Medicare Local Coverage Determination Policy

# JM Palmetto - MoIDX: Prometheus IBD sgi Diagnostic Policy

CPT: 81479, 82397, 83520, 86140

## CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

#### Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Prometheus IBD sgi Diagnostic test. The intended use of this test is to aid healthcare providers in the differentiating inflammatory bowel disease (IBD) vs non-IBD, and Crohn's disease (CD) vs UC in a comprehensive blood test. The test includes nine serological markers: ASCA IgA, ASCA IgG, anti-OmpC IgA, anti-CBir1 IgG, anti-A4 Fla2 IgG, anti-FlaX IgG, IBD-specific pANCA auto-antibody, IBD-specific pANCA IFA (perinuclear pattern), IBD-specific pANCA IFA DNAse Sensitivity; four genetic immune response markers (SNPs): ATG16L1, STAT3, NKX2-3, and ECM1; and five inflammatory biomarkers: ICAM-1, VCAM-1, VEGF, CRP and SSA. A proprietary Smart Diagnostic Algorithm interprets patterns among the multiple assay values to produce an IBD score. The test results are reported as "consistent with IBD" (consistent with UC; consistent with CD, or inconclusive for UC vs CD) or "not consistent with IBD". In addition to the algorithmic test interpretation, the results of the 17 biomarkers are also individually reported.

#### Summary of Evidence

CD and UC represent the two main forms of idiopathic chronic IBD. While the etiology remains idiopathic, evidence suggests that the ongoing inflammation in IBD results from persistent overly aggressive inflammatory responses to a subset of commensal microorganisms in a genetically susceptible host with exposure to environmental triggers. CD is characterized by discontinuous, transmural regions of intestinal inflammation most frequently involving the terminal ileum and colon, but can affect any part of the gastrointestinal tract, with symptoms of abdominal pain, weight loss and variable degrees of diarrhea, and complications of intestinal fibrosis, strictures and fistula formation. In contrast, UC is limited to the mucosa and submucosa of the colon, with particular involvement of the rectum. Classic symptoms of active UC include diarrhea, hematochezia, tenesmus and defecatory urgency. Extra intestinal manifestations of IBD occur in up to 25% of patients. Joints, skin and eyes may be affected. In both CD and UC, disease activity is typically relapsing and remitting, although the disease course of CD is typically progressive. Although UC and CD can usually be differentiated on the basis of clinical, radiographic, endoscopic, and histologic findings, these conditions can be difficult to distinguish in about 10% to 15% of IBD patients.

### To receive a Prometheus IBD sgi Diagnostic denial, please submit the following claim information:

Select the applicable CPT® code

Enter 1 unit of service (UOS)

An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services For a voluntary issued ABN, append with GX modifier

To indicate a statutorily excluded service, append with a GY modifier

Medicare Local Coverage Determination Policy

### JM Palmetto - MoIDX: Prometheus IBD sgi **Diagnostic Policy**

CPT: 81479, 82397, 83520, 86140

### CMS Policy for Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.

Code	Description	
N/A	N/A	

Visit QuestDiagnostics.com/MLCP to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.qov ▶

Last updated: 10/16/23

This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Quest Diagnostics does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

#### QuestDiagnostics.com

Quest, Quest Diagnostics, any associated logos, and all associated Quest Diagnostics registered or unregistered trademarks are the property of Quest Diagnostics. All third-party marks—® and ™—are the property of their respective owners. © 2016 Quest Diagnostics Incorporated. All rights reserved.