Diabetes Management, Equipment and Supplies

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 06/21/2017

Related Medicare Advantage Policy Guidelines:
- Closed-loop Blood Glucose Control Device-CBGCD (NCD 40.3)
- Diabetes Outpatient Self-Management Training (NCD 40.1)
- Home Blood Glucose Monitors (NCD 40.2)
- Home Health Visits to a Blind Diabetic (290.1)
- Infusion Pumps (NCD 280.14)
- Insulin Syringe (NCD 40.4)
- Medical Nutrition Therapy (NCD 180.1)
- Outpatient Intravenous Insulin Treatment (NCD 40.7)
- Therapeutic Continuous Blood Glucose Monitors

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I. COVERAGE

Coverage Statement: Diabetic self-management training (DSMT) services, medical nutrition therapy (MNT), home blood glucose monitors, and external continuous insulin pumps are 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 Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

**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, §30 – 300.5.1 - Diabetic Self-Management Training Services. (Accessed April 4, 2017)

   Also refer to the NCD for Diabetes Outpatient Self-Management Training (40.1) and CFR Title 42, Chapter IV, §410.140 - §410.146 - Outpatient Self-Management Training and Diabetes Outcome Measurements (Accessed April 4, 2017)

   Also refer to the MLN Matters #SE0905 - Training Medicare Patients on Use of Home Glucose Monitors and Related Billing Information. (Accessed April 4, 2017)

2. **Medical Nutrition Therapy (MNT)**

   a. 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). MNT consists of an initial visit assessment, follow-up visits for interventions, and reassessment as necessary during a 12-month period beginning with the initial assessment (“episode of care”) to assure compliance with dietary plan. The basic number of hours is 3 for the first year and 2 per year thereafter as determined to be medically necessary by the contracted treating physician. All of the following conditions must be met:

   1) The contracted treating physician must make a referral for MNT and indicate a diagnosis of diabetes or renal disease.
   2) The program meets the CMS guidelines.
   3) Services may be provided on an individual or group basis, without restrictions.
   4) For a member with a diagnosis of diabetes, diabetes self-management training (DSMT) and MNT services can be provided within the same time period and the maximum numbers of hours allowed under each benefit are covered. The only exception is that DSMT and MNT may not be provided on the same day to the same member.
   5) MNT services must be provided by a registered dietitian or nutrition professional).

   b. Medical nutrition therapy is not covered for the members receiving maintenance dialysis who have a diagnosis of renal disease for which payment is being made under section 1881 of the Act which provides for the establishment of end-stage renal disease (ESRD) Network Organizations.

   c. Additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.
d. If a member has both diabetes and renal disease, the beneficiary may only receive the maximum number of hours covered under the renal MNT benefit in one episode of care unless he/she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater.

See the NCD for Medical Nutrition Therapy (180.1). (Accessed March 23, 2016)

Also see the Medicare Claims Processing Manual, Chapter 4, §300 – Medical Nutrition Therapy Services. (Accessed April 4, 2017)

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:

a. The member has been diagnosed as having diabetes (including gestational diabetes);

b. The member’s physician states that he/she is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved; and

c. The device is designed for home rather than clinical use

See the NCD for Home Blood Glucose Monitors (40.2) (Accessed April 4, 2017)

Note: For guidelines on the appropriate quantities of strips and lancets, see the DME MAC LCD for Glucose Monitors (L33822). (Accessed August 9, 2017)

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 for standard home blood glucose monitor and the member’s physician certifies that the visual impairment is so severe that the member requires specific supplies, which include, but are not limited to:

- Voice synthesizers
- Automatic timers
- Specially designed supplies to promote self-management
- Lancet puncture devices

See the NCD for Home Blood Glucose Monitors (40.2) (Accessed April 4, 2017)

5. Continuous Glucose Monitoring (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.

See the DME MAC Local Coverage Article for Glucose Monitor - Policy Article (A52464). (Accessed August 9, 2017)
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 beneficiary has diabetes mellitus (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses); and,
2) The beneficiary has been using a BGM and performing frequent (four or more times a day) testing; and,
3) The beneficiary 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 beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary 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 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.

When a therapeutic CGM (code K0554) is covered, the related supply allowance (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 (code K0553) is billed as 1 Unit of Service (UOS) per month. Only one (1) UOS of code K0553 may be billed to the DME MACs at a time. Billing more than 1 UOS per month of 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 (code K0554) and associated supply allowance (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 LCDs for Glucose Monitors (L33822), (Accessed August 9, 2017)
- Also see the DME MAC Glucose Monitor - Policy Article (A52464) for additional
c. Continuous Glucose Monitoring (CPT codes 95250 and 95251)
   - Medicare does not have a National Coverage Determination for continuous glucose monitoring.
   - Local Coverage Determinations (LCDs) do not exist at this time.
   - For coverage guidelines, refer to the UnitedHealthcare Medical Policy for Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes.
   - Committee approval date: April 18, 2017
   - Accessed: April 4, 2017

6. 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 August 9, 2017)

   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 (Accessed August 9, 2017)

7. 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 April 4, 2017)

8. 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 April 4, 2017)

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

9. 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
10. 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 April 4, 2017)
   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 April 4, 2017)

II. DEFINITIONS

Outpatient Intravenous (IV) Insulin Therapy (OIVIT): Refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of insulin via any means, guided by the results of measurement of:
   • respiratory quotient; and/or
   • urine urea nitrogen (UUN); and/or
   • arterial, venous, or capillary glucose; and/or
   • potassium concentration; and
   • performed in scheduled recurring periodic intermittent episodes

This regimen is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment
(PI Vit), Pulse Insulin Therapy (PIT), and Pulsatile Therapy (PT).

In OIVIT, insulin is intravenously administered in the outpatient setting for a variety of indications. Most commonly, it is delivered in pulses, but it may be delivered as a more conventional drip solution. The insulin administration is adjunctive to the patient's routine diabetic management regimen (oral agent or insulin-based) or other disease management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits. Glucose or other carbohydrate is available ad libitum (in accordance with patient desire). NCD for Outpatient Intravenous Insulin Treatment (40.7). (Accessed April 4, 2017)

III. REFERENCES

See above.

IV. REVISION HISTORY

06/21/2017  Re-review with following updates:

Guideline 5.b (Therapeutic Continuous Glucose Monitors and Supplies):

- Removed HCPCS codes A9276, A9277 and A9278 from title.
- Updated guideline language to reflect changes in referenced DME MAC LCDs for Glucose Monitors (L33822).
- Added reference links to the DME MAC LCDs for Glucose Monitors (L33822) and the DME MAC Glucose Monitor - Policy Article (A52464).
- Removed the following language and Medicare references:

  “Therapeutic CGMs may be covered by Medicare when all of the following criteria are met:
  - The beneficiary has diabetes mellitus; and,
  - The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
  - The beneficiary is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
  - The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.

Notes:

- Therapeutic CGMs are primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. A receiver (or type of monitor) for a therapeutic CGM that has an expected life of at least 3 years and is the component performing the medically necessary function of accurately monitoring the trends of the patients' blood glucose levels so that he or she can make necessary diabetes treatment decisions meets the 3-year MLR [minimum lifetime requirements].

  For purposes of Medicare billing, the Ruling outlines therapeutic CGM as comprising two elements: (1) a DME component, (receiver) (HCPCS E1300); and, (2) an all-inclusive supply allowance (HCPCS code E9999).

- Coverage of the CGM system supply allowance is limited to those therapeutic CGM systems where the beneficiary ONLY uses a receiver classified as DME to display glucose data. If a beneficiary uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with a receiver classified as DME, the supply allowance is non-covered by Medicare.

- Therapeutic CGM devices replace a standard home blood glucose monitor
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• Guideline 3 (Blood Glucose Monitors)
  - Deleted the following duplicate language which is already addressed under 3.b: 
    *Physician must determine that the member or home support person(s) can be trained in equipment use and monitor the blood glucose*
  - Updated reference link of the DME LCD for Glucose Monitors (L33822) to reflect condensed LCD link.

• Guideline 5 [Continuous Glucose Monitoring System (CGMS)]
  - Changed title to Continuous Glucose Monitoring (CGM)
  - Separated into 2 sections (device and monitoring)
    First section 5.a (Continuous Glucose Monitors): no change in guideline content; updated reference link of the DME MAC LCA for Glucose Monitor (A52464) to reflect condensed link.
    Second section 5.b (Continuous Glucose Monitoring): added new guideline with default to the UnitedHealthcare Medical Policy for Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes since there are no applicable NCD and LCDs available at this time.

• Guideline 6 [External Continuous Subcutaneous Insulin Infusion (CSII) Pump]
  - Replaced current guideline with the following: *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).*
  - Note section for disposable delivery system: Updated reference link of the DME LCA for External Infusion Pumps (A52207) to reflect condensed link.

04/15/2015 Annual review with the following updates:

• Guideline #3 (Blood Glucose Monitors) –
  - Added reference links to the DME MAC LCDs for Glucose Monitors.
  - Deleted reference to “copayments/coinsurance”

• Guideline #6 [Continuous External Subcutaneous Insulin Infusion (CSII) Pump] -
  Deleted coverage summary guidelines for all 50 states language.

• Guideline #10a.2 [Used in conjunction with a continuous subcutaneous insulin infusion pump (CSII)]–
  - Added cross reference to guideline #6.
  - Deleted reference to NCD for Insulin Syringe (40.4)

• Guideline 10.b. (Insulin syringes, needles..)
  - Combined reference to “lancet holders, insulin pen devices and associated cartridges”
  - Added reference to NCD for Insulin Syringe (40.4)

• Guideline 10.c. (Alcohol, alcohol wipes, betadine, betadine wipes or iodine, iodine wipes)-
  Added 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.”

• Guideline 10.d.(Cotton swabs, peroxide or phisohex) -
  Added 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.”
- Guideline 10.e. (Member does not meet criteria for requested services/supplies) – Deleted from coverage summary.
- Guideline 10.g. (An implanted infusion pump for the infusion of insulin to treat diabetes) – Added reference to NCD for Infusion Pumps (280.14)
- Guideline 10.i. (Jet pressure powered type) – Unable to find CMS reference, deleted from coverage summary.

10/21/2014 Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

04/15/2014 Annual review with the following updates:
- Guideline #5 (Continuous Glucose Monitoring System)
  - Removed separate subsections for Guideline #5.a (Short-term Ambulatory Continuous Glucose Monitoring System); and Guideline #5.b (Long-term Continuous Glucose Monitoring System); the only available reference LCD used for Short Term Ambulatory CGMS, i.e., Novitas LCD for Continuous Glucose Monitoring (L31165) was retired October 31, 2013); and
  - Replaced guidelines for CGMS with the following (based on the only available Medicare reference, the DME MAC Local Articles for Glucose Monitor): 
    Continuous glucose monitors (A9276 - 9278) are considered precautionary, and are excluded from coverage under the Medicare DME benefit. However, although the device itself is not covered for daily personal use to manage diabetes, CGMS (CPT code 95250 & 95251) is covered for one-time or occasional testing as a Part B physician reimbursement, for intervals of not less than 24-hours, and as generally recommended for periods of 72 hours as medically necessary.
- Definitions
  - Continuous Glucose Monitoring System (removed; no CMS reference available)
  - Diabetic Self Management Training (moved to Guideline #1)
  - Medical Nutrition Therapy Services (deleted; already defined in Guideline #2)
  - Outpatient Intravenous (IV) Insulin Therapy (updated; added reference to NCD for Outpatient Intravenous Insulin Treatment 40.7)

08/20/2013 Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g)

04/29/2013 Annual review, no updates

04/23/2012 Annual review, no updates

04/26/2011 Guidelines 5.a (Short-term, Ambulatory Continuous Glucose Monitoring System): changed the LCD guidelines for states with no LCDs from Trailblazer L5224 (retired) to Highmark L31165

Guidelines #6 (Continuous External Subcutaneous Insulin Infusion (CSII) Pump): updated using the standard CS format and added noncoverage information for disposable drug delivery systems (e.g., OmniPod®)