

LCD - HbA1c (L33431)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information**Document Information****LCD ID**

L33431

LCD Title

HbA1c

Proposed LCD in Comment Period

N/A

Source Proposed LCD

N/A

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 03/10/2022

Revision Ending Date

N/A

Retirement Date**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

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Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under **Coverage Indications, Limitations and/or Medical Necessity**.

CMS National Coverage Policy

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.

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 3, §190.21 Glycated Hemoglobin/Glycated Protein

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Hemoglobin A1c (HbA1c) refers to the major component of hemoglobin A1.

Performance of the HbA1c test at least 2 times a year in patients who are meeting treatment goals and who have stable glycemic control is supported by the American Diabetes Association Standards of Medical Care in Diabetes - 2016 (ADA Standards).¹ For beneficiaries with stable glycemic control (defined as 2 consecutive HbA1c results meeting the treatment goals) performing the HbA1c test at least 2 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.² Beneficiaries eligible for the Medicare home health benefit, for example, 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).

Palmetto GBA will allow 1 additional HbA1c test every 3 months for a total of 8 tests per year in patients with uncontrolled blood glucose levels. Additional tests beyond that frequency may be reimbursed on appeal with appropriate documentation of medical necessity.

HbA1c may be inaccurate in certain situations including anemia, transfusions, hemoglobinopathies and conditions of rapid red cell turnover. Other tests to assess diabetes, including glucose, glycated protein, or fructosamine levels, may be used and are described in the Lab National Coverage Determination 190.21 (NCD for Glycated Hemoglobin / Glycated Protein). This NCD lists the ICD-10 codes for HbA1c for frequencies up to once every 3 months.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation Requirements

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

Utilization Guidelines

- A. Up to 1 additional test per 3 month period for Diabetes Mellitus out of control.
- B. Up to 1 monthly test for pregnant Type I diabetic patients.

Sources of Information

N/A

Bibliography

American Diabetes Association. [Older Adults](#). *Diabetes Care*. 2016;39(Supp 1):S81-85.

American Diabetes Association. [Prevention or Delay of Type 2 Diabetes](#). *Diabetes Care*. 2016;39(Supp 1):S36-38.

American Diabetes Association. Standards of medical care in diabetes-2013. *Diabetes Care*. 2013;36(Supp 1):S11-66.

Goldstein DE, Little RR, Lorenz RA, et al. Tests of glycemia in diabetes. *Diabetes Care*. 2004;27(7):1761-1773.

Sacks DB, Arnold M, Bakris GL, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Clinical Chemistry*. 2011;57(6):e1-e47.

[Wisconsin diabetes mellitus essential care guidelines 2012](#). Wisconsin Diabetes Prevention and Control Program. 2012.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
03/10/2022	R19	<p>Under Bibliography revised the broken hyperlinks for the second and sixth references. Formatting and typographical errors were corrected throughout the LCD.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
06/17/2021	R18	<p>Under Coverage Indications, Limitation and/or Medical Necessity deleted verbiage "The ICD-10-CM codes for test frequencies exceeding once every 3 months are listed below" from the fourth paragraph. Under Associated Information subheading Utilization Guidelines deleted verbiage "(Group 1)" from letter A. and "(Group 3)" from letter B. Under Bibliography added hyperlink to source #6 and changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the LCD.</p> <p><i>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.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance
10/10/2019	R17	<p>This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs. There has been no change in coverage with this LCD revision. Regulations regarding billing and coding were removed from the CMS National Coverage Policy section of this LCD and placed in the related Billing and Coding: HbA1c A56686 article.</p> <p><i>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.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance
07/11/2019	R16	<p>All coding located in the Coding Information section has been moved into the related Billing and Coding: HbA1c A56686 article and removed from the LCD.</p> <p><i>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p><i>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.</i></p>	
10/04/2018	R15	<p>Under Reason(s) for change the selection was changed to "Request for Coverage by a Practitioner (Part B)" as "Reconsideration Request" was inadvertently selected.</p> <p>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.</p>	<ul style="list-style-type: none"> Request for Coverage by a Practitioner (Part B)
09/27/2018	R14	<p>Under Coverage Indications, Limitations and/or Medical Necessity changed verbiage from "90 days" to "3 months" in the last paragraph. Under ICD-10 Codes that Support Medical Necessity Group 1: Paragraph changed verbiage from "90 days" to "3 months" in the first sentence. Under Group 1: Codes added ICD-10 codes E11.9 and E11.22. This revision has a retroactive effective date of 2/26/2018.</p> <p>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.</p>	<ul style="list-style-type: none"> Reconsideration Request
06/07/2018	R13	<p>Under CMS National Coverage Policy removed the last two sentences in the first regulation that contained verbiage related to the NCD and LCD review process. Under ICD-10 Codes that Support Medical Necessity Group 2: Codes added ICD-10 Code E11.638 Type 2 Diabetes Mellitus with other Oral Complications. Under Bibliography changes were made to citations to reflect AMA citation guidelines. The date 2012 was added at the end of the first sentence, the italics were removed from the second sentence, and the city, state, and the words "various pages" was removed from the third sentence in the third reference.</p>	<ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>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.</p>	
02/26/2018	R12	<p>The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.</p>	<ul style="list-style-type: none"> • Change in Affiliated Contract Numbers
10/01/2017	R11	<p>Under ICD-Codes that Support Medical Necessity Group 1: Codes deleted E11.10 and E11.11 due to the Clinical Laboratory National Coverage Determination non-coverage.</p> <p><i>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.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance
10/01/2017	R10	<p>Under CMS National Coverage Policy added CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Change Request 10156, Transmittal 3797, Dated June 16, 2017, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2017.</p> <p>Under ICD-10 Codes That Support Medical Necessity Group 1: Codes added ICD-10 codes E11.10 and E11.11. These codes were added due to the 2017 Annual ICD-10 Updates. Under ICD-10 Codes That Support Medical Necessity Group 2: Codes deleted ICD-10 codes E08.3529, E08.3539, E08.3549, E08.3559, E08.37X9, E09.3529, E09.3539, E09.3549, E09.3559, E09.37X9, E10.3529, E10.3539, E10.3549, E10.3559, E10.37X9, E11.3529, E11.3539, E11.3549, E11.3559, E11.37X9, E13.3529,</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>E13.3539, E13.3549, E13.3559 and E13.37X9. These codes were deleted due to CR 10156, Transmittal 3797.</p> <p>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.</p>	
05/04/2017	R9	<p>Under ICD-10 Codes that Support Medical Necessity - added codes to LCD to maintain compliance with NCD: E08.3529, E08.3539, E08.3549, E08.3559, E08.37X9, E09.3529, E09.3539, E09.3549, E09.3559, E09.37X9, E10.3529, E10.3539, E10.3549, E10.3559, E10.37X9, E11.3529, E11.3539, E11.3549, E11.3559, E11.37X9, E13.3529, E13.3539, E13.3549, E13.3559, E13.37X9, Z79.84. These codes are effective as of 10/01/2016.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
04/07/2017	R8	<p>Under CMS National Coverage Policy Removed duplicate SSA 1862(a)(1)(A). Added correct verbiage to SSA 1862(a)(1)(A) to read "allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or to improve the functioning of a malformed body member. Grammatical correction to remove the "s" from Internet-Only Manuals. Under Coverage Indications, Limitations and/or Medical Necessity- Revised verbiage to correct quotes taken from IOM Pub 100-03 Chapter 1 part 3 Section 190.21 Removed the word "diabetic" and added hyphen to "long-term" in sentence "HbA1c assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring a diabetic patient who is capable of maintaining long-term, stable control." Removed "severe hypoglycemic or ketoacidosis" and "or other" from sentence "... (for example, post-major surgery, severe hypoglycemic or ketoacidosis, or as a result of glucocorticoid or other therapy." In second paragraph removed verbiage "patients with" from sentence "HbA1c is widely accepted as medically necessary for the management and control of patients with diabetes." In third paragraph, removed the second "type" from sentence "Testing for uncontrolled type one or type two diabetes mellitus..." Under ICD-10 Codes that Support</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>Medical Necessity- Removed all "unspecified eye" codes: E08.3219, E08.3299, E08.3319, E08.3399, E08.3419, E08.3499, E08.3519, E08.3529, E08.3539, E08.3549, E08.3559, E08.3599, E08.37X9, E09.3219, E09.3299, E09.3319, E09.3399, E09.3419, E09.3499, E09.3519, E09.3529, E09.3539, E09.3549, E09.3559, E09.3599, E09.37X9, E10.3219, E10.3299, E10.3319, E10.3399, E10.3419, E10.3499, E10.3519, E10.3529, E10.3539, E10.3549, E10.3559, E10.3599, E10.37X9, E11.3219, E11.3299, E11.3319, E11.3399, E11.3419, E11.3499, E11.3519, E11.3529, E11.3539, E11.3549, E11.3559, E11.3599, E11.37X9, E13.3219, E13.3299, E13.3319, E13.3399, E13.3419, E13.3499, E13.3519, E13.3529, E13.3539, E13.3549, E13.3559, E13.3599, E13.37X9</p> <p>Under Sources of Information and Basis for Decision - Revise the reference listed to read: American Diabetes Association. Standards of medical care in Diabetes-2013. Diabetes Care. 2013;36(sup 1):S11-S66. Updated the reference: Wisconsin diabetes mellitus essential care guidelines to 2012 version from 2011.</p>	
10/01/2016	R7	<p>Under ICD-10 Codes That Support Medical Necessity Group 2: Codes added ICD-10 codes E08.3211, E08.3212, E08.3213, E08.3219, E08.3291, E08.3292, E08.3293, E08.3299, E08.3311, E08.3312, E08.3313, E08.3319, E08.3391, E08.3392, E08.3393, E08.3399, E08.3411, E08.3412, E08.3413, E08.3419, E08.3491, E08.3492, E08.3493, E08.3499, E08.3511, E08.3512, E08.3513, E08.3519, E08.3521, E08.3522, E08.3523, E08.3529, E08.3531, E08.3532, E08.3533, E08.3539, E08.3541, E08.3542, E08.3543, E08.3549, E08.3551, E08.3552, E08.3553, E08.3559, E08.3591, E08.3592, E08.3593, E08.3599, E08.37X1, E08.37X2, E08.37X3, E08.37X9, E09.3211, E09.3212, E09.3213, E09.3219, E09.3291, E09.3292, E09.3293, E09.3299, E09.3311, E09.3312, E09.3313, E09.3319, E09.3391, E09.3392, E09.3393, E09.3399, E09.3411, E09.3412, E09.3413, E09.3419, E09.3491, E09.3492, E09.3493, E09.3499, E09.3511, E09.3512, E09.3513, E09.3519, E09.3521, E09.3522, E09.3523, E09.3529, E09.3531, E09.3532, E09.3533, E09.3539, E09.3541, E09.3542, E09.3543, E09.3549, E09.3551, E09.3552, E09.3553, E09.3559, E09.3591, E09.3592, E09.3593, E09.3599, E09.37X1, E09.37X2, E09.37X3, E09.37X9, E10.3211, E10.3212, E10.3213,</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>E10.3219, E10.3291, E10.3292, E10.3293, E10.3299, E10.3311, E10.3312, E10.3313, E10.3319, E10.3391, E10.3392, E10.3393, E10.3399, E10.3411, E10.3412, E10.3413, E10.3419, E10.3491, E10.3492, E10.3493, E10.3499, E10.3511, E10.3512, E10.3513, E10.3519, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E10.37X1, E10.37X2, E10.37X3, E10.37X9, E11.3211, E11.3212, E11.3213, E11.3219, E11.3291, E11.3292, E11.3293, E11.3299, E11.3311, E11.3312, E11.3313, E11.3319, E11.3391, E11.3392, E11.3393, E11.3399, E11.3411, E11.3412, E11.3413, E11.3419, E11.3491, E11.3492, E11.3493, E11.3499, E11.3511, E11.3512, E11.3513, E11.3519, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E11.37X1, E11.37X2, E11.37X3, E11.37X9, E13.3211, E13.3212, E13.3213, E13.3219, E13.3291, E13.3292, E13.3293, E13.3299, E13.3311, E13.3312, E13.3313, E13.3319, E13.3391, E13.3392, E13.3393, E13.3399, E13.3411, E13.3412, E13.3413, E13.3419, E13.3491, E13.3492, E13.3493, E13.3499, E13.3511, E13.3512, E13.3513, E13.3519, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, E13.3599, E13.37X1, E13.37X2, E13.37X3 and E13.37X9. Under ICD-10 Codes That Support Medical Necessity Group 3: Codes added ICD-10 codes O24.415, O24.425 and O24.435 and the code descriptions were revised for O24.011, O24.012, O24.013, O24.019, O24.111, O24.112, O24.113, and O24.119. This revision is due to the Annual ICD-10 Code Update and becomes effective 10/1/16.</p>	
06/03/2016	R6	<p>Under Sources of Information and Basis for Decision updated the URLs for Standards of Medical Care in Diabetes - 2016 for Prevention or delay of type 2 diabetes and Older adults.</p>	<ul style="list-style-type: none"> • Other (Updated URLs)
05/05/2016	R5	<p>Under Coverage Indications, Limitations and/or Medical Necessity section added the following verbiage after the first sentence of the second paragraph:</p>	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>Performance of the HbA1c test at least two times a year in patients who are meeting treatment goals and who have stable glycemic control is supported by the <i>American Diabetes Association Standards of Medical Care in Diabetes - 2016</i> (ADA Standards)¹. For beneficiaries with stable glycemic control (defined as two consecutive HbA1c results meeting the treatment goals) 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.² Beneficiaries eligible for the Medicare home health benefit, for example, 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).</p> <p>Under Sources of Information and Basis for Decision section added the section titled Websites and the two URLs listed below:</p> <ol style="list-style-type: none"> 1. Prevention or delay of type 2 diabetes; Standards of Medical Care in Diabetes - 2016 2. Older adults; Standards of Medical Care in Diabetes – 2016 	
03/10/2016	R4	<p>Under ICD-10 Codes That Support Medical Necessity-Group 2-Secondary Dual Codes-diagnoses that must be used in conjunction with a Group 1 code that indicates a current state of uncontrolled diabetes (hyperglycemia) added E10.21 as it was inadvertently omitted from Group 2.</p>	<ul style="list-style-type: none"> • Other
03/10/2016	R3	<p>Under CMS National Coverage Policy added the first statement. Under Coverage Indications, Limitations and/or Medical Necessity language quoted from the Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals was italicized. In the last paragraph revised “Decision” to read “Determination”. Under ICD-10 Codes That Support Medical Necessity added verbiage to the first sentence, deleted the heading and the paragraph under the heading-Primary Codes, the heading and two paragraphs under the heading-Secondary (Dual) Codes, and the Group 1: Asterisk Note. The ICD-10 codes were distributed into Group</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		1 (Primary Codes), Group 2 (Secondary (Dual) Codes) and Group 3 (codes related to pregnancy). ICD-10 codes E13.00, E13.01 and E13.10 were added to Group 1. Under Associated Information-Utilization Guidelines A. revised the sentence to state, "Up to one additional test per 3 month period for Diabetes Mellitus out of control (Group 1). Under Associated Information-Utilization Guidelines-B revised the Group cited to now read "3".	
10/01/2015	R2	Under ICD-10 Codes That Support Medical Necessity added ICD-10 codes inadvertently omitted from the LCD: E15 E16.0 E16.1 E89.1	<ul style="list-style-type: none"> • Other (ICD-10 Conversion)
10/01/2015	R1	Under CMS National Coverage Policy added "(NCD)" into title of Medicare National Coverage Determinations Manual. Under Coverage Indications, Limitations and/or Medical Necessity in third paragraph changed "We" to now read "Palmetto GBA". Under Sources of Information and Basis for Decision revised citations to AMA format. Added authors and journal information for National Academy of Clinical Biochemistry source. Removed reference to NCD 190.21 and linked NCD to this policy in Related National Coverage Documents section.	<ul style="list-style-type: none"> • Provider Education/Guidance • Other (Maintenance Annual Review)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A56686 - Billing and Coding: HbA1c](#)

LCDs

[L35132 - Home Health Plans of Care: Monitoring Glucose Control in the Medicare Home Health Population with Type II Diabetes Mellitus](#)

Related National Coverage Documents

NCDs

[190.21 - Glycated Hemoglobin/Glycated Protein](#)

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
03/03/2022	03/10/2022 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

- Hemoglobin A1c
- HbA1c