Local Coverage Article:
Billing and Coding: MolDX: HEXA Gene Analysis (A55255)

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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

A55255

10/31/2016

Article Title
Billing and Coding: MolDX: HEXA Gene Analysis

Revision Effective Date
12/01/2019

Article Type
Billing and Coding

Revision Ending Date
N/A

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Retirement Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Article Guidance

Article Text:

The clinical diagnosis of Hexosaminidase A deficiency, a disorder also known as Tay-Sachs disease characterized by progressive weakness, loss of motor skills, and increased startle reflex in infants, relies on blood tests that result in absent or near absent beta-hexosaminidase A (HEX A) enzymatic activity. Molecular genetic testing identifies HEXA gene mutation carriers at risk for conceiving offspring with the disease. Therefore, HEXA genetic testing is not a Medicare benefit and is a statutorily excluded service. In addition to single gene testing, the MolDX Contractor will also deny panels of tests that include the HEXA gene as a statutorily excluded service.

To receive a HEXA gene test service denial, please submit the following claim information:

- Select the appropriate CPT® code based on type of testing
- An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services.
    - For a voluntary issued ABN, append with GX modifier
    - To indicate a valid ABN is on file for a known statutorily excluded service, append with a GY modifier
- Enter the DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following claim field/types:
    - Loop 2400 or SV101-7 for the 5010A1 837P
    - Item 19 for paper claim
- Enter the 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
81255	HEXA (HEXOSAMINIDASE A [ALPHA POLYPEPTIDE]) (EG, TAY-SACHS DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, 1278INSTATC, 1421+1G>C, G269S)
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,

CODE	DESCRIPTION
	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)

Group 2 Paragraph:

CPT® codes that are also referenced in other articles.

Group 2 Codes:

CODE	DESCRIPTION
81406	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 7 (EG, ANALYSIS OF 11-25 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 26-50 EXONS, CYTOGENOMIC ARRAY ANALYSIS FOR NEOPLASIA)
81412	ASHKENAZI JEWISH ASSOCIATED DISORDERS (EG, BLOOM SYNDROME, CANAVAN DISEASE, CYSTIC FIBROSIS, FAMILIAL DYSAUTONOMIA, FANCONI ANEMIA GROUP C, GAUCHER DISEASE, TAY-SACHS DISEASE), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 9 GENES, INCLUDING ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, AND SMPD1

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
GX	NOTICE OF LIABILITY ISSUED, VOLUNTARY UNDER PAYER POLICY
GY	ITEM OR SERVICE STATUTORILY EXCLUDED, DOES NOT MEET THE DEFINITION OF ANY MEDICARE BENEFIT OR, FOR NON-MEDICARE INSURERS, IS NOT A CONTRACT BENEFIT

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	R3	As required by CR 10901, article is converted to a formal billing and coding type article. There is no change in coverage. References were added to the CMS National Coverage Policy Section. Under **Article Title** changed title from "MolDX: HEXA Gene Analysis Coding and Billing Guidelines" to "Billing and Coding: MolDX: HEXA Gene Analysis". Under **Article Text** deleted the sentence "Select the appropriate diagnosis for the patient". Under **CPT/HCPCS Codes Group 1: Codes** deleted CPT® codes 81406 and 81412. Under **CPT/HCPCS Codes Group 2: Paragraph** added verbiage "CPT® codes that are also referenced in other articles." Under **CPT/HCPCS Codes Group 2: Codes** added CPT® codes 81406 and 81412. Under **CPT/HCPCS Modifiers** added modifiers GX and GY.
01/01/2019	R2	Article is revised to add 81412 and 81443 per the 2019 Annual HCPCS Code Update.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/31/2016	R1	Article is revised to add Part A billing instructions.

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 12/11/2019 with effective dates 12/01/2019 - N/A
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Keywords

- MolDX
- HEXA
- Hexosaminidase A
- Tay-Sachs Disease
- 81255
- 81406
- 81412
- 81443