schedules for all CPT codes: **https://www.cms.gov/apps/physician-fee-schedule/overview.aspx**

6. Additional Resources

For assistance with pro-CGM reimbursement-related questions, contact:

Abbott Diabetes Care Reimbursement Customer Support
www.FreeStyleLibrePro.us/reimbursement
877-549-9181
Hours of operation: 8am – 8pm EST

ICD-10 Code Descriptions

TYPE 1 DIABETES MELLITUS WITH... (E10)

E10.10	Ketoacidosis without coma
E10.11	Ketoacidosis with coma
E10.21	Diabetic nephropathy
E10.22	Diabetic chronic kidney disease
E10.29	Other diabetic kidney complication
E10.311	Unspecified diabetic retinopathy with macular edema
E10.319	Unspecified diabetic retinopathy without macular edema
E10.329	Mild nonproliferative diabetic retinopathy without macular edema
E10.331	Moderate nonproliferative diabetic retinopathy with macular edema
E10.339	Moderate nonproliferative diabetic retinopathy without macular edema
E10.341	Mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.349	Severe nonproliferative diabetic retinopathy without macular edema
E10.351	Proliferative diabetic retinopathy with macular edema
E10.359	Proliferative diabetic retinopathy without macular edema
E10.36	Diabetic cataract
E10.39	Other diabetic ophthalmic complication
E10.40	Diabetic neuropathy, unspecified
E10.41	Diabetic mononeuropathy
E10.42	Diabetic polyneuropathy
E10.43	Diabetic autonomic (poly)neuropathy
E10.44	Diabetic amyotrophy
E10.49	Other diabetic neurological complication
E10.51	Diabetic peripheral angiopathy without gangrene
E10.52	Diabetic peripheral angiopathy with gangrene
E10.59	Other circulatory complications
E10.610	Diabetic neuropathic arthropathy
E10.618	Other diabetic arthropathy
E10.620	Diabetic dermatitis
E10.621	Foot ulcer
E10.622	Other skin ulcer
E10.628	Other skin complications
E10.630	Periodontal disease
E10.638	Other oral complications
E10.641	Hypoglycemia with coma
E10.649	Hypoglycemia without coma
E10.65	Hyperglycemia
E10.69	Other specified complication
E10.8	Unspecified complications
E10.9	Diabetes mellitus without complications

TYPE 2 DIABETES MELLITUS WITH... (E11)

E11.00	Hyperosmolarity w/o nonket hyprgly-hypros coma (NKHHC)
E11.00	Hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Hyperosmolarity with coma
E11.21	Diabetic nephropathy
E11.22	Diabetic chronic kidney disease
E11.29	Other diabetic kidney complication
E11.311	Unspecified diabetic retinopathy with macular edema
E11.319	Unspecified diabetic retinopathy without macular edema
E11.321	Mild nonproliferative diabetic retinopathy with macular edema
E11.329	Mild nonproliferative diabetic retinopathy without macular edema
E11.331	Moderate nonproliferative diabetic retinopathy with macular edema
E11.339	Moderate nonproliferative diabetic retinopathy without macular edema
E11.341	Severe nonproliferative diabetic retinopathy with macular edema
E11.349	Severe nonproliferative diabetic retinopathy without macular edema
E11.351	Proliferative diabetic retinopathy with macular edema
E11.359	Proliferative diabetic retinopathy without macular edema
E11.36	Diabetic cataract
E11.39	Other diabetic ophthalmic complication
E11.40	Diabetic neuropathy, unspecified
E11.41	Diabetic mononeuropathy
E11.42	Diabetic polyneuropathy
E11.43	Diabetic autonomic (poly)neuropathy
E11.44	Diabetic amyotrophy
E11.49	Other diabetic neurological complication
E11.51	Diabetic peripheral angiopathy without gangrene
E11.52	Diabetic peripheral angiopathy with gangrene
E11.59	Other circulatory complications
E11.610	Diabetic neuropathic arthropathy
E11.618	Other diabetic arthropathy
E11.620	Diabetic dermatitis
E11.621	Foot ulcer
E11.622	Other skin ulcer
E11.628	Other skin complications
E11.630	Periodontal disease
E11.638	Other oral complications
E11.641	Hypoglycemia with coma
E11.649	Hypoglycemia without coma
E11.65	Hyperglycemia
E11.69	Other specified complication
E11.8	Unspecified complications
E11.9	Type 2 diabetes mellitus without complications

ICD-10 Code Descriptions - CONTINUED

OTHER SPECIFIED DIABETES MELLITUS WITH... (E13)

E13.00	Hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.01	Hyperosmolarity with coma
E13.10	Ketoacidosis without coma
E13.11	Ketoacidosis with coma
E13.21	Diabetic nephropathy
E13.22	Diabetic chronic kidney disease
E13.29	Diabetic kidney complication
E13.311	Unspecified diabetic retinopathy with macular edema
E13.319	Unspecified diabetic retinopathy without macular edema
E13.321	Mild nonproliferative diabetic retinopathy with macular edema
E13.329	Mild nonproliferative diabetic retinopathy without macular edema
E13.331	Moderate nonproliferative diabetic retinopathy with macular edema
E13.339	Moderate nonproliferative diabetic retinopathy without macular edema
E13.341	Severe nonproliferative diabetic retinopathy with macular edema
E13.349	Severe nonproliferative diabetic retinopathy without macular edema
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E13.618	Other diabetic arthropathy
E13.620	Diabetic dermatitis
E13.621	Foot ulcer
E13.622	Other skin ulcer
E13.628	Other skin complications
E13.630	Periodontal disease
E13.638	Other specified diabetes mellitus with other oral complications
E13.641	Other specified diabetes mellitus with hypoglycemia with coma
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia
E13.69	Other specified diabetes mellitus with other specified complication
E13.8	Other diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications

Z79.4	Long term (current) use of insulin
Z96.41	Presence of insulin pump (external) (internal)

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FreeStyle Libre Pro
FLASH GLUCOSE MONITORING SYSTEM

Indications and Important Safety Information

The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns and glucose level excursions above or below the desired range, facilitating therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for use by health care professionals and requires a prescription.

IMPORTANT: The device may inaccurately indicate hypoglycemia. The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81-160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use.

CONTRAINDICATIONS: Remove the Sensor before MRI, CT scan, X-ray, or diathermy treatment. WARNINGS/LIMITATIONS: The FreeStyle Libre Pro System does not provide real-time results and patients should adhere to their blood glucose monitoring routine while using the system. If a sensor breaks, contact physician and call Customer Service. Patients with high levels of ascorbic acid (Vitamin C) or salicylic acid (used in Aspirin) or severe dehydration or excessive water loss or medications containing acetaminophen (Tylenol) may experience inaccurate results with this system. The FreeStyle Libre Pro System is not approved for pregnant women, persons on dialysis, or recommended for critically ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken.

Review all product information before use or contact Abbott toll-free (855-632-5297) or visit www.FreeStyleLibrePro.us for detailed indications for use and safety information

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