March 26, 2022

National Government Services
Medical Policy Unit
P.O. Box 7108
Indianapolis, IN 46207-7108
PartBLCDComments@anthem.com

Dear Dr. Boren and Dr. Cunningham,

On behalf of the Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP), we thank you for the opportunity to review and comment on the proposed policy for Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) (DL39226)

The AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

The CAP is the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.
We are submitting joint comments because currently our organizations share the same position regarding this draft LCD. Together, we would like to thank you for proposing limited coverage for GPP tests for acute gastroenteritis.

We believe thoughtful consideration was given to the published literature and the resulting proposed LCD will positively impact patient care through accurate detection and implementation of appropriate treatment therapy. After reviewing the proposed policy's coverage criteria, we ask that National Government Services consider incorporating the following AMP and CAP recommendations into the final coverage policy.

Coverage Guidance

Indications and Limitations of Coverage

1. The proposed LCD appears to cover only Food and Drug Administration (FDA) approved/cleared assays for acute gastroenteritis. Laboratory developed tests (LDTs) play a critical role in assisting clinicians diagnose and treat patients. To limit coverage to only FDA approved/cleared panels could negatively impact patient care by denying many patients access to high-quality laboratory developed tests (LDTs) that are not FDA approved. **AMP and CAP recommend NGS allow for coverage of laboratory developed panel tests when a test meets appropriate analytical and clinical validity (AV/CV) standards and fulfills the "reasonable and necessary" criteria as outlined in the proposed LCD.**

2. The proposed policy states:

"One FDA approved/cleared multiplex GPP is covered when at least ONE of the following applies:

1. Community-acquired acute diarrhea (≥3 loose or watery stools/day for ≤14 days) with at least ONE of the following (1-3):

a. >1 week duration
b. Severe illness (profuse watery diarrhea, signs of hypovolemia, passage of ≥6 unformed stools per 24 hours, severe abdominal pain, need for hospitalization)
c. Inflammatory diarrhea (bloody diarrhea, small volume mucous stools, fever)
d. High-risk host (e.g., age ≥70 years, cardiac disease, immunocompromising condition, inflammatory bowel disease, pregnancy)

e. Public health concerns (e.g., food handler, health care or day care worker)

2. Pre-transplant evaluation (4)"

AMP and CAP are concerned with the coverage criterion shown in bold font above. This criteriion contradicts IDSA guidelines, which refer to diarrhea as passage of three or more loose or liquid stools per 24 hours[1]. **Based on professional society guidelines this coverage criteria seems to be too restrictive and we would recommend revising this to state "≥3 unformed stools per 24 hours."**

3. The proposed LCD appears to allow only 'one' FDA approved/cleared multiplex GPP. Diarrheal illnesses pose a considerable diagnostic challenge, where the history, presenting signs and symptoms, and other features are often non-specific. The number and type of microbes tested depend on the composition of the panel used. While some panels may be limited to testing for a few bacteria that are the most common causes of GI infections, for example, other panels may be more comprehensive and test for a variety of bacteria, viruses, and parasites. If a patient has a GI infection caused by a less common bacterium, parasite, or virus that is not included in the GI pathogen panel, additional tests may be required to help establish a diagnosis. Some clinical settings, such as those in rural areas, may not have access to large panel tests. If, after a small panel test is ordered and performed, the results are negative, additional related testing may be necessary to establish a diagnosis if a patient's symptoms continue. Some vendors have small panels that can be tested in parallel depending on the pathogens of interest (e.g., BD Max with GI; Hologic Panther Fusion with respiratory). These tests should be considered part of the clinician's order.

For these reasons, AMP and CAP recommend NGS allow coverage of one additional panel test for the same clinical indication if the first panel yielded a negative result AND there is a high index of suspicion for a pathogen as the cause of symptoms, AND the patient's clinical condition is not improving or is deteriorating, AND as long as the test fulfills the criteria for coverage set forth in the LCD.

Contraindications to Coverage

1. Under Contraindications for Coverage, item #2 states that NGS will not cover tests "More than 72 hours after hospitalization." **We request that the LCD language state clearly that NGS will not cover tests more than 72 hours after a patient is admitted to the hospital and is still an inpatient.**

2. Under Contraindications for Coverage, item #3 states that NGS will not cover tests if a patient has used "*laxatives in the prior 48 hours*."

AMP and CAP believe that the requirement stating that a patient must not have used laxatives prior to 48 hours of the test, is overly restrictive. Patients who utilize laxatives are still capable of contracting an infection, regardless of laxative use. Further, there are medications other than laxatives that may exacerbate normal bowel movements. This draft LCD requirement would have a negative impact on multiple patient groups; for example, those patients with Clostridioides difficile (C. diff). **We request that NGS strike item #3 from the final LCD.**

<u>Billing and Coding</u>

Group 2 Codes

1. The billing and coding article for Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) (DA58963), outline the requirements for billing group 2 codes:

Highly Multiplexed GPPs- Group 2 Codes

Must be billed in POS 20, 21, 22, 23, or 81 (Urgent Care, Inpatient Hospital, Outpatient Hospital (observation), or Emergency Room), or in POS 81 (Independent Laboratory) in the case of a pre-transplant evaluation for an immune-compromised beneficiary.

*Outside of one of these POS, the test must be ordered by a clinician specialist in one of the following: Infectious Diseases (44), Gastroenterology (10), Oncology (83,90,91), or Transplant who is diagnosing and treating the beneficiary. **

**An exception may be made in geographic locations where neither specialist can be reasonably reached by the beneficiary and the ordering provider is located closer to the beneficiary's place of residence than the nearest*

infectious disease specialist. We would generally expect that beneficiaries for whom the test is ordered under this exception to be living in rural locations, islands, or some other location where access to care is limited.

AMP and CAP believe these requirements are too narrow for a routine outpatient that has severe diarrhea but not so severe that they need travel to an urgent care, emergency room, or hospital. For example, a patient's diarrhea may be severe enough to warrant testing, but they are not sick enough to go to an emergency room, instead the patient will see their general provider. In this instance it would be inappropriate for the patient to have to wait for an infectious disease clinic visit. Limiting ordering to the named specialties will be problematic and produce substandard patient outcomes. In many cases, the patient's infectious disease physician and/or gastroenterologist is not directly involved in the outpatient encounter. A strict requirement for these consultations, in the outpatient setting, will only add time and cost to the visit and delay test results. **We recommend that the following language be added after "*Testing is ordered by a clinician specialist in Infectious Diseases or Gastroenterology*": "or a healthcare guideline or algorithm with contribution of infectious disease or gastrointestinal specialist." This language should also be added for the section on immunocompromised patients.**

ICD-10 Codes
We recommend that the following ICD-10 codes be added to the LCD.

R19.7	Diarrhea, unspecified
R10.84	Generalized abdominal pain
R11.2	Nausea with vomiting, unspecified

Thank you again for the opportunity to review and comment on this proposed policy. We welcome the opportunity to provide you with additional clinical or other information to assist you as you finalize this draft LCD. Should you have any questions, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org.

Sincerely,

Association for Molecular Pathology
College of American Pathologists

Reference

1. Shane AL, Mody RK, Crump JA, Tarr PI, et al. 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. Guideline from Infectious Diseases Society of America. *Clinical Infectious Diseases* 2017;65(12):e45–e80.