Local Coverage Determination (LCD):

**HOME Health Plans of Care:** Monitoring GLUCOSE Control in the Medicare HOME Health Population with Type II Diabetes Mellitus (L35132)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

### Contractor Information

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
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<tbody>
<tr>
<td>Palmetto GBA</td>
<td>A and B and HHH MAC</td>
<td>11004 - HHH MAC</td>
<td>J - M</td>
<td>Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, North Carolina, New Mexico, Ohio, Oklahoma, South Carolina, Tennessee, Texas</td>
</tr>
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### LCD Information

#### Document Information

**LCD ID**

L35132

**Original Effective Date**

For services performed on or after 10/01/2015

**Revision Effective Date**

For services performed on or after 07/04/2019

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**Notice Period Start Date**

11/14/2014

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

DL35132
Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act, §1814(a)(2)(C) Requirement of requests and certifications

Title XVIII of the Social Security Act, §1835(a)(2)(A) Procedure for payment of claims of providers of services
The goal of this Local Coverage Determination (LCD) is to ensure that evidence-based medicine addressing the risks of acute and chronic complications of diabetes mellitus (DM) are integrated into the delivery of home health (HH) services for Medicare beneficiaries with Type II DM. Initial treatment of individuals diagnosed with DM must take into account many factors, including the level of hyperglycemia/hypoglycemia and comorbidities. Physicians often recommend diet, exercise and medications alone or in combination to help reduce long-term risks of hyperglycemia.

Skilled nurse visits are permitted for the administration of daily insulin injections for the population of Medicare beneficiaries that are “either physically or mentally unable to self-inject insulin” and there is no other person who is able and willing to inject the beneficiary. Reasonable and necessary plans of care must contain sufficient information concerning the identified functional limitations to explain why an individual is physically or mentally unable to self-inject insulin. In the absence of another skilled service, failure to include the specific structural or functional impairments, together with the related activity limitations to support the determination that the individual beneficiary is either physically or mentally unable to self-inject insulin will result in a claim denial.

Evidence-based medicine supports ascertaining glucose control and the risk of secondary conditions known to occur in individuals with DM by monitoring glucose and hemoglobin A1c (HbA1c) levels in individuals with DM. This information and its communication between the physician and HH agency caring for a given beneficiary helps ensure that a HH plan of care (POC) is not only patient-centered, but also addresses prognosis - as required by the Medicare Benefit Policy Manual. Performing the HbA1c test quarterly in patients whose therapy has changed or who are not meeting glycemic goals is supported by the American Diabetes Association Standards of Medical Care in Diabetes - 2016 (ADA Standards). Based on Palmetto GBA’s claims data and the increased risk of emergency department (ED) encounters and acute inpatient admissions related to hypoglycemia in this population, physicians and HH agencies should consider the inclusion of HbA1c testing in the HH POC.

For other beneficiaries with stable glycemic control (defined as 2 consecutive HbA1c results meeting the treatment goals specified in the POC) performing the HbA1c test at least 2 times a year may be considered. The Americans with Disabilities Act (ADA) framework for considering treatment goals recognizes that “patient characteristics/health status” are important factors when considering glycemic goals. Beneficiaries eligible for the Medicare HH benefit often have multiple coexisting chronic illnesses that would support a higher target goal for the HbA1c (e.g., < 8.5%) in order to avoid adverse events (e.g., hypoglycemia-related ED visits and acute inpatient hospitalization).

Reducing Hypoglycemia-related ED visits/Inpatient Hospitalizations among Beneficiaries with DM

Hypoglycemia-related ED visits and acute inpatient hospitalizations among elderly patients with DM are recognized as potentially preventable adverse drug events (ADE). The United States (U.S.) Department of Health and Human Services (HHS) Healthy People 2020, a decade-long work plan for improving the health of the U.S. population,
contains a specific Medical Product Safety (MPS) objective [MPS-5.2 reduce ED visits for overdose from injectable antidiabetic agents] aimed at reducing the baseline rate by 10% by 2020. Insulin-related hypoglycemia and errors (IHEs) are especially prevalent in individuals with advanced age, limited life expectancy and frailty. This LCD seeks to help reduce these adverse events by promoting evidence-based HH plans of care.

**Summary of Evidence**

N/A

**Analysis of Evidence**

(Rationale for Determination)

N/A

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**Coding Information**

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**

Group 1 Paragraph:

N/A

Group 1 Codes:

Created on 09/24/2019. Page 4 of 13
ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:
N/A

Group 1 Codes:

<table>
<thead>
<tr>
<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
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<td>XX000</td>
<td>Not Applicable</td>
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ICD-10 Codes that DO NOT Support Medical Necessity
N/A

Additional ICD-10 Information
N/A

General Information

Associated Information

Documentation Requirements

In order for HH patients to be eligible to receive services under the Medicare HH benefit the following must be documented for certification/recertification:

a) Patient is under a physician care
b) Homebound status-with documentation of confinement to home in medical records
c) Established POC-must be signed and dated by the certifying physician
d) Face-to-Face-no more than 90 days prior or 30 days after start of home health care
e) Skilled need-services must be medically necessary and documentation of the skilled need should be in the patients medical records

If the requirements for certification are not met then claims for subsequent episodes of care, which require a recertification, will not be covered- even if the requirements for recertifications are met. Recertifications are needed at least every 60 days when there is a need for continuing home care.

1. Documentation should show that the patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient.

2. Documentation must be legible, relevant and sufficient to justify the services billed. This documentation must be made available to the A/B MAC upon request.
Sources of Information

N/A

Bibliography


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**Revision History Information**

<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
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<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
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| 07/04/2019            | R13                     | All coding located in the **Coding Information** section has been moved into the related Billing and Coding: Home Health Plans of Care: Monitoring Glucose Control in the Medicare Home Health Population with Type II Diabetes Mellitus A56674 article and removed from the LCD.  

*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*  | • Provider Education/Guidance |
<p>| 06/20/2019            | R12                     | Under <strong>Sources of Information</strong> sources were removed and placed under Bibliography. Under <strong>Bibliography</strong> sources were added and changes were made to citations to reflect AMA                                                                 | • Provider Education/Guidance |</p>
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| 10/11/2018            | R11                     | At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Formatting, punctuation and typographical errors were corrected throughout the LCD. Acronyms were inserted and defined where appropriate throughout the LCD. Under **Coverage Indications, Limitations and/or Medical Necessity** punctuation was corrected, acronyms were defined and words were capitalized or changed to lower case as appropriate. Under **Bibliography** changes were made to citations to reflect AMA citation guidelines. | • Provider Education/Guidance  
• Public Education/Guidance |
| 10/19/2017            | R10                     | Under **CMS National Coverage Policy** replaced change request 9189 citation with CMS Internet-Only Manual citation. DATE (10/6/17): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. | • Provider Education/Guidance  
• Other (Annual Validation) |
| 01/01/2017            | R9                      | Under **CPT/HCPCS Codes** the description was revised for HCPCS code G0300. This revision is due to the 2017 Annual CPT/HCPCS Code Update and becomes effective 1/1/17. | • Provider Education/Guidance  
• Revisions Due To CPT/HCPCS Code Changes |
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<td>11/10/2016</td>
<td>R8</td>
<td>Under <strong>CMS National Coverage Policy</strong> corrected the title for Title XVIII of the Social Security Act, §1814(a)(2)(C) and corrected the section number cited for CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 7 to now read 40.1.3. Under <strong>Sources of Information and Basis for Decision-Websites 3</strong>, corrected the title.</td>
<td>Provider Education/Guidance, Typographical Error</td>
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<td>06/03/2016</td>
<td>R6</td>
<td>Under <strong>Coverage Indications, Limitations and/or Medical Necessity</strong> removed “When a daily medication is required the first-line agent is generally an oral medication like Metformin, unless there is a contraindication to its use. This policy establishes the expectation that for those Medicare beneficiaries requiring medications to achieve long-term control of glucose levels, Metformin shall be considered first-line therapy unless there is a specific contraindication to its use. Likewise Medicare beneficiaries who despite being maintained on daily insulin regimens are poorly controlled should be considered for treatment with Metformin.” Removed “Reasonable and necessary home health plans of care for Medicare beneficiaries with Type II diabetes must therefore include the monitoring and reporting of not only intermittent capillary blood/serum glucose levels but also quarterly (and no less often than 120 days) HbA1c levels.” Removed “Palmetto GBA will maintain the current quarterly (and no less often than 120 days) HbA1c frequency for the home health beneficiary population “whose therapy has changed or who are not meeting glycemic goals” and added “physicians and home health agencies should consider the inclusion of HbA1c testing in the Home Health Plan of Care.” Removed reasonable and necessary from the first sentence of the fourth paragraph. Under <strong>Documentation</strong></td>
<td>Reconsideration Request</td>
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<td>05/05/2016</td>
<td>R5</td>
<td><strong>Requirements</strong> removed 2. The results of the most recent HbA1c. Under <strong>Sources of Information and Basis for Decision</strong> updated the URLs for Standards of Medical Care in Diabetes - 2016 for Prevention or delay of type 2 diabetes and Older adults.</td>
<td>Provider Education/Guidance, Reconsideration Request</td>
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</tbody>
</table>

Performing the HbA1c test quarterly in patients whose therapy has changed or who are not meeting glycemic goals is supported by the American Diabetes Association Standards of Medical Care in Diabetes - 2016 (ADA Standards). Based on Palmetto GBA’s claims data and the increased risk of emergency department (ED) encounters and acute inpatient admissions related to hypoglycemia in this population, Palmetto GBA will maintain the current quarterly (and no less often than 120 days) HbA1c frequency for the home health beneficiary population “whose therapy has changed or who are not meeting glycemic goals”.

For other beneficiaries with stable glycemic control (defined as two consecutive HbA1c results meeting the treatment goals specified in the plan of care) performing the HbA1c test at least two times a year may be considered reasonable and necessary. The ADA framework for considering treatment goals recognizes that “patient characteristics/health status” are important factors when considering glycemic goals. Beneficiaries eligible for the Medicare home health benefit often have multiple coexisting chronic illnesses that would support a higher target goal for the HbA1c (e.g., < 8.5%) in order to avoid adverse events (e.g., hypoglycemia-related emergency department visits and acute inpatient hospitalization).

**Reducing Hypoglycemia-related ED visits/Inpatient Hospitalizations among Beneficiaries with DM**

Hypoglycemia-related emergency department visits and acute inpatient hospitalizations among elderly patients with diabetes mellitus are recognized as potentially preventable adverse drug events (ADE). The US Department of Health and Human Services (HHS) Healthy People 2020, a decade-long work plan for improving the health of the US population, contains a...
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• Public Education/Guidance  
• Revisions Due To CPT/HCPCS Code Changes |
| 11/13/2015            | R3                      | Under **CMS National Coverage Policy** merged all references to CMS Internet-Only Manual, Pub 100-02, Chapter 7 into 1 source. Under **Coverage Indications, Limitations and/or Medical Necessity** in the first paragraph added “/hypoglycemia”. Punctuation corrections were made throughout. Under **Sources of Information and Basis for Decision** corrected all sources to AMA formatting; removed hyperlink to Nathan, Buse and Davidson reference, removed reference to CMS IOM 100-02, Chapter 7, section 30.2.1 as it is already correct. | • Provider Education/Guidance  
• Public Education/Guidance  
• Revisions Due To CPT/HCPCS Code Changes  
• Typographical Error  
• Other (Annual Validation; CR 9369 Transmittal 3378) |

Specific Medical Product Safety (MPS) objective [MPS-5.2 Reduce emergency department (ED) visits for overdose from injectable antidiabetic agents] aimed at reducing the baseline rate by 10% by 2020.\(^3\) Insulin-related hypoglycemia and errors (IHEs) are especially prevalent in individuals with advanced age, limited life expectancy and frailty. This LCD seeks to help reduce these adverse events by promoting evidence-based home health plans of care.\(^4\)

Under **Sources of Information and Basis for Decision** section added the section titled **Websites** and the four URLs listed below:

1. Prevention or delay of type 2 diabetes; Standards of Medical Care in Diabetes - 2016
2. National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations
3. Healthy People 2020 Objective MPS-5: Reduce emergency department (ED) visits for common, preventable adverse events from medications
4. Older adults; Standards of Medical Care in Diabetes - 2016
properly referenced in CMS National Coverage Policy; and placed all sources in alphabetical order.

10/01/2015 R2 Under CMS National Coverage Policy added the following: 42 CFR §424.22-Requirements for Home Health, 42 CFR §409.42- Beneficiary qualifications for coverage of services, §409.43 Plan of care requirements, Title XVIII of the Social Security Act, §1835 (a)(2)(A) Procedure for payment of claims of providers of services, Title XVIII of the Social Security Act, §1814 (a)(2)(C) Requirements of requests and certifications, CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 7, §30.2.1 and CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Transmittal 603, dated July 21, 2015, Change Request 9189. Under ICD-10 Codes That Support Medical Necessity added “the” to the second sentence of the paragraph. Under Associated Information-Documentation Requirements added the requirements for certification/recertification and added “the” to statement #1.

- Provider Education/Guidance
- Other (Change Request 9189, Transmittal 603)

10/01/2015 R1 Under CMS National Coverage Policy added the following: 42 CFR §424.22-Requirements for Home Health, 42 CFR §409.42- Beneficiary qualifications for coverage of services, §409.43 Plan of care requirements, Title XVIII of the Social Security Act, §1835 (a)(2)(A) Procedure for payment of claims of providers of services, Title XVIII of the Social Security Act, §1814 (a)(2)(C) Requirements of requests and certifications, CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 7, §30.2.1 and CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Transmittal 603, dated July 21, 2015, Change Request 9189. Under ICD-10 Codes That Support Medical Necessity added “the” to the second sentence of the paragraph. Under Associated Information-Documentation Requirements added the requirements for certification/recertification and added “the” to statement #1.

- Other (Bill type and revenue code removal)

Associated Documents

Attachments
N/A

Related Local Coverage Documents
Article(s)
A56674 - Billing and Coding: Home Health Plans of Care: Monitoring Glucose Control in the Medicare Home Health Population with Type II Diabetes Mellitus
L33431 - HbA1c
L35413 - (MCD Archive Site)

Related National Coverage Documents
N/A

Public Version(s)
Created on 09/24/2019. Page 12 of 13
Keywords

- Home Health
- Diabetes
- Insulin
- Glucose Monitoring