### Coverage Summary

**Diabetes Management, Equipment and Supplies**

**Policy Number:** D-001  
**Products:** UnitedHealthcare Medicare Advantage Plans  
**Original Approval Date:** 11/01/2006  
**Approved by:** UnitedHealthcare Medicare Benefit Interpretation Committee  
**Last Review Date:** 10/20/2020

#### Related Medicare Advantage Policy Guidelines:

<table>
<thead>
<tr>
<th>Related Items</th>
<th>Medicare Advantage Policy Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed-Loop Blood Glucose Control Device (CBGCD) (NCD 40.3)</td>
<td>Insulin Syringe (NCD 40.4)</td>
</tr>
<tr>
<td>Diabetes Outpatient Self-Management Training (NCD 40.1)</td>
<td>Medical Nutrition Therapy (NCD 180.1)</td>
</tr>
<tr>
<td>Home Blood Glucose Monitors (NCD 40.2)</td>
<td>Outpatient Intravenous Insulin Treatment (NCD 40.7)</td>
</tr>
<tr>
<td>Infusion Pumps (NCD 280.14)</td>
<td>Therapeutic Continuous Glucose Monitors</td>
</tr>
</tbody>
</table>

---

**INDEX TO COVERAGE SUMMARY**

<table>
<thead>
<tr>
<th>I. COVERAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diabetic Self-management Training (DSMT)</td>
</tr>
<tr>
<td>2. Medical Nutrition Therapy (MNT)</td>
</tr>
<tr>
<td>3. Blood Glucose Monitors</td>
</tr>
<tr>
<td>4. Modified/Special Blood Glucose Monitors</td>
</tr>
<tr>
<td>5. Non-Implantable Continuous Glucose Monitors (CGM)</td>
</tr>
<tr>
<td>6. Implantable Continuous Glucose Monitors (I-CGM)</td>
</tr>
<tr>
<td>7. External Continuous Subcutaneous Insulin Infusion (CSII) Pump</td>
</tr>
<tr>
<td>8. Closed-loop Blood Glucose Control Device (CBGCD)</td>
</tr>
<tr>
<td>9. Home Health Benefits to a Blind Diabetic</td>
</tr>
<tr>
<td>10. Outpatient Intravenous Insulin Treatment (OIVIT)</td>
</tr>
<tr>
<td>11. Additional Examples of Benefits that are Not Covered</td>
</tr>
</tbody>
</table>

| II. DEFINITIONS |
| III. REFERENCES |
| IV. REVISION HISTORY |
| V. ATTACHMENTS |

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This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member’s Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member’s EOC/SB, the member’s EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).
Coverage Statement: Diabetic management equipment and supplies may be covered in accordance with Medicare criteria.

DME Face to Face Requirement: Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including external ambulatory infusion pump and home blood glucose monitor). For DME Face to Face Requirement information, refer to the Coverage Summary for Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

COVID-19 Public Health Emergency Waivers & Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain services. For details, see the following Coronavirus Waivers/Flexibilities:

- Physicians and Other Practitioners (PDF)
- Participants in the Medicare Diabetes Prevention Program (PDF)


(Accessed October 12, 2020)

Guidelines/Notes:

1. Diabetic Self-management Training (DSMT)

   Diabetic self-management Training (DSMT) services are intended to educate patients in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose, education about diet and exercise, an insulin treatment plan developed specifically for the patients, and motivation for patients to use the skills for self-management. Diabetic self-management training (DSMT) services may be covered when criteria are met. For coverage criteria, refer to the Medicare Benefit Policy Manual, Chapter 15, §300 – Diabetic Self-Management Training Services. (Accessed October 15, 2020)

   Also refer to the NCD for Diabetes Outpatient Self-Management Training (40.1) and CFR Title 42, Chapter IV, §410.132-§410.146 – Outpatient Self-Management Training and Diabetes Outcome Measurements. (Accessed March 30, 2020)

   Also refer to the MLN Matters #SE0905-Training Medicare Patients on Use of Home Glucose Monitors and Related Billing Information. (Accessed March 30, 2020)

2. Medical Nutrition Therapy (MNT)

   Medical nutrition therapy (MNT) is covered for diabetic members when criteria are met. A Registered dietitian or a nutritional professional must render medical nutrition therapy (MNT).

   See the NCD for Medical Nutrition Therapy (180.1). (Accessed March 30, 2020)

   Also see the Medicare Claims Processing Manual, Chapter 4, §300 – Medical Nutrition Therapy Services. (Accessed April 13, 2020)

3. Blood Glucose Monitors

   Home blood glucose monitors and supplies (e.g., blood testing strips and lancets, replacement batteries) are covered when the following criteria are met. See the NCD for Home Blood Glucose Monitors (40.2). (Accessed March 30, 2020)

   Note: For guidelines on the appropriate quantities of strips and lancets, see the DME MAC LCD for Glucose Monitors (L33822). (Accessed January 4, 2021)
4. Modified/Special Blood Glucose Monitors
Modified/special blood glucose monitors and supplies for the visually impaired are covered if the member meets the coverage criteria.
See the NCD for Home Blood Glucose Monitors (40.2). (Accessed March 30, 2020)

5. Non-Implantable Continuous Glucose Monitors (CGM)
For coverage of insulin pump/CGM combination, see the Guideline 6 (External Continuous Subcutaneous Insulin Infusion Pump) below.

a. Non-Therapeutic Continuous Glucose Monitors and Supplies (HCPCS codes A9276-A9278)
Non-Therapeutic CGMs and supplies are considered precautionary, and are excluded from coverage under the Medicare DME benefit.

CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as "non-therapeutic" CGMs.
Also see the CMS Ruling No. [CMS-1682-R] issued January 12, 2017. (Accessed July 30, 2020)

b. Therapeutic Continuous Glucose Monitors and Supplies
CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGMs. Refer to the Non-Medical Necessity Coverage and Payment Rules in the LCD-related Policy Article for additional information.

Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met:
1) The member has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and
2) The member has been using a BGM and performing frequent (four or more times a day) testing; and
3) The member is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and
4) The member’s insulin treatment regimen requires frequent adjustment by the patients on the basis of BGM or CGM testing results; and
5) Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the patient 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 patient to assess adherence to their CGM regimen and diabetes treatment plan.

When a therapeutic CGM (HCPCS code K0554) is covered, the related supply allowance (HCPCS code K0553) is also covered.

If any of coverage criteria (1-6) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

The supply allowance (HCPCS code K0553) is billed as 1 Unit of Service (UOS) per month. Only one (1) UOS of HCPCS code K0553 may be billed to the DME MACs at a time. Billing more than 1 UOS per month of HCPCS code K0553 will be denied as not
reasonable and necessary.

Therapeutic CGM devices replace a standard home blood glucose monitor (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233-A4236, A4244-A4247, A4250, A4253, A4255-A4259). Claims for a BGM and related supplies, billed in addition to an approved CGM device (HCPCS code K0554) and associated supply allowance (HCPCS code K0553), will be denied. Refer to the Coding Guidelines in the LCD-related Policy Article for additional information.

All therapeutic CGM devices billed to Medicare using HCPCS code K0554 must be reviewed for correct coding by the Pricing, Data Analysis and Coding contractor (PDAC). Continuous Glucose Monitor systems that have not been reviewed and listed on the Product Classification List for HCPCS code K0554 will be denied as incorrect coding. Refer to the Coding Guidelines in the LCD related Policy Article for additional information.

See the DME MAC LCD for Glucose Monitors (L33822), (Accessed January 4, 2021)
Also see the DME MAC Glucose Monitor – Policy Article (A52464) for additional coverage guidelines. (Accessed January 4, 2021)

c. Ambulatory Continuous Glucose Monitoring (CPT codes 95249, 95250 and 95251)
   - Medicare does not have a National Coverage Determination (NCD) for continuous glucose monitoring.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.
   - For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy for Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
   - Committee approval date: April 21, 2020
   - Accessed March 31, 2020

6. Implantable Continuous Glucose Monitors (I-CGM) (CPT codes 0446T and 0448T)
   - Medicare does not have a National Coverage Determination (NCD) for implantable continuous glucose monitors.
   - Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment A).
   - For coverage guidelines for states/territories with no LCDs/LCAs, refer to the Wisconsin Physicians Implantable Continuous Glucose Monitors (I-CGM) (L38686). (IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
   - Committee approval date: October 20, 2020
   - Accessed January 4, 2021

7. External Continuous Subcutaneous Insulin Infusion (CSII) Pump (HCPCS code E0784)
External continuous subcutaneous insulin infusion (CSII) pump and related drugs and supplies are covered when coverage criteria are met. See the NCD for Infusion Pumps (280.14). Also see the DME MAC LCD for External Infusion Pumps (L33794). (Accessed January 4, 2021)

Notes:
   - Combination Insulin pump and Continuous Glucose Monitoring (CGM): Insulin pumps
with integrated features such as CGM are also billed using HCPCS code E0784. Although the integrated CGM features and related supplies are not covered, coverage decisions for the device should be made based on its primary use. See Guideline 5 [Continuous Glucose Monitoring (CGM)] above for coverage guideline of CGM.

**Disposable drug delivery systems (e.g., OmniPod® Insulin Management System):**
Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, A9274) are non-covered devices because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items. See the DME MAC External Infusion Pumps – Policy Article (A52507). (Accessed January 4, 2021)

**Note:** These items may be covered if the member has Part D coverage for drugs under UnitedHealthcare. Refer to the member’s pharmacy booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for Part D prescription drug plan benefit. See the CMS Communication to Part D Plan Sponsors dated January 5, 2018; available at [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Medical-Supplies-Associated-with-the-Injection-of-Insulin.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Medical-Supplies-Associated-with-the-Injection-of-Insulin.pdf). (Accessed March 31, 2020)

8. **Closed-loop Blood Glucose Control Device (CBGCD)**
Closed-loop blood glucose control device (CBGCD) is covered for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel. See the NCD for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3). (Accessed March 30, 2020)

9. **Home Health Benefits to a Blind Diabetic**
Home health benefits to a blind diabetic may be covered when criteria are met. See the NCD for Home Health Visits to a Blind Diabetic (290.1). (Accessed March 30, 2020)

Also see the Coverage Summary for Home Health Services, Home Health Visits, and Respite Care.

10. **Outpatient Intravenous Insulin Treatment (OIVIT)**
Effective for claims with dates of service on and after December 23, 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence is adequate to conclude that OIVIT does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act. Services comprising an Outpatient Intravenous Insulin Therapy regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen. See the NCD for Outpatient Intravenous Insulin Treatment (40.7). (Accessed March 30, 2020)

11. **The following are additional examples of benefits that are not covered, but are not limited to:**
   a. Insulin, except when:
      1) Member has coverage under the UnitedHealthcare Medicare Part D Prescription Drug Plan.
         **Note:** Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Services Department to determine coverage eligibility for prescription drug plan benefit.
      2) Used in conjunction with a continuous subcutaneous insulin infusion pump (CSII). See
Guideline 6 [External Continuous External Subcutaneous Insulin Infusion (CSII) Pump] for additional information.

b. Insulin syringes, needles, lancet holders, insulin pen devices and associated cartridges unless member has coverage under the UnitedHealthcare Medicare Part D Prescription Drug Plan.

Note: Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Services Department to determine coverage eligibility for prescription drug plan benefit.

See the NCD for Insulin Syringe (40.4). (Accessed March 30, 2020)

c. Alcohol, alcohol wipes, betadine, betadine wipes or iodine, iodine wipes.

Note: These items may be covered if the member has Part D coverage for drugs under UnitedHealthcare. Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for Part D prescription drug plan benefit.

d. Cotton swabs, peroxide or pHisoHex.

Note: These items may be covered if the member has Part D coverage for drugs under UnitedHealthcare. Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for Part D prescription drug plan benefit.

e. An implanted infusion pump for the infusion of insulin to treat diabetes. See the NCD for Infusion Pumps (280.14). (Accessed March 30, 2020)

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

10/20/2020 Coverage Statement

- Updated language pertaining to diabetic management equipment and supplies to clarify coverage may be provided in accordance with Medicare criteria
- Added notation pertaining to COVID-19 Public Health Emergency Waivers & Flexibilities to indicate:
  - In response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid (CMS) has updated some guidance for certain services; for details, see the following Coronavirus Waivers & Flexibilities:
    - Physicians and Other Practitioners
    - Participants in the Medicare Diabetes Prevention Program

Guideline 5 [Non-Implantable Continuous Glucose Monitors (CGM)]

- Changed guideline title; previously titled Continuous Glucose Monitoring (CGM)

Guideline 6 [Implantable Continuous Glucose Monitors (I-CGM) (CPT codes 0446T and 0448T)] (new to policy)
- Added coverage guidelines to indicate:
  - Medicare does not have a National Coverage Determination (NCD) for implantable continuous glucose monitors
  - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable
    - For state-specific LCDs/LCAs, see Attachment A: LCD/LCA Availability Grid for Implantable Continuous Glucose Monitors (I-CGM)
    - For states/territories with no LCDs/LCAs, refer to the Wisconsin Physicians Service Insurance Corporation (WPS) local coverage determination Implantable Continuous Glucose Monitors (I-CGM) (L38686) for coverage guidelines

**Attachments**
- Added Attachment A: LCD/LCA Availability Grid for Implantable Continuous Glucose Monitors (I-CGM)

### V. ATTACHMENTS

<table>
<thead>
<tr>
<th>ID #</th>
<th>Title</th>
<th>Contractor Type</th>
<th>Contractor Name</th>
<th>States/Territories</th>
</tr>
</thead>
<tbody>
<tr>
<td>L38662</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>A and B MAC</td>
<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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<tr>
<td>L38664</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<tr>
<td>L38659</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY</td>
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<tr>
<td>L38657</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>A and B MAC</td>
<td>Noridian Healthcare Solutions, LLC</td>
<td>AS, CA, GU, HI, MP, NV</td>
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<td>L38617</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
</tr>
</tbody>
</table>

(Notes: States notated with an asterisk should follow the other available state-specific LCD/LCA listed on this grid. This WPS LCD/LCA only applies to states without an asterisk.)

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>L38686</td>
<td>Implantable Continuous Glucose Monitors (I-CGM)</td>
<td>MAC Part B</td>
<td>Wisconsin Physicians Service Insurance Corp.</td>
<td>IN, IA, KS, MI, MO, NE</td>
</tr>
</tbody>
</table>

End of Attachment A