Local Coverage Article:
Billing and Coding: MolDX: HBB Gene Tests (A55253)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

Article Information

General Information

Article ID **Original Effective Date**

A55253

10/31/2016

Article Title
Billing and Coding: MolDX: HBB Gene Tests

Revision Effective Date
12/01/2019

Article Type
Billing and Coding

Revision Ending Date
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Retirement Date
N/A

CMS National Coverage Policy

N/A

Article Guidance

Article Text:

HBB gene testing may be performed during the diagnosis of Sickle cell disease (SCD). Since clinical symptoms and diagnosis usually occur prior to Medicare eligibility and carrier testing is not a covered benefit, the MolDX Team has determined HBB gene testing is a statutorily excluded service. MolDX will also deny panels of tests that include the HBB gene.

To receive a HBB gene sequencing service denial, please submit the following claim information:

- Select the appropriate CPT® code based on gene test
- An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services
    - For a voluntary issued ABN, append with GX modifier
    - To indicate a statutorily excluded service, append with a GY modifier
- Enter DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following Part B claim field/types:
    - Loop 2400 or SV101-7 for the 5010A1 837P
    - Item 19 for paper claim
- Enter DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following Part A claim field/types:
    - Line SV202-7 for 837I electronic claim
    - Block 80 for the UB04 claim form

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
81361	HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); COMMON VARIANT(S) (EG, HBS, HBC, HBE)
81362	HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); KNOWN FAMILIAL VARIANT(S)
81363	HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); DUPLICATION/DELETION VARIANT(S)
81364	HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); FULL GENE SEQUENCE

Group 2 Paragraph:

CPT® codes that are also referenced in other articles.

Group 2 Codes:

CODE	DESCRIPTION
81443	GENETIC TESTING FOR SEVERE INHERITED CONDITIONS (EG, CYSTIC FIBROSIS, ASHKENAZI JEWISH-ASSOCIATED DISORDERS [EG, BLOOM SYNDROME, CANAVAN DISEASE, FANCONI ANEMIA TYPE C, MUCOLIPIDOSIS TYPE VI, GAUCHER DISEASE, TAY-SACHS DISEASE], BETA HEMOGLOBINOPATHIES, PHENYLKETONURIA, GALACTOSEMIA), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 15 GENES (EG, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)

CPT/HCPCS Modifiers

N/A

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

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

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
12/01/2019	R4	As required by CR 10901, article is converted to a formal billing and coding type article. There is no change in coverage. CPT 81443 was moved from Group 1 to Group 2.
01/01/2018	R3	Article is revised to add 81443 per the 2019 Annual HCPCS Code Update.
01/01/2018	R2	Article is revised to replace CPT codes 81401 with 81361, 81403 with 81363, 81404 with 81364 and add CPT code 81362.
10/31/2016	R1	Article is revised to update "the assigned identifier" to "DEX Z-Code™ identifier" and add Part A claim filing information.

Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 12/10/2019 with effective dates 12/01/2019 - N/A
Updated on 12/21/2018 with effective dates 01/01/2018 - N/A
Updated on 02/12/2018 with effective dates 01/01/2018 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

- MolDX
- HBB
- Sickle Cell Disease
- 81361
- 81362
- 81363
- 81364
- 81443