



CLINICAL MEDICAL POLICY	
Policy Name:	Laboratory Studies for Diagnosing and Managing Inflammatory Bowel Disease
Policy Number:	MP-123-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	08/01/2024; 08/01/2023
Effective Date:	09/01/2024; 09/01/2023
Next Annual Review:	06/2025
Implementation Date:	06/19/2024; 06/21/2023
Products:	Highmark Wholecare <sup>SM</sup> Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

#### Policy History

Date	Action
09/01/2024	Provider Effective date
07/22/2024	PARP Approval
06/19/2024	QI/UM Committee review
06/19/2024	Annual Review: No changes to clinical criteria. Revised 'Procedures' section, Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2023	Provider Effective date
07/11/2023	PARP Approval
06/21/2023	QI/UM Committee review
06/21/2023	Policy initially developed

#### Disclaimer

Highmark Wholecare<sup>SM</sup> medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

#### Policy Statement

Highmark Wholecare<sup>SM</sup> may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary laboratory studies for diagnosing and managing inflammatory bowel disease.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

## **Definitions**

**Prior Authorization Review Panel (PARP)** – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

**Inflammatory Bowel Disease (IBD)** - a chronic and relapsing inflammatory disorder of the gastrointestinal tract (GIT) accompanied by abdominal pain, rectal bleeding and malabsorption. It comprises two (2) major entities, ulcerative colitis (UC) and Crohn's disease (CD).

**Ulcerative colitis (UC)** - an inflammatory bowel disease (IBD) that causes inflammation and ulcers (sores) in your digestive tract. Ulcerative colitis affects the innermost lining of your large intestine, also called the colon, and rectum. In most people, symptoms usually develop over time, rather than suddenly.

**Crohn's disease (CD)** - a type of inflammatory bowel disease (IBD). It causes swelling of the tissues (inflammation) in your digestive tract, which can lead to abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition.

## **Procedures**

1. Fecal calprotectin testing may be considered medically necessary for ANY of the following:
  - A. Evaluation of individuals when the differential diagnosis is IBD; OR
  - B. Evaluation of individuals demonstrating symptoms of active disease; OR
  - C. Evaluation for mucosal healing when colonoscopy is being considered; OR
  - D. Evaluation for response to biologic or therapy escalation when colonoscopy is being considered; OR
  - E. IBD for which endoscopy with biopsy is being considered.
2. When laboratory studies for diagnosing and managing IBD is not considered medically necessary
  - Testing for serological and/or genetic markers to identify individuals at increased risk of recurrence of Crohn's disease is considered experimental/investigational because the effectiveness has not been established. Examples of serological markers/laboratory tests include, but not limited to:
    - Anti-neutrophilic cytoplasmic antibody (ANCA), perinuclear anti-neutrophilic cytoplasmic antibody (pANCA)
    - Anti-saccharomyces cerevisiae antibody (ASCA)
    - Anti-outer membrane porin C (anti-OmpC) antibody
    - Anti-CBir1 flagellin (anti-CBir1) antibody

- Anti-I2
  - Anti-laminaribioside carbohydrate IgG (ALCA)
  - Anti-laminarin (anti-L)
  - Anti-chitobioside carbohydrate IgA (ACCA)
  - Anti-mannobioside antibodies IgG (A $\Sigma$ MA ) or AMCA)
  - Pseudomonas associated sequence I-2 (Anti-I2)
  - Antibodies against exocrine pancreas (PAB)
  - Antibodies to goblet cells (GAB)
  - Fecal calprotectin testing not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.
3. Post-payment Audit Statement
- The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare<sup>SM</sup> at any time pursuant to the terms of your provider agreement.
4. Place of Service
- Laboratory studies for diagnosing and managing IBD is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.
5. Related Policies
- MP-018-MD-PA - Genetic Testing for Colorectal Cancer Susceptibility

### **Governing Bodies Approval**

#### **CLIA**

Laboratory studies for diagnosing and managing IBD are offered as laboratory-developed tests under Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories. Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratories offering such tests as a clinical service must meet general regulatory standards of CLIA and must be licensed by CLIA for high complexity testing.

#### **CMS**

The Centers for Medicare and Medicaid Services (CMS) has no published guidance on this topic.

## **Coding Requirements**

### Procedure Codes

<b>CPT Code</b>	<b>Description</b>
83993	Calprotectin, fecal

### Diagnosis Codes

<b>ICD-10 Code</b>	<b>Description</b>
K05.00	Acute gingivitis, plaque induced
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications

K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with fistula
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.3	Indeterminate colitis
K52.81	Eosinophilic gastritis or gastroenteritis
K52.82	Eosinophilic colitis
K52.831	Collagenous colitis
K52.832	Lymphocytic colitis
K52.838	Other microscopic colitis
K52.839	Microscopic colitis, unspecified
K58.0	Irritable bowel syndrome with diarrhea

K58.1	Irritable bowel syndrome with constipation
K58.2	Mixed irritable bowel syndrome
K58.8	Other irritable bowel syndrome
K58.9	Irritable bowel syndrome without diarrhea
K59.1	Functional diarrhea
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.30	Lower abdominal pain, unspecified
R10.31	Right lower quadrant pain
R10.32	Left lower quadrant pain
R10.33	Periumbilical pain
R10.811	Right upper quadrant abdominal tenderness
R10.812	Left upper quadrant abdominal tenderness
R10.813	Right lower quadrant abdominal tenderness
R10.814	Left lower quadrant abdominal tenderness
R10.816	Epigastric abdominal tenderness
R10.817	Generalized abdominal tenderness
R10.819	Abdominal tenderness, unspecified site
R10.84	Generalized abdominal pain
R10.9	Unspecified abdominal pain
R19.5	Other fecal abnormalities
R19.7	Diarrhea, unspecified
R19.8	Other specified symptoms and signs involving the digestive system and abdomen
Z79.899	Other long term (current) drug therapy

### **Reimbursement**

Participating facilities will be reimbursed per their Highmark Wholecare<sup>SM</sup> contract.

### **Reference Sources**

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