Policy Name: Serological Markers for Diagnosis and Management of Inflammatory Bowel Disease (IBD) or Irritable Bowel Syndrome (IBS)
Effective Date: 2/17/2020

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.

Coverage Policy
Serological markers, including but not limited to: perinuclear anti-neutrophilic cytoplasmic antibody (pANCA), antisaccharomyces cerevisiae antibody (ASCA), escherichia coli antibodies (anti-OmpC), pseudomonas fluorescens (Anti-12), and clostridium species antibodies (anti-CBir1), either alone or as a combination test that includes genetic and inflammation markers, used to diagnose or manage inflammatory bowel disease or irritable bowel syndrome or to differentiate ulcerative colitis from Crohn’s disease are investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy, Fecal Calprotectin Testing.

Description
Inflammatory bowel disease (IBD) is a chronic, relapsing, inflammatory, intestinal condition. Signs and symptoms include abdominal pain, diarrhea, weight loss, rectal bleeding, growth impairment, perirectal disease, jaundice, conjunctivitis, joint pain, and erythema nodosum. The two major forms of IBD are ulcerative colitis (UC) and Crohn’s disease (CD). A synopsis of clinical, radiologic, endoscopic and histologic results generally enables these two forms of IBD to be differentiated.

Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder of unclear etiology characterized by abdominal discomfort or pain associated with defecation or a change in bowel habit. A comprehensive history, physical examination, and tailored laboratory and radiographic studies can establish a diagnosis of IBS in most patients.

IBD may be associated with the production of certain antibodies. Several serological markers measure antibodies in the patient’s blood and are purported to assist in the diagnosis or management of IBD and IBS and in differentiating UC from CD.
FDA Approval
Laboratory 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 does not market the test for distribution. Examples of laboratories offering a combination of serological marker tests for IBD/IBS include but are not limited to, Prometheus, Quest, and LabCorp. Example of this type of combination test is Prometheus® IBD sgi Diagnostic®.

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
• 0176U – Cytolethal distending toxin B (CdtB and vinculin IgG antibodies by immunoassay (ie, ELISA)

Original Effective Date: 4/1/2008
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1/16/2020
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7/1/2020 – administrative update; code added