Local Coverage Determination (LCD): MolDX: APC and MUTYH Gene Testing (L36882)

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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

LCD Information

Document Information

LCD ID **Original Effective Date**

L36882

LCD Title
MolDX: APC and MUTYH Gene Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL36882

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

For services performed on or after 05/15/2017

Revision Effective Date
For services performed on or after 11/01/2019

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.

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

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.

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.

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. Jasperson KW, Burt RW. APC-Associated Polyposis Conditions. 1998 Dec 18 [Updated 2014 Mar 27]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2016. http://www.ncbi.nlm.nih.gov/books/NBK1345/

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.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R5	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
11/01/2019	R4	11/01/2019: This LCD is being revised in order to adhere to CMS requirements per Chapter 13, Section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs. There has been no change in coverage with this LCD revision. Regulations regarding billing and coding were removed from the **CMS National Coverage Policy** section of this LCD and placed in the related Billing and Coding: MolDX: APC and MUTYH Gene Testing A57352 article. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage.	• Provider Education/Guidance
11/01/2019	R3	As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.	• Revisions Due To Code Removal
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 Within a 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 the Evidence, Bibliography and Analysis of Evidence.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57352 - Billing and Coding: MolDX: APC and MUTYH Gene Testing
A55463 - Response to Comments: MolDX: APC and MUTYH Gene Testing
LCD(s)
DL36882
- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/28/2020 with effective dates 11/01/2019 - N/A
Updated on 12/03/2019 with effective dates 11/01/2019 - N/A
Updated on 10/07/2019 with effective dates 11/01/2019 - N/A
Updated on 05/22/2018 with effective dates 05/15/2017 - 10/31/2019
Updated on 08/14/2017 with effective dates 05/15/2017 - N/A
Updated on 03/17/2017 with effective dates 05/15/2017 - N/A

Keywords

N/A