Policy Name: Fecal / Stool DNA (sDNA) Testing for Colorectal Screening
Effective Date: 12/21/2016

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, Medicaid and MinnesotaCare members, this policy will apply unless these 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.

Coverage Policy
Fecal or stool DNA (sDNA) testing for colorectal cancer screening in individuals at low or average risk or individuals with known or suspected hereditary colorectal cancer syndromes, is COVERED.

Description
Colorectal cancer is the third most common cancer in both men and women in the United States. Approximately 4.8% of the population will be diagnosed with colorectal cancer during their lifetime. The prognosis for a person with colorectal cancer improves substantially if the disease is detected early. Regular screening for colorectal cancer, particularly in individuals over 50 years of age, has been recommended by several health care organizations including the American Cancer Society, National Cancer Institute, the U.S. Preventive Services Task Force and the American College of Gastroenterology.

Traditional screening methods include fecal occult blood testing, flexible sigmoidoscopy, barium enema and colonoscopy. However, patient compliance with these methods has generally been poor, and only about 60% of those recommended for screening are compliant. As a result, noninvasive tests have been developed to detect DNA mutations in cells shed from cancerous or precancerous tissue into stool.

This type of testing may be used as an alternative or an adjunct to conventional colorectal cancer screening tests such as colonoscopy, fecal occult blood test (FOBT), or flexible sigmoidoscopy in asymptomatic individuals at average risk for colorectal cancer. Cologuard, the only fecal DNA test approved by the FDA, is designed to detect methylated DNA derived from two genes known to be methylated in colorectal cancer and adenomas, and seven mutant alleles of the KRAS oncogene. The test also incorporates a fecal immunochemical test (FIT) component to detect blood in stool samples. A positive result to the test is intended to be followed up with a standard optical colonoscopy to confirm results and provide an opportunity for biopsy.

FDA Approval
In August 2014, Cologuard (Exact Sciences, Madison, WI), was given approval by the FDA. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for colorectal cancer.
Prior Authorization
Prior authorization is not applicable.

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 Code:
81528 - Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

Original Effective Date: 12/1/2005

Re-Review Date(s): 8/26/2008
9/13/2011
10/15/2014
1/21/2016 – administrative code update
12/21/2016