Local Coverage Article:
MolDX: CFTR Gene Analysis Coding and Billing Guidelines (A53615)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Article Information

General Information

Article ID
A53615

Original ICD-9 Article ID
A53616

Article Title
MolDX: CFTR Gene Analysis Coding and Billing Guidelines

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
10/01/2015

Revision Effective Date
01/01/2019

Revision Ending Date
10/23/2019

Retirement Date
N/A

Article Guidance

Article Text:

Effective for dates of service on and after 01/01/2013

Genetic testing for cystic fibrosis (CF) transmembrane conductance regulator (CFTR) is typically performed to screen adults with a positive family history of CF. Therefore, the MolDX team has determined that CFTR gene testing to identify parents at risk is not a Medicare benefit and is a statutorily excluded test. In addition to single disease testing, MolDX will also deny panels of tests that include the CFTR gene test for CF as statutorily excluded tests.

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

- Select the appropriate CPT code for the CFTR test performed:
    - 81220 - common variant
    - 81221- known familial variant

    - 81222- duplication/deletion variants
    - 81223- full gene sequence
    - 81224- intron 8 poly-T
    - 81412- Ashkenazi Jewish associated disorders, at least 9 gene panel
    - 81443 – Genetic testing for severe inherited conditions
    - 81479- panel
- An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services
    - For a voluntary issued ABN, append with GX HCPCS modifier
    - To indicate a statutorily excluded service, append with a GY HCPCS modifier
- Select the appropriate diagnosis for the patient
- 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
    - Box 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

Reference: Sec. 1862 (1)(A) Statutory Exclusion covers diagnostic testing "except for items and 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,…"

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:

CODE	DESCRIPTION
81220	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; COMMON VARIANTS (EG, ACMG/ACOG GUIDELINES)
81221	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS
81222	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS
81223	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; FULL GENE SEQUENCE
81224	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; INTRON 8 POLY-T ANALYSIS (EG, MALE INFERTILITY)
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
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)
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that are Covered

N/A

ICD-10 Codes that are Not Covered

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2019	R7	Added 81443 to the article. Added 81220, 81221, 81222, 81223, 81224, 81412, 81443, and 81479 to HCPCS/CPT Group 1. This addition is due to the 2018 CPT/HCPCS Annual update and effective 1/1/19.
02/26/2018	R6	The Jurisdiction "J" Part A and Part B Contracts for Alabama (10111/10112), Georgia (10211/10212) and Tennessee (10311/10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these 6 contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 6 Part A and B contract numbers) have been completed in this revision.
10/26/2017	R5	Annual review completed. Added Part A contract number. Added DEX Z-Code identifier information.
11/19/2015	R4	Changed "MolDX ID (MID) field" back to read SV101-7
12/31/2015	R3	Added 2016 CPT code to CPT/HCPC section
11/13/2015	R2	Added CPT 2016 81412
10/29/2015	R1	Annual review completed. Replaced reference to Palmetto and/or Palmetto GBA with MolDX

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 12/21/2018 with effective dates 01/01/2019 - N/A

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Keywords

N/A