Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP218

Section: Medical Benefit Policy

Subject: Serum Antibodies and Gene Testing for the Diagnosis of Inflammatory Bowel Disease

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Serum Antibodies and Gene Testing for the Diagnosis of Inflammatory Bowel Disease

II. Purpose/Objective:
To provide a policy of coverage regarding Serum Antibodies and Gene Testing for the Diagnosis of Inflammatory Bowel Disease

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
The Prometheus system is a commercially available diagnostic system that uses combinations of tests for anti-neutrophil cytoplasmic antibody (ANCA) and/or anti- Saccharomyces cerevisiae antibody (ASCA) to aid in the diagnosis of Inflammatory Bowel Disease (IBD). Tests/test panels include, but are not limited to the following:

Prometheus® IBD Serology 7

The American College of Gastroenterology states that serological studies are evolving to provide adjunctive support for the diagnosis of Crohn's disease but are not sufficiently sensitive or specific to be recommended for use as screening tools. Similarly, as reported in published ACG practice guidelines for ulcerative colitis, pANCA, and ASCA currently are not a definitive step in diagnosis or clinical decision making. pANCA detection alone is of little value in distinguishing between ulcerative colitis and Crohn's disease. The low sensitivity of pANCA for the diagnosis of ulcerative colitis prevents it from serving as a useful diagnostic tool.

The ACG also states that the measurement of genetic mutations of Crohn's disease has not been proven to be of clinical benefit for the diagnosis, management, or prediction of response to specific therapies.

EXCLUSIONS:
The Plan does not cover the use of anti-neutrophil cytoplasmic antibody (ANCA) and/or anti- Saccharomyces cerevisiae antibody (ASCA) (e.g., Prometheus IBD Serology Testing) for the diagnosis of IBD because it is considered **experimental, investigational or unproven** and **NOT COVERED.** Although the specificity of these tests are relatively high (82-100%), the sensitivity is low (32 -50%), which indicates that a negative result will not be clinically helpful. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

The Plan does not cover the use of gene testing to establish the risk or diagnosis of inflammatory bowel disease (including but not limited to, Prometheus Crohn's Prognostic panel, NOD2/CARD15 genotyping, PredictSURE IBD Test™, etc.) because it is considered **experimental, investigational or unproven** and therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

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CODING ASSOCIATED WITH: Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

81401 Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81479 Unlisted molecular pathology procedure
0164U Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results {*ibs-smart™}*

0176U Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA) {*IBSchek®}*
0203U Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness {*PredictSURE IBD™ Test*}

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

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