CLINICAL MEDICAL POLICY	
Policy Name:	Gastrointestinal Pathogen Assays
Policy Number:	MP-113-MD-PA
Responsible Department(s):	Medical Management
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Next Annual Review:	01/2026
Revision Date:	01/15/2025; 01/17/2024; 01/18/2023
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 11

Policy History

Date	Activity
04/01/2025	Provider Effective date
02/07/2025	PARP Approval
01/15/2025	QI/UM Committee review
01/15/2025	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/01/2024	Provider Effective date
05/02/2024	PARP Approval
01/17/2024	QI/UM Committee review
01/17/2024	Annual Review: No changes to clinical criteria. Added CPT code 0369U. Revised 'Coding Requirements' section formatting. Updated 'Summary of Literature' and 'Reference Sources' sections.
04/01/2023	Provider Effective date
02/17/2023	PARP Approval
01/18/2023	QI/UM Committee review
01/18/2023	Annual Review: No changes to clinical criteria. CPT code 87507 now requires a dual diagnosis, with one code from Group 1 and another code from Group 2 required for billing. Removed deleted procedure code 0097U. Added following ICD-10 codes to Group 2 diagnosis codes: per CMS guidance. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2022	Provider Effective date
02/03/2022	PARP Approval

01/19/2022	QI/UM Committee review
01/19/2022	Annual Review: No changes to clinical criteria. Added TAG determination information and Program Exception statement. Updated Summary of Literature and Reference Sources sections.
05/17/2021	Provider effective date
03/30/2021	PARP approval
01/20/2021	QI/UM Committee approval
11/17/2020	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary gastrointestinal pathogen assays.

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.

Acute Gastroenteritis (AGE) - A diarrheal disease of rapid onset, with or without accompanying symptoms and signs, such as nausea, vomiting, fever or abdominal pain.

Gastrointestinal Pathogen (GIP) Testing Assays- A gastrointestinal microorganism multiplex nucleic acid-based assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple gastrointestinal microbial nucleic acids extracted from human stool specimens. The device detects specific nucleic acid sequences for organism identification as well as for determining the presence of toxin genes. The detection and identification of a specific gastrointestinal microbial nucleic acid from individuals exhibiting signs and symptoms of gastrointestinal infection aids in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings.

A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.

Procedures

Program Exception: Gastrointestinal pathogen panels testing (GIP) requires a Program Exception. The ordering physician must provide a supporting statement indicating why the requested therapy is medically necessary, and the alternative options have been, or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

1. GIP is considered medically necessary when an individual is immunocompromised with acute or persistent diarrhea lasting more than seven (7) days and ANY ONE of the following is present:
    A. The individual has had negative endoscopies (when appropriate) and traditional stool tests; OR
    B. The individual has acute or persistent diarrhea with signs or risk factors for severe disease (fever, bloody diarrhea, dysentery, dehydration, severe abdominal pain, or hospitalization).

2. If the above indications are not met, GIP testing is considered not medically necessary as safety and efficacy has not been established by 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℠ at any time pursuant to the terms of your provider agreement.

4. Place of Service
   The proper place of service for GIP testing is inpatient.

Governing Bodies Approval

There are several FDA approved GIP assays are currently on the market, and all are closed system tests that do not allow random access for physicians to select likely etiologic agents of diarrhea. These include:

- **Hologic/Gen-Probe's ProGastro SSCS:**
    - Targets identified:
        - Salmonella,
        - Shigella,
        - Campylobacter (C. jejuni and C. coli only, undifferentiated) nucleic acids, and
        - Shiga toxin 1 (stx1) /Shiga toxin 2 (stx2) genes (STEC typically harbor one or both genes that encode for Shiga toxins 1 and 2)
    - TAT (turn-around time) - 4 hr.
- **BD Diagnostics' BD MAX Enteric Bacterial Panel (EBP):**
    - Targets identified:
        - Campylobacter spp. (jejuni and coli),

        - Salmonella spp.,
        - Shigella spp.,
        - Enterohemorragic E.coli (EHEC)
        - Shiga toxin 1 (stx1)/Shiga toxin 2 (stx2) genes (found in STEC, as well, as Shigella dysenteriae)
    - TAT – 3-4 hr.
- **Nanosphere's Verigene Enteric Pathogens (EP):**
    - Targets identified:
        - Campylobacter Group (comprised of C. coli, C. jejuni, and C. lari),
        - Salmonella species,
        - Shigella species (including S. dysenteriac, S. boydii, S. sonnei and S. flexneri),
        - Vibrio Group (comprised of V. cholera and V. parahoemolyticus),
        - Yersinia enterocolitica,
        - Shiga toxin I gene and Shiga toxin 2 gene virulence markers, Shiga toxin-producing E coli (STEC)
        - Norovirus
        - Rotavirus
    - TAT – 2 hr.
- **Luminex's xTAG Gastroenterology Pathogen Panel (GPP):**
    - Targets identified:
        - Campylobacter (C. jejuni, C. coli and C. lari only)
        - Clostridium difficile (C. difficile) toxin A/B
        - Cryptosporidium (C. parvum and C. hominis only)
        - Escherichia coli (E. coli) O157
        - Enterotoxigenic E. coli (ETEC) LT/ST
        - Giardia (G. lamblia only) (aka G. intestinalis and G. duodenalis)
        - Norovirus GI/GII
        - Rotavirus A
        - Salmonella
        - Shiga-like Toxin producing E. coli (STEC) stx 1/stx 2
        - Shigella (S. boydii, S. sonnei, S. flexneri and S. dysenteriae)
        - E. histolytica
        - Adenovirus 40/41
        - Vibrio cholera
    - TAT - <5 hr.
- **Biofire Diagnostic's FilmArray GI Panel:**
    - Targets identified:
        - Campylobacter (C. jejuni/C. coli/C.upsaliensis),
        - Clostridium difficile (C. difficile) toxin A/B ,
        - Plesiomonas shigelloides,

        - Salmonella,
        - Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae), including specific identification of Vibrio cholera,
        - Yersinia enterocolitica,
        - Enteroaggregative Escherichia coli (EAEC),
        - Enteropathogenic Escherichia coli (EPEC),
        - Enterotoxigenic Escherichia coli (ETEC) lt/st,
        - Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the
            - E. coli O157 serogroup within STEC),
        - Shigella/ Enteroinvasive Escherichia coli (EIEC),
        - Cryptosporidium,
        - Cyclospora cayetanensis,
        - Entamoeba histolytica,
        - Giardia lamblia (also known as G. intestinalis and G. duodenalis),
        - Adenovirus F 40/41,
        - Astrovirus,
        - Norovirus GI/GII,
        - Rotavirus A,
        - Sapovirus (Genogroups I, II, IV, and V)
    - TAT -1-2 hr.

Gastrointestinal pathogen panel tests 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 published the following GIP related guidance:

- Local Coverage Determination (LCD) Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (L38229)
- Local Coverage Article (LCA) Billing and Coding: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (A56642)

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of November 2020, the TAG workgroup assigned GIP testing an Option # 3, specifically for CPT codes 87505, 87506, and 87507.

Summary of Literature

A wide variety of viruses, bacteria, and parasites can be the cause of digestive tract infections. Conventional methods for identification of a digestive pathogen, for example, antigen tests, microscopic examinations, and culture, are time-consuming and expensive and have limited sensitivity. The GIP simultaneously tests for the presence of multiple disease. The GI pathogen panel detects the genetic material (RNA or DNA) of some of the more common pathogens. It can identify co-infections (more than one microbe causing infection) and identify microbes that might be missed with traditional testing. Results of a GI pathogen panel may be available within a few hours, compared to a few days with some traditional testing (LabCorp, 2021).

Infectious gastroenteritis is a significant global health concern characterized by diarrhea, vomiting, and other symptoms; severe cases can lead to life-threatening dehydration. Causes include infections with bacteria (e.g., Clostridium difficile, Escherichia coli, Shigella), viruses (e.g., norovirus, rotavirus), or parasites (e.g., Cryptosporidium, Giardia). In the United States, there were nearly half a million emergency department visits associated with infectious gastroenteritis in 1 year, 39% of which led to hospitalization. Worldwide, diarrheal disease is estimated to impact 1.7 billion children per year, and it is the second leading cause of death in children under age 5 (Hayes, 2021).

The American College of Gastroenterology (ACG) has provided the following GIPP clinical guidelines:

- Traditional methods of diagnosis (bacterial culture, microscopy with and without special stains and immunofluorescence, and antigen testing) fail to reveal the etiology of the majority of cases of acute diarrheal infection. If available, the use of Food and Drug Administration-approved culture-independent methods of diagnosis can be recommended at least as an adjunct to traditional methods. (Strong recommendation, low level of evidence).
- Diarrheal disease by definition has a broad range of potential pathogens particularly well suited for multiplex molecular testing. Several well-designed studies show that molecular testing now surpasses all other approaches for the routine diagnosis of diarrhea. Molecular diagnostic tests can provide a more comprehensive assessment of disease etiology by increasing the diagnostic yield compared with conventional diagnostic tests (Table 2). They are also faster, providing results in hours rather than days (37). The new diagnostics' best applicability is for the clinician in practice, seeing one patient at a time rather than in the public health setting, e.g., in outbreak investigations. One potential drawback of molecular technologies is the need to predefine the particular microbes being sought. In addition the significance of an identified organism may not be clear as these molecular technologies, which involve nucleic acid amplification, are limited to our existing knowledge of a microbes' genome and do not discriminate between viable and non-viable organisms. As a result they can detect microbes at non-pathogenic levels. Given the high rates of asymptomatic carriage of enteropathogens, this can be a considerable problem. To confound matters, further multiplex techniques are more commonly associated with increased detection of mixed infections and the relative importance of each pathogen may be unclear.

The Infectious Diseases Society of America (ISDA) has published the following recommendations in their clinical practice guidelines for the diagnosis and management of infectious diarrhea:

- A broad differential diagnosis is recommended in immunocompromised people with diarrhea, especially those with moderate and severe primary or secondary immune deficiencies, for evaluation of stool specimens by culture, viral studies, and examination for parasites (strong, moderate). People with acquired immune deficiency syndrome (AIDS) with persistent diarrhea should undergo additional testing for other organisms including, but not limited to, Cryptosporidium, Cyclospora, Cystoisospora, microsporidia, Mycobacterium avium complex, and cytomegalovirus (CMV) (strong, moderate).
- Multipathogen nucleic acid amplification tests can simultaneously detect viral, parasitic, and bacterial agents, including some pathogens that previously could not be easily detected in the clinical setting such as norovirus, and enterotoxigenic E. coli (ETEC), enteropathogenic E. coli (EPEC), and enteroaggregative E. coli (EAEC) in less time than traditional methods. The short time to results could reduce inappropriate use of antimicrobial agents to treat infections that do not require antimicrobial therapy and could shorten the time to targeted management and isolation measures for certain infections such as STEC O157. With these assays, it is common to detect the presence of >1 pathogen that may differ with regard to clinical management. Furthermore, even a positive result for 1 pathogen should be interpreted in the context of the patient's clinical presentation, because less is known about the clinical significance of tests that detect nucleic acid as compared with traditional assays that generally detect viable organisms. The importance of detection of multiple pathogens in the same specimen is often unclear; it is unknown if all pathogens detected in the specimen are clinically relevant or if one is more strongly associated with the illness.
- Culture-independent, including panel-based multiplex molecular diagnostics from stool and blood specimens, and, when indicated, culture-dependent diagnostic testing should be performed when there is a clinical suspicion of enteric fever (diarrhea uncommon) or diarrhea with bacteremia (strong, moderate). Additionally, cultures of bone marrow (particularly valuable if antimicrobial agents have been administered), stool, duodenal fluid, and urine may be beneficial to detect enteric fever (weak, moderate). Serologic tests should not be used to diagnose enteric fever (strong, moderate).

Rationale

In 2013 Halligan, et al noted GIP testing simplifies clinician ordering of laboratory tests for IG (Infectious gastroenteritis), enables consolidation of laboratory testing, gave confidence in setting minimum repeat testing times using GIP, provided opportunity for earlier de-isolation in 50% of inpatients and rapidly gained the confidence of test requestors. The low prevalence of bacterial pathogens in HA-IG (hospital acquired) makes GIP potentially more appropriate for testing of CA-IG (community acquired). There was also a greater opportunity for releasing isolation rooms in CA cases. Realizing this benefit requires optimization of laboratory workflow and ideally quicker laboratory turnaround to enable a same-day service.

Khare, et al discussed the advantages and disadvantages of the FilmArray GI Panel and the Luminex xTag panel. The FilmArray is a closed system that offers a rapid result (∼1 h turnaround time) with minimal hands-on time (∼5 min) and requires minimal user training. However, the FilmArray analyzes 1 sample at a time and therefore is best suited for laboratories requiring a lower throughput. A single FilmArray system accommodates 7 to 8 samples in an 8-h shift. In contrast, the Luminex platform is an open system, requires ∼60 min of hands-on time, and has turnaround time of 5 to 6 h. Despite the longer turnaround time, the Luminex system processes up to 96 samples in an 8-h shift, making it more suitable for high-volume reference laboratories. Importantly, open molecular platforms pose an increased risk of amplicon

contamination, and therefore laboratories using the Luminex system should use unidirectional workflow and follow strict good laboratory practice.

Both systems also have several advantages compared to routine laboratory methods. Results are available in <6 h, whereas routine testing commonly requires up to several days if culture-based methods are used. This may have a significant impact on patient management. In addition, test utilization and antimicrobial stewardship may be affected by the use of multiplex testing platforms. In our prospective study, there was an average of 3 routine tests ordered per sample. The ability to cover for a broad spectrum of GI pathogens in a single test is an appealing advantage of multiplex technology. However, the impact of multiplex tests on the management and treatment of patients with GI illness is still unclear, as no standard therapy exists for some of the pathogens represented on these panels. It is possible that the detection of common viral causes of GI disease may help curb the use of antibiotic therapy. This will be an exciting area for future research as multiplex panels become a more common feature in diagnostic laboratories (Khare, et al., 2013).

Coding Requirements

Procedure Codes
Group 1

CPT Code	Description
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87507*	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
0369U*	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique

*CPT codes 87507 & 0369U require an additional diagnosis code from the Group 2 coding group below.

Diagnosis Code
Group 1

ICD-10 Code	Description
R19.7	Diarrhea, unspecified

Group 2 Code

The following ICD-10-CM code supports medical necessity and provides coverage for CPT codes **87507** and **0369U**:

ICD-10 Code	Description
B20	Human immunodeficiency virus [HIV] disease
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.8	Other immunodeficiencies with predominantly antibody defects
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.4	Nezelof's syndrome
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.810	Biotinidase deficiency
D81.818	Other biotin-dependent carboxylase deficiency
D81.89	Other combined immunodeficiencies
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.81	Immunodeficiency due to conditions classified elsewhere
D84.821	Immunodeficiency due to drugs
D84.822	Immunodeficiency due to external causes
D84.89	Other immunodeficiencies
D89.0	Polyclonal hypergammaglobulinemia
D89.1	Cryoglobulinemia
D89.3	Immune reconstitution syndrome

D89.41	Monoclonal mast cell activation syndrome
D89.42	Idiopathic mast cell activation syndrome
D89.43	Secondary mast cell activation
D89.49	Other mast cell activation disorder
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

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