Local Coverage Article:
Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests (A55181)

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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

A55181

10/24/2016

Article Title
Billing and Coding: MolDX: ENG and ACVRL1 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:

Hereditary hemorrhagic telangiectasia (HHT) is an autosomal dominant disorder with variable clinical presentation. Most common manifestations are epistaxis, recurrent gastrointestinal bleeding, iron deficiency anemia, and mucocutaneous telangectasias. Arteriovenous malformations (AVMs), of various organs (lung, liver, brain) are common.

The two most prevalent forms of HHT, Type 1 and Type 2, are caused by mutations in the endoglin (ENG) or the ACVRL1 gene respectively. Although identification of these gene mutations can confirm the diagnosis of HHT, these tests are not necessary in many cases. HHT is generally established using well vetted consensus criteria (most often the International Curaçao Criteria (ICC)). The ICC uses the clinical characteristics of epistaxis, cutaneous or mucosal telangectasias, visceral AVMs, and a first-degree relative with HHT to judge likelihood of a given patient having HHT. A 'definite' diagnosis is established when a patient has 3 or 4 of these criteria. Genetic testing for ENG/ACVRL1 is not warranted. A patient with 0 to 1 criteria is 'unlikely' to have HHT, and similarly would not be a candidate for genetic testing. Patients with 2 or 3 Curaçao criteria are defined as "suspected" of HHT and are candidates for ENG/ACVRL1 testing.

Since screening of patients without signs or symptoms of HHT, who have a first-degree relative with HHT, is not a Medicare benefit, the MolDX Team has determined ENG and/or ACVRL1 genetic testing and panels of tests that include ENG/ACVRL1 are statutorily excluded services.

EXCEPTIONS: For patients with "suspected" HHT in which diagnosis confirmation would demonstrate an improved outcome, approval will be made on a case-by-case basis through the appeal process.

For tests that include ENG and ACVRL1 registered and assigned a single Identifier, submit CPT® code 81479.

To receive an ENG and/or ACVRL1 gene test denial, please submit the following claim information:

- 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
- For CPT® non-NOC codes, Labs may either use the SV101-7 or SV202-7 (preferred) or the NTE field to submit this required information.
- Enter the appropriate 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 the appropriate 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
81405	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 6 (EG, ANALYSIS OF 6-10 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 11-25 EXONS, REGIONALLY TARGETED CYTOGENOMIC ARRAY ANALYSIS)
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)
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

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. CPT codes 81405, 81406 and 81479 were added to Group 1
01/01/2019	R2	CPT code 81403 is removed. The ENG gene is not included in this code. AMA coding guidance does not support the use of a tier code if the gene is not listed in the CPT manual for the code. Update is a result of the 2019 Annual HCPCS Code Update.
10/24/2016	R1	Added 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 01/01/2019 - N/A
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Keywords

- MolDX
- ENG
- ACVRL1
- 81405
- 81406
- 81479