

MEDICA®

UTILIZATION MANAGEMENT POLICY

TITLE: GENETIC TESTING FOR SUSCEPTIBILITY TO COLORECTAL CANCER (CRC) SYNDROMES

EFFECTIVE DATE: August 20, 2018

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage.

With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage.

Medica may use tools developed by third parties, such as MCG Care Guidelines®, to assist in administering health benefits. Medica utilization management (UM) policies and MCG Care Guidelines are not intended to be used without the independent clinical judgment of a qualified health care provider taking into account the individual circumstances of each member's case. Medica UM policies and MCG Care Guidelines do not constitute the practice of medicine or medical advice. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica UM policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity for genetic testing for susceptibility to certain colorectal cancer (CRC) syndromes. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

MEDICAL NECESSITY CRITERIA

For medical necessity criteria, Medica uses MCG™ Care Guidelines, 21st edition, 2017:

- ACG: A-0533 (AC), Lynch Syndrome - EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes
- ACG: A-0534 (AC), Familial Adenomatous Polyposis - APC Gene
- ACG: A-0828 (AC), MUTYH-Associated Polyposis – MUTYH Gene
- ACG: A-0799 (AC), Peutz-Jeghers Syndrome – STK11 Gene

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for genetic testing for susceptibility to colorectal cancer syndromes. Please see the prior authorization list for product specific prior authorization requirements.
2. Prior authorization **is not required** for microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of tumor tissue. These services are covered as an initial screen in members with colorectal cancer, in order to identify those individuals who should proceed with Lynch syndrome (HNPCC) mutation analysis.
3. Genetic testing for Lynch syndrome, APC-associated polyposis, MUTYH-associated polyposis, PJS, and JPS is *investigative and therefore not covered* for all other indications not addressed in this policy.
4. Genetic testing is excluded and therefore not covered when performed in the absence of symptoms or high risk factors for a genetic disease or when knowledge of genetic status will not affect treatment decisions or screening for the disease. (See Medica's *Genetic Testing and Pharmacogenetic Testing* coverage policy).
5. Coverage may vary according to the terms of the member's plan document. Please see the prior authorization list for product specific prior authorization requirements.
6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.

7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica Provider Administrative Manual.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: <http://www.cms.hhs.gov/mcd/search.asp?>

DOCUMENT HISTORY

Original MPC Effective Date	February 1, 2010
MPC Endorsement Date(s)	11/2010, 11/2011, 11/2012, 11/2013, 11/2014
Began use of MCG™ Care Guidelines	02/2016 (19 th edition)
MCG Care Guidelines Edition Updates (<i>Medica Effective Date</i>)	20 th edition: 10/10/2016, 21 st edition: 08/31/2017, 21 st edition reaffirmed: 08/20/2018
Administrative update(s)	05/01/2017

Appendix 1

Revised Bethesda Guidelines for Testing Colorectal Tumors for the Lynch Syndrome by IHC and/or (MSI)

Tumors from individuals should be tested for MSI in the following situations:

1. Colorectal cancer diagnosed in a patient who is less than 50 years of age.
2. Presence of synchronous, metachronous colorectal, or other LS-related tumors,* regardless of age.
3. Colorectal cancer with the MSI-H histology diagnosed in a patient who is less than 60 years of age.
4. Colorectal cancer diagnosed in one or more first-degree relatives with an LS-related tumor, with one of the cancers being diagnosed under age 50 years.
5. Colorectal cancer diagnosed in two or more first- or second-degree relatives with LS-related tumors, regardless of age.

Lynch Syndrome-related tumors include colorectal, endometrial, gastric, ovarian, pancreas, ureter and renal pelvis, biliary tract, and brain (usually glioblastoma as seen in Turcot syndrome), and small intestinal cancers, as well as sebaceous gland adenomas and keratoacanthomas in Muir–Torre syndrome.

MSI-H = microsatellite instability–high in tumors refers to changes in two or more of the five National Cancer Institute–recommended panels of microsatellite markers.

Presence of tumor infiltrating lymphocytes, Crohn’s-like lymphocytic reaction, mucinous/signet-ring differentiation, or medullary growth pattern.

There was no consensus among the Workshop participants on whether to include the age criteria in guideline 3 above; participants voted to keep less than 60 years of age in the guidelines.

Source: Umar A, Boland CR, Terdiman JP, et al. Revised Bethesda Guidelines for hereditary nonpolyposis colorectal cancer (Lynch syndrome) and microsatellite instability. *J Natl Cancer Inst.* 2004;96(4):261-268.

Revised Amsterdam Criteria II (1999) (families must fulfill all criteria):

At least 3 relatives with a Lynch syndrome–associated cancer (CRC, cancer of the endometrium, small bowel, ureter, or renal pelvis) and **ALL** of the following criteria should be met:

- One must be a first-degree relative of the other two;
- At least two successive generations must be affected;
- At least one of the relatives with cancer associated with Lynch syndrome must have received the diagnosis before the age of 50 years;
- FAP should be excluded in the CRC case(s), if any.
- Tumors should be verified by pathological examination whenever possible.

Source: Adapted from National Comprehensive Cancer Center Network (NCCN) Practice Guidelines in Oncology v.2.2014. Genetic/Familial High-Risk Assessment: Colorectal.