

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.088.MH
Last Review Date: 11/14/2019
Effective Date: 01/01/2020

MP.884.MH – Colorectal Cancer, Mutation Testing for Treatment

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Mutation Testing for Treatment of Colorectal Cancer (CRC) – KRAS Mutation testing** medically necessary for a diagnosis of CRC when it is used in predicting nonresponse to anti-epidermal growth factor receptor (EGFR) monoclonal antibodies (cetuximab and panitumumab) in the treatment of metastatic colorectal carcinoma from either primary tumor or metastatic tumor tissue.

Limitations

KRAS mutation testing for CRC not listed above is considered not medically necessary and will therefore not be covered.

Background

Over 108,000 cases of colon and 40,700 cases of rectal cancer are expected to occur annually in the United States. CRC is the third leading cause of cancer-related deaths in the United States. The American Cancer Society (ACS) states that the risk of CRC increases with age, with over 90% of the diagnoses in patients over 50 years of age. The 5-year survival rate for those diagnosed with CRC is 67% over all stages; however, this drops to 12% in those with metastatic disease.

Cetuximab (Erbix; Imclone Systems/Bristol-Myers Squibb) and panitumumab (Vectibix; Amigen Inc.) are anti-EGFR monoclonal antibodies used for treatment in patients with metastatic disease. To determine benefit from this treatment, biomarkers are needed to select the potential patient population. The KRAS (v-Ki-ras2 Kirsten rat sarcoma) mutation test is to identify those individuals who are unlikely to respond to treatment with anti-EGFR monoclonal antibodies. The KRAS mutation assay detects mutations at codons 12 and 13 of the KRAS gene and these mutations have been associated with lack of response to EGFR targeted therapies.

On July 17, 2009, the Food and Drug Administration (FDA) made class labeling changes to the product labels of cetuximab (Erbix) and panitumumab (Vectibix) to indicate the drugs are now not recommended for the treatment of colorectal cancer for patients with KRAS mutation.

Codes:

MP.088.MH – Colorectal Cancer, Mutation Testing for Treatment

Policy Number: MP.088.MH

Last Review Date: 11/14/2019

Effective Date: 01/01/2020

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT Codes	
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene)(e.g. carcinoma) gene analysis, variants in codons 12 and 13
The following code(s) will require prior authorization:	
81479	Unlisted molecular pathology procedure
ICD-10 codes covered if selection criteria are met:	
C17.0-C17.9	Malignant neoplasm of small intestine
C18.0-C18.9	Malignant neoplasm of colon
C19-C21.8	Malignant neoplasm of rectum and anus
C78.5	Secondary malignant neoplasm of large intestine and rectum
D01.0-D01.3	Carcinoma in situ of colon, rectum, and anus

References

1. Allegra CJ, Jessup JM, Somerfield MR, et al. American Society of Clinical Oncology Provisional Clinical Opinion, Testing for KRAS gene mutations in patients with metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy. J Clin Oncol. 2009 Apr; 27(12): 2091-2096. <http://jco.ascopubs.org/content/27/12/2091.full.pdf+html>
2. American College of Pathologists. The Pathologist's Message. KRAS Mutation Testing for Colorectal Cancer (CRC). Last updated: Dec. 17, 2010. http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtl_t_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtl_t&cntvwrPtl_t%7BactionForm.contentReference%7D=committees%2Ftechnology%2FKRAS_Mutation.html&_state=maximized&_pageLabel=cntvwr
3. Carethers JM. DNA testing and molecular screening for colon cancer. Clin Gastroenterol Hepatol. 2014 Mar;12(3):377-381. doi: 10.1016/j.cgh.2013.12.007. Epub 2013 Dec 17. [http://www.cghjournal.org/article/S1542-3565\(13\)01933-2/abstract](http://www.cghjournal.org/article/S1542-3565(13)01933-2/abstract)
4. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L35396 - Biomarkers for Oncology. (Contractor: Novitas Solutions, Inc.). Revision Effective Date: 06/13/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35396&ver=187&Date=&DocID=L35396&bc=iAAAABAAAAAA&>

MP.088.MH – Colorectal Cancer, Mutation Testing for Treatment

Policy Number: MP.088.MH

Last Review Date: 11/14/2019

Effective Date: 01/01/2020

5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Biomarkers for Oncology (A52986). (Contractor: Novitas Solutions, Inc.). Revision Effective Date: 06/13/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52986&ver=124&Date=&DocID=A52986&bc=hAAAABAAAAA&A&>
6. Hayes Genetic Testing Evaluation. KRAS Sequence Variant Analysis for Predicting Response to Colorectal Cancer Drug Therapy. Annual Review May 27, 2015.
7. National Comprehensive Cancer Network (NCCN): NCCN Clinical Practice Guidelines in Oncology- Colon Cancer NCCN Quick Guide https://www.nccn.org/patients/guidelines/quick_guides/colon/index.html
8. Plesec TP, Hunt JL. KRAS mutation testing in colorectal cancer. *Adv Anat Pathol*. 2009 Jul; 16(4): 196-203. <http://www.ncbi.nlm.nih.gov/pubmed/19546608>
9. Quest Diagnostics®. Test Center: KRAS Mutation Analysis. Content reviewed: 03.2014 . ©2000-2019, Quest Diagnostics, Inc. http://www.questdiagnostics.com/testcenter/testguide.action?dc=TS_KRAS

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.