Local Coverage Determination (LCD): MolDX: APC and MUTYH Gene Testing (L36884)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

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LCD Information

Document Information

LCD ID
L36884

LCD Title
MolDX: APC and MUTYH Gene Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL36884

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
For services performed on or after 05/15/2017

Revision Effective Date
For services performed on or after 05/15/2017

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
03/30/2017

Notice Period End Date
05/14/2017

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.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, *Medicare Benefit Policy Manual,*Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

This policy provides Medicare coverage for APC and MUTYH gene testing for individuals suspected to have Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP) with a personal history of ≥20 adenomas over a lifetime.

Summary of Evidence

FAP and AFAP are autosomal dominant syndromes caused by a germ-line mutation in the APC gene. The distinction between FAP and AFAP is largely based on the number of polyps present. Individuals with >100 are said to have FAP, while those with <100 are said to have AFAP. FAP affected individuals generally develop

adenomas throughout the colon beginning in their teens, whereas individuals with AFAP frequently have a right-sided distribution to polyps. The average age of symptomatic FAP diagnosis ranges from 35-45 years of age[1]. The clinical expression of AFAP is more variable with adenomas developing at a later age, and some patients with <10 cumulative adenomatous polyps[2]. With nearly 100% penetrance of the APC gene, colorectal cancer (CRC) is inevitable in patients with FAP if colectomy is not performed. The cumulative risk of CRC cancer in AFAP is estimated to be nearly 70% at age 80[3], with up to 30% of cancers occurring over age 40[4]. The average age of CRC diagnosis is >50 years for AFAP. FAP accounts for up to 1% of colorectal cancers.

Additional findings may be associated with classical FAP including congenital hypertrophy of retinal pigment epithelium (CHRPE); osteomas, supernumerary teeth, and odontomas; desmoids and epidermoid cysts; duodenal and other small bowel adenomas; gastric fundic gland polyps; and increased risk for medulloblastoma, papillary carcinoma of the thyroid and hepatoblastoma; and pancreatic, gastric and duodenal cancers. Although upper GI findings, thyroid and duodenal cancer risks are similar to classical FAP, other extraintestinal manifestations, including CHRPE and desmoids are unusual in AFAP.

Mutations in the MUTYH gene cause MUTYH-Associated Polyposis syndrome (MAP). Affected individuals have large numbers of adenomatous polyp, similar to patient with AFAP, and a high risk for CRC. The average age of patients with MAP-associated CRC is >50 years, with nearly 25% of patients diagnosed after age 60[6]. Individuals with MUTYH mutations also may develop extra-colonic findings including duodenal polyps and duodenal cancer.

Treatment and surveillance recommendations for FAP, AFAP and MAP are available in the current NCCN Genetic/Familial High-Risk Assessment: Colorectal guidelines[5].

Analysis of Evidence
(Rationale for Determination)

Level of Evidence:

Quality – High

Strength – Good

Weight - Good

Based on the results of multiple studies and the surveillance and treatment recommendations of at least one national society guideline, APC and MUTYH gene testing is reasonable and necessary for individuals suspected to have Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP) with a personal history of ≥20 adenomas over a lifetime.

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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.

999x Not Applicable

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:

81201	APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; FULL GENE SEQUENCE
81202	APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS
81203	APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS
81401	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 2 (EG, 2-10 SNPS, 1 METHYLATED VARIANT, OR 1 SOMATIC VARIANT [TYPICALLY USING NONSEQUENCING TARGET VARIANT ANALYSIS], OR DETECTION OF A DYNAMIC MUTATION DISORDER/TRIPLET REPEAT)
81403	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 4 (EG, ANALYSIS OF SINGLE EXON BY DNA SEQUENCE ANALYSIS, ANALYSIS OF >10 AMPLICONS USING MULTIPLEX PCR IN 2 OR MORE INDEPENDENT REACTIONS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 2-5 EXONS)
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)
81435	HEREDITARY COLON CANCER DISORDERS (EG, LYNCH SYNDROME, PTEN HAMARTOMA SYNDROME, COWDEN SYNDROME, FAMILIAL ADENOMATOSIS POLYPOSIS); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 10 GENES, INCLUDING APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, AND STK11
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
D12.6	Benign neoplasm of colon, unspecified
D12.7	Benign neoplasm of rectosigmoid junction
D12.8	Benign neoplasm of rectum
Z85.038	Personal history of other malignant neoplasm of large intestine
Z86.010	Personal history of colonic polyps

ICD-10 Codes that DO NOT Support Medical Necessity N/A
ICD-10 Additional Information Back to Top

General Information

Associated Information
N/A

Sources of Information
N/A
Bibliography
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4. Nielsen M, et al. Germline mutations in APC and MUTYH are responsible for the majority of families with attenuated familial adenomatous polyposis. Clin Genet. 2007 May;71(5):427-33. PubMed PMID: 17489848.

5. NCCN® Clinical Practice Guidelines in Oncology, Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2016, Accessed 8/2/16 at www.nccn.org.

6. Lubbe SJ, et al. Clinical implications of the colorectal cancer risk associated with MUTYH mutation. J Clin Oncol. 2009 Aug 20;27(24):3975-80. doi: 10.1200/JCO.2008.21.6853. Epub 2009 Jul 20. PubMed PMID: 19620482.

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
05/15/2017	R2	LCD is revised to add CPT 81401. Note that 81401 was inadvertently left out of the draft and final LCDs.	• Creation of Uniform LCDs With Other MAC Jurisdiction
05/15/2017	R1	LCD is revised to add ICD-10 code D12.0, effective 5/12/17 and to add the following required fields: Summary of Evidence, Bibliography and Analysis of Evidence.	• Creation of Uniform LCDs Within a MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55464 - Response to Comments: MolDX: APC and MUTYH Gene Testing LCD(s) DL36884 - (MCD Archive Site)

Related National Coverage Documents N/A

Keywords

- 81201
- 81202
- 81203
- 81401
- 81403
- 81406
- 81435
- 81479
- APC
- MUTYH Gene
- Familial
- Adenomatous
- Polyposis
- Attenuated
-

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