Subject: Genetic Testing for Lynch Syndrome

Medical Policy #: 7.5

Original Effective Date: 09/25/2019

Status: Reviewed

Last Review Date: 11-16-2022

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

For Medicare Medicaid and Commercial members:
Presbyterian Health Plan follows the most recent NCCN Guideline for hereditary nonpolyposis colorectal cancer. In NCCN go to guideline tab and select Detection, Prevention and Risk Reduction, then select Genetic/Familial High-Risk Assessment: Colorectal.

For proprietary reasons, NCCN Guideline cannot be reproduced in this Medical Policy. Please contact Health Services for a copy of the NCCN Guidelines at (505) 923-5757 or 1-888- 923-5757, Monday through Friday from 8:00 a.m. to 6:00 p.m.

Gene-Specific Lynch Syndrome Cancer Risks and Surveillance/Prevention Strategies are:

- MLH1 (LS-B)
- MSH2 and EPCAM (LS-C)
- MSH6 (LS-D)
- PMS2 (LS-E)

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
81288	MLH1 (MUTL homolog 1, colon cancer, nonpolyposis type 2) (ego, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; promoter methylation analysis
81292	MLH1 (MUTL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis
81293	MLH1 (MUTL homolog 1, colon cancer, nonpolyposis type 2) (ego, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; known familial variants
81294	MLH1 (MUTL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; duplication/deletion variants
81295	MSH2 (MUTS homolog 2, colon cancer, nonpolyposis type 1) (ego, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis
81296	MSH2 (MUTS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; known familial variants
81297	MSH2 (MUTS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; duplication/deletion variants
81298	MSH6 (MUTS homolog 6 [E. Coli]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis
81299	MSH6 (MUTS homolog 6 [E. Coli]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; known familial variants
81300	MSH6 (MUTS homolog 6 [E. Coli]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; duplication/deletion variants
81317	PMS2 (post meiotic segregation increased 2 [S. Cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; full sequence analysis

CPT Codes	Description
81318	PMS2 (post meiotic segregation increased 2 [s. Cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; known familial variants
81319	PMS2 (post meiotic segregation increased 2 [s. Cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; duplication/deletion variants
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
0101U	Hereditary colon cancer disorders (eg, lynch syndrome, pten hamartoma syndrome, cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, SANGER, MLPA, and array CGH, with MMRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM AND GREM1 [DELETION/DUPLICATION ONLY])
81301	Microsatellite instability analysis (ego, hereditary non-polyposis colorectal cancer, lynch syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
81403	Molecular pathology procedure, level 4 (e.g., 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)
81435	Hereditary colon cancer disorders (e.g., 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
81436	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
0130U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: Gray Clarke MD
Senior Medical Director: David Yu MD
Date Approved: 11-16-2022

References

1. LCD, MolDX: Genetic Testing for Lynch Syndrome LCD L36793, Effective Date 02/16/2017, Revision date 08-20-2022, R9 RETIRED. [Cited 10/15/2021]
2. Local Coverage Article: Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome (A55135), revision date 08-20-2022, R11 RETIRED. [Cited 10/15/2021]
3. LCD, MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer LCD L39040, Effective Date: 07-03-2022, R1. Related LCA (A58756), revision date 10-01-2022, R3. [Cited 11/04/2022]
4. NCCN Clinical Practice Guidelines, Genetic/Familial High-Risk Assessment: Colorectal Version 1.2022 — June 8, 2022, High-Risk Colorectal Cancer Syndromes [Cited 11-04-2022]
5. Hayes, Screening for Lynch Syndrome, archived Sep 10, 2018. [Cited 11-04-2022]

Publication History

09-25-19 Creation of MPM 7.5 to moved Lynch Syndrome from MPM 7.1. Reviewed and approved by Medical Directors to use LCD L36793 for Medicare members only and for Commercial and Medicaid use NCCN criteria.

11-18-20 Annual review. Reviewed on 11-03-20. No change. Continue to follow L36793/A55135 for Medicare members. Medicaid and Commercial will continue to follow NCCN guideline. New codes 81432, 81433 and 81436. All the codes listed in the policy as well as codes 81432, 81433 and 81436 will continue to require PA.

11-17-21 Annual review. Reviewed by PHP Medical Policy Committee on 10/20/2021 & 10/20/2021. No change. Medicaid and commercial will continue to follow NCCN guidelines. Medicare will continue to follow L36793 and A55135. The criteria language from LCD L36793 were removed from policy and only the weblinks LCD/LCA will be provided. Added three new CPT codes to policy: 0101U (will require PA); 88341 and 88342 (will not require PA, since these are not genetic codes).

11-16-22 Annual review. Reviewed by PHP Medical Policy Committee on 11-04-22. Removed to follow CMS newly incorporated LCD (L39040) and to have Medicare to also follow National Comprehensive Cancer Network (NCCN) guideline. Code update: Add: 0130u, 0238U to policy, which will now require PA for ALOB; and removed 81210, 81432, 81433.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.