DiversifyRx Demo Pharmacy

Detailed Product Description

Glucose Monitors and Supplies

PATIENT		DMEPOS SUPPLIER	
Name:		**Name:**	DiversifyRx Demo Pharmacy
DOB:		**Address:**	123 Main Street
Address:			Dallas, TX 75067
		Phone #:	800-222-1212
Phone #:		**Fax #:**	800-222-1212

ICD-10 code(s) that justify *Medical Necessity*

1	❒ ICD-10 CM: E11.9 ❒ NIDDM ❒ IDDM	**2**	❒ ICD-10 CM: E10.9 ❒ NIDDM ❒ IDDM	**3**	❒ Other: _____ ❒ NIDDM ❒ IDDM	**4**	❒ Other: _____ ❒ NIDDM ❒ IDDM

DEFINITIONS:

- NIDDM – Non-insulin-dependent diabetes mellitus – Medicare Allowable for testing – **Once (1) daily – Dispense 100 Strips for 90 days**
- IDDM – Insulin-dependent diabetes mellitus – Medicare Allowable for testing – **Three (3) times daily – Dispense 100 Strips for 30 days**
- Adjunctive Continuous Glucose Monitors (CGM) used to check glucose levels and trends which must be verified with a blood glucose monitor to make diabetes treatment decisions
- Non-adjunctive Continuous Glucose Monitors (CGM) can be used to make treatment decisions without the need for a stand-alone home Blood Glucose Monitor (BGM) to confirm testing results

Number of times testing per day: (Circle) 1 2 3 4 | **HbA1c** _____ | Date _____

HCPCS Modifiers

1		2		3		4		5	

QTY	HCPCS Codes	HCPCS Description	# Refills
		# Face to Face and Written Order Prior to Delivery Required	
Group 1 Codes			
	E0607	Home blood glucose monitor	
	E0620	Skin piercing device for collection of capillary blood, laser, each **(#) (non-covered D/T not reasonable and necessary)**	
	E1399	Durable medical equipment, miscellaneous	
	E2100	Blood glucose monitor with integrated voice synthesizer **(#) (severe visual impairment of 20/200 or worse present in both eyes)**	
	E2101	Blood glucose monitor with integrated lancing/blood sample **(severe visual impairment of 20/200 or worse present in both eyes and/or severe manual dexterity impairments)**	
	E2102	Adjunctive non-implanted continuous glucose monitor or receiver	
	E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver	
Group 2 Accessories/Supplies			
	A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips **(face-to-face visit required for higher utilization)**	
	A4259	Lancets, per box of 100 **(face-to-face visit required for higher utilization)**	
	A4233	Replacement battery, alkaline (other than j cell), for use with medically necessary home blood glucose monitor owned by patient, each	
	A4234	Replacement battery, alkaline, j cell, for use with medically necessary home blood glucose monitor owned by patient, each	
	A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each	
	A4236	Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each	
	A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service	

See page 2 for additional HCPCS Codes

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Patient Name:

QTY	HCPCS Codes	HCPCS Description	# Refills
	A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service	
	A4244	Alcohol or peroxide, per pint **(non-covered)**	
	A4245	Alcohol wipes, per box **(non-covered)**	
	A4246	Betadine or phisohex solution, per pint **(non-covered)**	
	A4247	Betadine or iodine swabs/wipes, per box **(non-covered)**	
	A4250	Urine test or reagent strips or tablets (100 tablets or strips) **(non-covered)**	
	A4255	Platforms for home blood glucose monitor, 50 per box	
	A4256	Normal, low and high calibrator solution/chips	
	A4257	Replacement lens shield cartridge for use with laser skin piercing device, each **(non-covered D/T not reasonable and necessary)**	
	A4258	Spring-powered device for lancet, each (1 every 6 months)	
	A9275	Home glucose disposable monitor, includes test strips **(non-covered)**	
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply	
	A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system	
	A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system	
	A9999	Miscellaneous DME supply or accessory, not otherwise specified	

Supplier: The Standard Written Order (SWO) is sufficient to dispense the product and can serve as the Written Order Prior to Delivery (WOPD) if received before delivery. The clinical notes must include the product and/or device to be dispensed with the diagnosis description. The Treating Medical Practitioner must have a face-to-face encounter with the patient within the last 6 months and a WOPD is required for certain items in order to receive payment.

HCPCS MODIFIERS:

CG – Policy criteria applied
EY – No physician or other licensed health care provider order for this item or service
KF – Item designated by FDA as Class III device
KS – Glucose monitor supply for diabetic beneficiary not treated by insulin
KX – Requirements specified in the medical policy have been met

Please see LCD - Glucose Monitors (L33822) (cms.gov) and Article - Glucose Monitors - Policy Article (A52464) (cms.gov) for detailed information on coverage criteria, documentation requirements, and coding.

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The Face to Face and Written Order Prior to Delivery list can be found here: https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf.

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the patient must meet both of the following basic criteria (1)-(2):

1. The patient has diabetes (refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The patient's treating practitioner has concluded that the patient (or the patient's caregiver) has sufficient training using the particular device prescribed as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing.

Home blood glucose monitors with special features (HCPCS codes E2100, E2101) are covered when the basic coverage criteria (1)-(2) are met and the treating practitioner certifies that the patient has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring use of this special monitoring system.

Code E2101 is also covered for those with impairment of manual dexterity when the basic coverage criteria (1)-(2) are met and the treating practitioner certifies that the patient has an impairment of manual dexterity severe enough to require the use of this special monitoring system. Coverage of code E2101 for patients with manual dexterity impairments is not dependent upon a visual impairment.

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Usual Utilization:
For a patient who is not currently being treated with insulin administrations, up to 100 test strips and up to 100 lancets every 3 months are covered if the basic coverage criteria (1)-(2) (above) are met.

For a patient who is currently being treated with insulin administrations, up to 300 test strips and up to 300 lancets every 3 months are covered if basic coverage criteria (1)-(2) (above) are met.

High Utilization:
For a patient who is not currently being treated with insulin administrations, more than 100 test strips and more than 100 lancets every 3 months are covered if criteria (a)-(c) below are met.

For a patient who is currently being treated with insulin administrations, more than 300 test strips and more than 300 lancets every 3 months are covered if criteria (a)-(c) below are met.

a. Basic coverage criteria (1)-(2) listed above for all home glucose monitors and related accessories and supplies are met; and,
b. Within the six (6) months prior to ordering quantities of strips and lancets that exceed the utilization guidelines, the treating practitioner has had an in-person visit with the patient to evaluate their diabetes control and their need for the specific quantity of supplies that exceeds the usual utilization amounts described above; and,
c. Every six (6) months, for continued dispensing of quantities of testing supplies that exceed the usual utilization amounts, the treating practitioner must verify adherence to the high utilization testing regimen.

If neither basic coverage criterion (1) or (2) is met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips or lancets that exceed the utilization guidelines are provided and criteria (a)-(c) are not met, the amount in excess will be denied as not reasonable and necessary.

To be eligible for coverage of a CGM and related supplies, the patient must meet all of the following initial coverage criteria (1)-(5):

1. The patient has diabetes mellitus (refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The patient's treating practitioner has concluded that the patient (or patient's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
3. The CGM is prescribed in accordance with its FDA indications for use; and,
4. The patient for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
   A. The patient is insulin-treated; or,
   B. The patient has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article (A52464)):
      - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medications(s) and/or modify the diabetes treatment plan; or,
      - A history of one level 3 hypoglycemic event (glucose <54 mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the patient to evaluate their diabetes control and determine that criteria (1)-(4) above are met.

Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity of BGM testing supplies at a time.

For high utilization of testing supplies, the medical practitioner must verify in the patient's medical record every 6 months the patient's adherence to a daily high-frequency testing schedule.

CGM devices billed to Medicare that have not been approved by the Pricing, Data Analysis and Coding contractor (PDAC) will be denied as non-covered (no Medicare benefit).

Refer to the External Infusion Pumps LCD (L33794) for additional information on billing a CGM receiver incorporated into an insulin infusion pump.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) contractor for guidance on the correct coding of these orthosis items.

Use of an ABN is required for non-covered items

Source: Noridian Medical Equipment, Prosthetics, Orthotics, and Supplies Local Coverage Determination, Jurisdictions A and D

