**Medica Coverage Policy**

**Policy Name:** Gene Expression Profiling for Predicting Colon Cancer Recurrence Risk  
**Effective Date:** 7/16/2018

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**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 those programs require different coverage. 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 coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

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**Coverage Policy**

Gene expression profiling assays for predicting colon cancer recurrence risk are investigative and therefore **NOT COVERED**. Reliable evidence does not permit conclusions concerning their effectiveness.

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**Description**

Gene expression profiling assays for assessment of risk of colon cancer recurrence analyze gene expression from tumor tissue samples. The proposed purpose of these tests is to provide prognostic and predictive information to assist in decisions regarding appropriate adjuvant therapy in individuals with stage II or III colon cancer. Multiple gene expression profile assays are available, including but not limited to:

1. **Oncotype DX colon recurrence score** (Genomic Health, Inc.). Oncotype DX quantifies expression of seven recurrence-risk genes and five reference genes. Prognosis is classified as either low, intermediate or high likelihood of recurrence.
2. **ColoPrint (Agendia)**. This test quantifies expression of 18 genes and classified prognosis as either low versus high recurrence risk. This assay is also purported to predict three-year relapse rates in individuals with stage II colon cancer. According to the manufacturer, ColoPrint® is no longer being provided for this indication.
3. **GeneFx® Colon**. GeneFx® Colon is Helomics’ U.S. licensed product of ColDx (Almac). This microarray-based multigene assay uses 482 genes to identify individuals with stage II colon cancer at high risk of recurrence.
4. **ColonPRS® (Signal Genetics)**. ColonPRS® is a 163 gene expression assay for predicting risk of recurrence in individuals with colon cancer.
5. **OncoDefender-CRC® (Everist Genomics)**. OncoDefender-CRC® is a five-gene assay used to assess the risk of recurrence of cancer in individuals previously treated with surgical resection of stage I or II colon cancer or stage I rectal cancer.
6. **ColonSentry® (GeneNews)**. The ColonSentry test is a molecular diagnostic risk assessment test rather than a cancer detection test.
7. ResponseDX: Colon® (Response Genetics). This panel utilizes testing of multiple genes. The test predicts disease prognosis and selects patients who might benefit from alternative therapies and aids in selection of metastatic colorectal cancer patients that might benefit from EGFR-targeted monoclonal antibody therapies.

**FDA Approval**
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes**
81525 - Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score

Original Effective Date: 2/1/2011

Re-Review Date(s): 9/1/2012
6/17/2015
1/4/2016 – administrative update – code update
5/16/2018

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