Local Coverage Determination (LCD):
MolDX: APC and MUTYH Gene Testing (L37224)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L37224

LCD Title
MolDX: APC and MUTYH Gene Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL37224

Original Effective Date
For services performed on or after 09/16/2017

Revision Effective Date
For services performed on or after 01/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
08/01/2017

Notice Period End Date
09/15/2017

CMS National Coverage Policy

Title XVIII of the Social Security Act (the "Act"), Section 1862(a)(1)(A). This section limits coverage and payment to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

42 C.F.R. § 410.32 "Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Condition."

Medicare Internet Online Manual Pub. 100-2 (Medicare Benefit Policy Manual), Chapter 15, Section 80, "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests"

Medicare Internet Online Manual Pub. 100-4 (Medicare Claims Processing Manual), Chapter 16, Sections:
50.5 Jurisdiction of Laboratory Claims
60.12 Independent Laboratory Specimen Drawing
60.2 Travel Allowance

Medicare Internet Online Manual Pub. 100-4 (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 of 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]. 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; an 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.

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:

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
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 - C18.9	Malignant neoplasm of cecum - Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
D12.0 - D12.8	Benign neoplasm of cecum - 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

NA

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General Information

Associated Information

NA

Sources of Information
N/A
Bibliography

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2. Burt RW, et al. Genetic testing and phenotype in a large kindred with attenuated familial adenomatous polyposis. Gastroenterology. 2004 Aug;127(2):444-51. PubMed PMID: 15300576.
3. Neklason DW, et al. American founder mutation for attenuated familial adenomatous polyposis. Clin Gastroenterol Hepatol. 2008 Jan;6(1):46-52. Epub 2007 Dec 11. PubMed PMID: 18063416.
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
01/01/2018	R2	01/01/2018- Code update-81403 & 81406 description change.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2017	R1	10/01/2017-Added The clinical expression of AFAP is more variable with adenomas developing at a later age, and some patients with <10 cumulative adenomatous polyps[2].	• Other (Educational)

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55642 - Response to Comments: MolDX: APC and MUTYH Gene Testing (DL37224). LCD(s) DL37224 - MolDX: APC and MUTYH Gene Testing

Related National Coverage Documents N/A

Public Version(s) Updated on 12/18/2017 with effective dates 01/01/2018 - N/A Updated on 09/20/2017 with effective dates 10/01/2017 - 12/31/2017 Updated on 07/19/2017 with effective dates 09/16/2017 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top