Glucose Monitors

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

For medical necessity, The Health Plan will follow:

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>CMS Pub. 100-3, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review/Revisions Date</td>
<td>For services on or after 10/01/13</td>
</tr>
<tr>
<td></td>
<td>Reviewed: 07/01/2017, 01/01/2016</td>
</tr>
</tbody>
</table>

Effective January 1, 2006 all claims for Medicare and Commercial plans for blood glucose equipment and supplies must be submitted to The Health Plan’s pharmacy benefits manager (PBM), Express Scripts. Any claim submitted to The Health Plan on a HCFA 1500 using the HCPCS codes for test supplies or for monitoring devices, will be denied. Claims should be sent to Express Scripts using the NDC number of the item(s) billed. The Health Plan has implemented a closed formulary for diabetic monitors and supplies. Only products manufactured by LifeScan (a Johnson & Johnson Company) will be covered for our members. The monitors include the One Touch Ultra, One Touch Ultra Smart, and Sure Step monitoring systems and related supplies. Any member not currently receiving LifeScan products will be converted to a LifeScan monitoring device. LifeScan is providing an exchange program for members already using a glucose monitor, but not currently using one of their machines. *Exception would be the test strips that come with certain insulin pumps - see External Pump Policy

Mountain Health Trust (WV Medicaid) must be billed directly to The Health Plan for diabetic equipment and supplies.

Certain self-funded groups are to be billed directly to The Health Plan for diabetic equipment and supplies. Please refer to the individual plans benefit.
DESCRIPTION

Diabetes is an abnormal condition marked by deficient insulin (a hormone from the pancreas) in the blood. This deficiency causes sugar to remain in the blood instead of entering the cells of the body. Management/treatment of the disease may be non-insulin dependent or insulin dependent. Failure to control diabetes may lead to blindness, poor circulation that can result in ulcerated wounds that may lead to the need for amputation, and major organ failure.

COVERAGE GUIDELINES

Home blood glucose monitors, E0607, are covered for patients who can control their blood glucose levels by checking these levels and appropriately contacting their attending physician for advice and treatment. To be eligible for coverage, the patient must meet all of the following basic requirements:

1. The patient has a diagnosis of diabetes (ICD-10 E08.9, E09.9, E10.8-E13.9, E10.65), which is being treated by a physician, and
2. The glucose monitor and related accessories and supplies have been ordered by the physician who is treating the patient’s diabetes, and the treating physician maintains records reflecting the care provided including, but not limited to, evidence of medical necessity for the prescribed frequency of testing, and
3. The patient (or patient’s caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips, and lancing devices, and
4. The patient (or patient’s caregiver) is capable of using the test results to assure the patient’s appropriate glycemic control and
5. The device is designated for home use.

Home glucose monitors with special features (E2100 and E2101) are covered when the basic coverage criteria (1-5) listed above are met and the treating physician certifies that the patient has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring the use of this special monitoring system.

Code E2101 is also covered for those with impairment of manual dexterity when the basic coverage criteria (1-5) listed above are met and the treating physician certifies that the patient has an impairment of manual dexterity severe enough to require the use of this special monitoring system.

Coverage of E2101 for patients with manual dexterity impairment is not dependent upon a visual impairment. E2101 may also be covered for a patient with visual impairment.

NOTE: The medical necessity for E2100 or E2101 in a patient with impaired visual acuity must be documented by a narrative statement from the physician that includes the patient’s specific visual acuity (e.g., 20/400) and that this result represents “best corrected” vision.

If an E2100 or E2101 glucose monitor is provided and basic coverage criteria (1-5) listed above are met, but the additional criterion is not met, the claim will be denied. Appeals and claims with an ABN signed by the patient may be considered.

The quantity of supplies are as follows: (Unless otherwise indicated in member’s benefit plan or contractual document)
Member not treated with insulin - up to 100 test strips and up to 100 lancets every three months if criteria 1-5 above met.

Member being treated with insulin injections - up to 100 test strips and up to 100 lancets every month are covered if criteria 1-5 above are met.

Member not being treated with insulin injections no than 100 test strips and no more than 100 lancets every three months are covered if “a” and “b” below are met. If member is being treated with insulin injections, more than 100 test strips and more than 100 lancets every month are covered if criteria “a” and “b” are met:

a. Coverage criteria (1-5) listed above are met, and
b. A face-to-face visit with the treating physician within the six month period of the supply order that exceed utilization with medical necessity documented.

NOTE: If the above documentation is not received, the testing supplies in excess of utilization allowable may be denied for no medical necessity.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary’s expected utilization. Suppliers should stay attuned to atypical utilization patterns on behalf of their clients and verify with the ordering physician that the atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than three month supply of glucose testing supplies at a time.

An order does not have to be approved by the ordering physician, however, a beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has “authorized” this in advance.

Providers are reminded to follow appropriate guidelines on refill requirements.

COVERAGE OF CONTINUOUS GLUCOSE MONITOR

The Health Plan will cover continuous glucose monitoring systems (A9276, A9277, A9278) for Commercial plan members identified as Type I diabetics, who have had several documented episodes of hypoglycemia(<50mg/dl), when preliminary 72-hour monitoring does not prove diagnostic and other modifications have been attempted in insulin regimen. The member has proven compliant with self-monitoring finger sticks at least four times a day, and agrees to active participation in The Health Plan Diabetes Management Program. Continuous glucose monitoring system must be ordered by an endocrinologist. Requests for hypoglycemic unawareness require the results from the 72-hour monitor, the member’s blood sugar logs and the completed Hypoglycemia Awareness Questionnaire that is attached at the end of the external Infusion pump policy, pages 20-21

OR

The patient with diabetes had been using a CGM prior to enrollment with a The Health Plan group and has documented frequency of fingerstick blood glucose testing a minimum of 2 times a day while wearing the CGM in the month prior to enrollment

Dates of Service On or After July 1, 2017 for the Dexcom CGM device will be as follows:
K0553 - SUPPLY ALLOWANCE FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1
MONTH SUPPLY = 1 UNIT OF SERVICE

• K0554 - RECEIVER (MONITOR), DEDICATED, FOR USE WITH THERAPEUTIC CONTINUOUS GLUCOSE MONITOR SYSTEM

Criteria is as follows:

1. Has diabetes mellitus; and
2. Has been using a home blood glucose monitor (BGM), and performing frequent (four or more times a day) BGM testing, and
3. Is insulin-treated with multiple daily injections (three or more) of insulin or a continuous subcutaneous insulin infusion pump; and requires frequent adjustment, and
4. The insulin regime requires frequent adjustments by the member based on the BGM/CGM test results., and
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

Note: Only the Dexcom G5® CGM is covered no other CGM systems are covered and must not be coded K0553 and K0554.

NONCOVERED ITEMS

Continuous glucose monitoring systems (A9276, A9277, and A9278) for Medicare and Medicaid plans. See above comments- This coding remains non Covered for Medicare and Medicaid Plans and must be used for all CGM systems other than the Dexcom G5®.

The medical necessity for a laser skin piercing device (E0620) has not been established. If an E0620 is ordered and purchased for use with a covered blood glucose monitor, it will be denied. The related lens shield cartridge (A4257) will also be denied. Alcohol (A4244), peroxide (A4245), betadine (A4246), or phisophex (A4247), and urine test reagent strips or tables (A4250) are not covered for use with glucose monitors.

Reflectance colorimeter devices used for monitoring blood glucose levels in clinical settings are not covered as DME for use in the home due to the need for frequent professional re-calibration that makes them unsuitable for home use.

Disposable home glucose monitors and strips (A9275) noncovered, as they are not DME.

Continuous glucose monitors (A9276 - A9278) for Medicare and Medicaid member are not covered, as they are precautionary and non therapeutic.
# GLUCOSE MONITORS

## CODING INFORMATION

### HCPCS MODIFIERS

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
</tr>
<tr>
<td>KS</td>
<td>GLUCOSE MONITOR SUPPLY FOR DIABETIC BENEFICIARY NOT TREATED WITH INSULIN</td>
</tr>
<tr>
<td>KX</td>
<td>SPECIFIC REQUIRED DOCUMENTATION ON FILE, FOR DIABETIC BENEFICIARY BEING TREATED WITH INSULIN</td>
</tr>
</tbody>
</table>

### HCPCS CODES

#### EQUIPMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0607</td>
<td>HOME BLOOD GLUCOSE MONITOR</td>
</tr>
<tr>
<td>E0620</td>
<td>SKIN PIERCING DEVICE FOR THE COLLECTION OF CAPILLARY BLOOD, LASER, EACH – THERE IS NO EVIDENCE TO SUPPORT THE NEED FOR THIS ITEM</td>
</tr>
<tr>
<td>E2100</td>
<td>BLOOD GLUCOSE MONITOR WITH INTEGRATED VOICE SYNTHESIZED</td>
</tr>
<tr>
<td>E2101</td>
<td>BLOOD GLUCOSE MONITOR WITH INTEGRATED LANCING/BLOOD SAMPLE</td>
</tr>
</tbody>
</table>

#### ACCESSORIES/SUPPLIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4233</td>
<td>REPLACEMENT BATTERY, ALKALINE (OTHER THAN J CELL), FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH</td>
</tr>
<tr>
<td>A4234</td>
<td>REPLACEMENT BATTERY, ALKALINE, J CELL, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH</td>
</tr>
<tr>
<td>A4235</td>
<td>REPLACEMENT BATTERY, LITHIUM, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY THE PATIENT, EACH</td>
</tr>
<tr>
<td>A4236</td>
<td>REPLACEMENT BATTERY, SILVER OXIDE, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH</td>
</tr>
<tr>
<td>A4244</td>
<td>ALCOHOL OR PEROXIDE, PER PINT – NOT COVERED AS NOT REQUIRED FOR PROPER FUNCTION OF THE DEVICE/COVERED FOR MHT</td>
</tr>
<tr>
<td>A4245</td>
<td>ALCOHOL WIPES, PER BOX – NOT COVERED AS NOT REQUIRED FOR PROPER FUNCTION OF THE DEVICE/ COVERED FOR MHT</td>
</tr>
</tbody>
</table>
GLUCOSE MONITORS

<table>
<thead>
<tr>
<th>A4246</th>
<th>BETADINE OR PHISOHEX SOLUTION, PER PINT – <strong>NOT COVERED AS NOT REQUIRED FOR PROPER FUNCTION OF THE DEVICE/COVERED FOR MHT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>A4247</td>
<td>BETADINE OR IODINE SWABS/WIPES, PER BOX – <strong>NOT COVERED AS NOT REQUIRED FOR PROPER FUNCTION OF THE DEVICE/ COVERED FOR MHT</strong></td>
</tr>
<tr>
<td>A4250</td>
<td>URINE TEST OR REAGENT STRIPS OR TABLETS (100 TABLETS OR STRIPS) – <strong>NOT COVERED SINCE THEY ARE NOT USED WITH A GLUCOSE MONITOR/COVERED FOR MHT</strong></td>
</tr>
<tr>
<td>A4253</td>
<td>BLOOD GLUCOSE TEST OR REAGENT STRIPS FOR HOME BLOOD GLUCOSE MONITOR, PER 50 STRIPS = ONE UNIT – INSULIN DEPENDENT, UP TO 100 (2 UNITS) PER MONTH</td>
</tr>
<tr>
<td>A4255</td>
<td>PLATFORMS FOR HOME BLOOD GLUCOSE MONITOR, 50 PER BOX</td>
</tr>
<tr>
<td>A4256</td>
<td>NORMAL, LOW, AND HIGH CALIBRATION SOLUTION/CHIPS</td>
</tr>
<tr>
<td>A4257</td>
<td>REPLACEMENT LENS SHIELD CARTRIDGE FOR USE WITH LASER SKIN PIERCING DEVICE</td>
</tr>
<tr>
<td>A4258</td>
<td>SPRING-POWERED DEVICE FOR LANCET, EACH</td>
</tr>
<tr>
<td>A4259</td>
<td>LANCETS, PER BOX OF 100 = ONE UNIT</td>
</tr>
<tr>
<td>A9270</td>
<td>BLOOD GLUCOSE TEST OR REAGENT STRIPS THAT USE A VISUAL READING AND ARE NOT USED IN A GLUCOSE MONITOR MUST BE CODED A9270 – <strong>NOT COVERED ITEM OR SERVICE</strong></td>
</tr>
<tr>
<td>A9275</td>
<td>HOME GLUCOSE DISPOSABLE MONITOR, INCLUDES TEST STRIPS – <strong>ARE NOT COVERED AS THEY DO NOT MEET THE DEFINITION OF DME</strong></td>
</tr>
<tr>
<td>A9276</td>
<td>SENSOR, INVASIVE (E.G. SUBCUTANEOUS) DISPOSABLE, FOR USE W/INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY</td>
</tr>
<tr>
<td>A9277</td>
<td>TRANSMITTER, EXTERNAL, FOR USE W/INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM</td>
</tr>
<tr>
<td>A9278</td>
<td>RECEIVER (MONITOR), EXTERNAL, FOR USE W/INTERSTITIAL CONTINUOUS GLUCOSE MONITOR SYSTEM</td>
</tr>
<tr>
<td>K0553</td>
<td>SUPPLY ALLOWANCE FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE</td>
</tr>
<tr>
<td>K0554</td>
<td>RECEIVER (MONITOR), DEDICATED, FOR USE WITH THERAPEUTIC CONTINUOUS GLUCOSE MONITOR SYSTEM</td>
</tr>
</tbody>
</table>

**NOTE:** A9276, A9277, AND A9278 ARE **NOT COVERED BY MEDICARE. THEY WOULD BE DENIED AS THEY ARE CONSIDERED PRECAUTIONARY. SEE EXTERNAL PUMP POLICY FOR COVERAGE FOR COMMERCIAL PLANS.**

**ICD-9 CODES**
Manufacturers often include sample amounts of glucose test strips, lancets, and other supplies with a new glucose monitor. Claims for supplies included in the new monitor “kits” must be coded A9900.

In the following table, a Column II code is included in the allowance for the corresponding Column I code when provided at the same time.

<table>
<thead>
<tr>
<th>COLUMN I</th>
<th>COLUMN II</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0607</td>
<td>A4233, A4234, A4235, A4236, A4256, A4258</td>
</tr>
<tr>
<td>E2100</td>
<td>A4233, A4234, A4235, A4236, A4256, A4258</td>
</tr>
<tr>
<td>E2101</td>
<td>A4233, A4234, A4235, A4236, A4256, A4258</td>
</tr>
</tbody>
</table>

**DOCUMENTATION REQUIREMENTS**

- The supplier must have an order for each item, signed and dated by the treating/ordering physician, kept on file, and made available upon request to The Health Plan’s Medical Management Department.
- Items billed before a signed and dated order has been received or before the item(s) is delivered to the member will be denied.

**COORDINATION OF BENEFITS WHEN THE HEALTH PLAN IS SECONDARY**

Since The Health Plan outsources the provision of glucose monitors and supplies to another entity, the guidelines in this policy apply chiefly to situations where The Health Plan is secondary. If the member’s primary carrier processes diabetic equipment and supplies under their medical plan, The Health Plan will coordinate benefits under the member’s medical plan, if the provider is contracted with The Health Plan.

Care will have to be taken in coordinating benefits in these circumstances and the primary carrier’s explanation of benefits (EOB) must accompany the claim. Mountain Health Trust members and the members of some ASO plans do not use our pharmacy benefits manager for diabetic equipment and supplier.
Claims are submitted to, processed, and paid by The Health Plan. Authorization through The Health Plan’s Medical Management Department may be required in these cases.

- The order for home blood glucose monitors and/or diabetic testing supplies must include all of the following elements:
  1. The item(s) to be dispensed;
  2. The specific frequency of testing;
  3. The treating physician’s signature;
  4. The date of the treating physician’s signature; and
  5. A start date of the order-only required if the start date is different from the date of the signature.

- The ICD-10 diagnosis code describing the condition that necessitates glucose testing must be included on each claim for monitor, accessories, and supplies.

- If the patient is being treated with insulin injections, the **KX** modifier must be added to the code for the monitor and each related supply on every claim submitted.

- If a patient is not being treated with insulin injections, the **KS** modifier must be added to the code for the monitor and each related supply on every claim submitted.

- Additional documentation requirements apply to:
  1. A diabetic patient who is not insulin-treated (KS modifier present) and whose prescribed frequency of testing is more often than once per day, or
  2. A diabetic patient who is insulin-treated (KX modifier present) and whose prescribed frequency of testing is more often than three times per day.

**NOTE:** When refills for quantities of supplies that exceed the utilization guidelines are dispensed, the documentation as described above must be available upon request.

- Failure of the provider to request and receiver authorization from The Health Plan’s Medical Management Department.
- Claims billed directly to The Health Plan as primary payer will be denied. All diabetic equipment and supply claims, with the exception of some ASO groups and Mountain Health Trust, must be billed to the pharmacy benefits manager.
- Claims billed to The Health Plan as secondary without the primary payer’s explanation of benefits will be denied.

  **NOTE:** When The Health Plan is secondary and the member primary EOB is attached, we will coordinate benefits under the member’s medical benefit as long as all other criteria for coverage is met, and the primary carriers EOB is included with the claim.

- Failure to provide any of the above documentation either on the request for authorization or the claim for the item(s) will result in denial of the claim.

- If any of the coverage criteria above has not been met, the claim will be denied as not reasonable and necessary.
- An order that states “as needed” will be denied as not reasonable and necessary. A new order must be obtained when there is a change in testing frequency.
GLUCOSE MONITORS

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INTERNET LINKS AND SOURCES


The Health Plan Pharmacy Formulary: Provider’s: Member’s with Diabetes Section. Retrieved at https://www.healthplan.org/search/content/diabetes

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11


National Government Services Local Coverage Determination Policy: Glucose Monitors LCD L27231 and Article A7238. Last accessed 01/01/16

Retrieved from apps.ngsmedicare.com/applications/lcd.aspx?CatID=3&RegID=51