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Developed By: Medical Criteria Committee	

Csaba Mera M.D.

Approved:

Csaba Mera, MD

Date:

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Description:

Inflammatory bowel disease (IBD) is a chronic relapsing inflammatory intestinal condition that can be subdivided into ulcerative colitis (UC) and Crohn's disease (CD). Patients with IBD may have a wide variety of symptoms including diarrhea, abdominal pain, and rectal bleeding. Diagnosis is established by a combination of radiographic, endoscopic, and histologic work-up. However, in approximately 10% of patients with IBD, the distinction between ulcerative colitis and Crohn's disease cannot be made with certainty and the diagnosis becomes "indeterminate colitis." Two serum antibodies, anti-neutrophilic cytoplasmic antibody (ANCA) and anti-saccharomyces cerevisiae (ASCA) have been investigated as a technique to improve the efficiency and accuracy of diagnosing IBD. ANCA has been detected in UC patients 50-80%, and less frequently in CD patients, 10-20%. ASCA is more frequently detected in patients with CD than those with UC. Prometheus Laboratories offers the IBD First Step Test® and IBD Diagnostic System. These non-invasive tests examine serological panels of antibodies, including ASCA and ANCA, to diagnose IBD and differentiate between UC and CD.

Criteria:

ODS will cover ANCA and ASCA laboratory tests up to plan limitations when **one** of the following criteria is met:

1. The patient is an adult with indeterminate colitis following colonoscopy; or
2. The patient is an adult with significant symptoms of IBD and colonoscopy is contraindicated (i.e. pregnancy, recent abdominal surgery, bleeding disorder with persistent bleeding, post-transplant); or
3. During the initial work-up of pediatric patients with IBD, when the results will be used to determine the need for more invasive testing

The use of ANCA and ASCA in the initial work-up of adults with IBD is considered Investigational.

In addition, the following tests offered by Prometheus Laboratories, which are designed to determine therapeutic direction and monitor response to 6-mercaptopurine and azathioprine (Imuran) therapy in patients with UC and CD, are considered to be investigational by ODS:

- PRO-PredictRx® Metabolites
- PRO-PredictRx® TPMT Genetics
- PRO-PredictRx® EnzAct

The PRO-Predict® series of tests were developed by Prometheus in order to provide guidance in determining therapeutic direction and predicting therapeutic response in individual patients. PRO-Predict® Metabolites is a test used during treatment for the ongoing evaluation of patient response to thiopurine therapies. PRO-Predict® TPMT Genetics is a genotype test for use prior to treatment to help determine patient candidacy for thiopurine therapy. PRO-Predict® EnzAct is a phenotype test that provides a quantitative measurement of TPMT enzyme activity levels to assist physicians with dosing strategies. There is insufficient scientific evidence in the current medical literature to support the routine use of these tests in clinical practice.

Information to be Submitted with Pre-Authorization Request:

Chart notes and history and physical from ordering specialist
Results of colonoscopy and other diagnostic studies performed
Histology results

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