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Re: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) – DL38227 (First Coast) and DL38229 (Novitas)

Dear Medical Directors:

Thank you for the opportunity to review and comment on First Coast and Novitas' proposed coverage policy for Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (DL38227 and DL38229). The Association for Molecular Pathology (AMP), Association of Public Health Laboratories (APHL), and the College of American Pathologists (CAP), representing multiple areas of practice, have collaborated to present comments spanning their areas of expertise on your draft local coverage determination (LCD). The members of the organizations developing these comments are subject matter experts in diagnosis and treatment of the conditions covered by this policy and its possible implementation will directly impact their patients and practices. We are submitting joint comments because our organizations share similar concerns regarding this draft LCD.

We applaud First Coast and Novitas' efforts to provide coverage for GIP panels utilizing multiplex NAATs, and we recognize the effort that has gone into the development of this policy. We greatly appreciate the improvement of this coverage policy over the years; however, our organizations have significant concerns regarding the coverage indications and limitations outlined in the draft policy. As such, we offer the following comments and recommendations for your consideration.

Coverage Indications

The draft LCD provides the following coverage indications:

1. *GIP panels utilizing NAATs are medically reasonable and necessary for the evaluation of Medicare beneficiaries with the following:*
    - *Acute diarrhea present for at least seven days duration; or*
    - *Persistent diarrhea of 14-30 days; or*
    - *Acute diarrhea with signs or risk factors for severe disease to include any of the following:*
        a. *fever,*
        b. *bloody diarrhea,*

c. *dysentery,*
d. *dehydration,*
e. *severe abdominal pain,*
f. *hospitalization, or*
g. *an immunocompromised state*

2. *GIP panels utilizing NAATs, 12 or more targets, are medically reasonable and necessary for the evaluation of Medicare beneficiaries with the following:*
    - *An immunocompromising medical condition with acute or persistent diarrhea.*

Comment and Recommendation #1

We recognize the draft policy separates coverage indications for patients who are and are not immunocompromised. Specifically, the draft policy provides coverage for GIP panels utilizing NAATs of 11 or fewer targets, under certain conditions, and 12 or more targets for immunocompromised patients with acute or persistent diarrhea. We believe this division is out of date and does not align with current medical practice as most laboratories would utilize the same broad test panel when testing both immunocompromised patients and non-immunocompromised patients. **Therefore, First Coast and Novitas should expand the coverage indications to include larger panels with greater targets for all patients, regardless of their status as immunocompromised.**

The coverage policy as drafted does not reflect real-world testing availability and capabilities and will cause laboratories to be denied payment for testing with a clinically appropriate panel that happens to have more than 11 targets. In current medical practice, laboratories do not typically maintain a small panel and a large panel as commercial manufacturers typically do not offer more than one FDA cleared panel per platform. Rather, they normally use a single panel associated with the platform in use. Many laboratories lack resources to add multiple platforms for various infectious disease panels. Commercial 22-target panels are one of the most used panels. Therefore, if a clinician sees a patient who has persistent diarrhea of 14-30 days, the laboratory's most appropriate option might be to utilize commercial 22-target panels, if they are the only platform for ID panel tests that the laboratory utilizes. Additionally, if a clinician has a patient with acute diarrhea or severe disease, the 22-target panel would be most appropriate.

For these reasons, our organizations recommend the following changes be made to the coverage indications proposed in this draft LCD:

1. *GIP panels utilizing NAATs ~~11 or fewer targets~~ are medically reasonable and necessary for the evaluation of Medicare beneficiaries with the following:*
    - *Acute diarrhea present for at least seven days duration; or*
    - *Persistent diarrhea of 14-30 days; or*
    - *Acute diarrhea with signs or risk factors for severe disease to include any of the following:*
        a. *fever,*
        b. *bloody diarrhea,*
        c. *dysentery,*
        d. *dehydration,*
        e. *severe abdominal pain,*
        f. *hospitalization, or*
        g. *an immunocompromised state*

~~2. *GIP panels utilizing NAATs, 12 or more targets, are medically reasonable and necessary for the evaluation of Medicare beneficiaries with the following:*~~
    - ~~*An immunocompromising medical condition with acute or persistent diarrhea.*~~

Comment and Recommendation #2

The coverage indications outlined in this draft policy should provide for an exception for patients who have a clear epidemiologic risk factor, such as for infection caused by *Entamoeba histolytica*

or *Vibrio cholerae*. We recommend there be exceptions for patients who do not align with the description of diarrhea or risk factors presented in this LCD but who have documented travel or geographic exposures of significance for which molecular testing via a panel is the most sensitive and timely approach to diagnosis. For the majority of community acquired diarrhea patients, testing for these conditions is not necessary; however, there are no other commercial molecular tests for these conditions beyond the 22-target panel, which would be clinically indicated for patients with specific travel or exposure history.

For these reasons, we recommend First Coast and Novitas include an additional criterion to the coverage indications:

1. *GIP panels utilizing NAATs are medically reasonable and necessary for the evaluation of Medicare beneficiaries with the following:*
    - *Acute diarrhea present for at least seven days duration; or*
    - *Acute diarrhea present for less than seven days, and significant exposure evidence (e.g., potential geographic outbreak or exposure to a certain product); or*
    - *Persistent diarrhea of 14-30 days; or*
    - *Acute diarrhea with signs or risk factors for severe disease to include any of the following:*
        a. *fever,*
        b. *bloody diarrhea,*
        c. *dysentery,*
        d. *dehydration,*
        e. *severe abdominal pain,*
        f. *hospitalization, or*
        g. *an immunocompromised state*

There may be patients who have not reached the seven-day mark and who may not have severe symptoms but may present a concern for a national or regional outbreak or traceback to contamination introduced in food production facilities. This would pose significant risks to those with underlying health conditions or the immunocompromised, while otherwise healthy individuals might have milder symptoms. Under these circumstances, when investigating a potential national or regional outbreak or contamination of a food source, it may not be clinically appropriate to wait seven days to test someone to rapidly confirm the pathogen and initiate public health response.

Coverage Limitations

The draft LCD proposes the following coverage limitations:

- *GIP panels utilizing multiplex NAATs are considered not medically reasonable and necessary for any of the following:*
    1. *To test for clearance of the pathogen (i.e., "test of cure").*
    2. *Testing of asymptomatic patients.*
    3. *Repeat testing utilizing the same or a different GIP panel within seven days during the same episode of diarrhea by the same or different provider.*
    4. *Performance of more than one GIP panel on the same date of service by the same or different provider.*

Comment and Recommendation #3

Our organizations agree that there should be no indication for retesting the same panel; however, we believe there should be allowance for repeat testing when appropriate for a t panel with additional targets. For example, a clinician may want to begin diagnosis by using a narrow panel, such as the BD Max bacterial panel (*Salmonella*, *Shigella*, *STEC*, *Campylobacter*) but then, if they are fortunate to have more than one in house, run or send out for a commercial 22-target assay panel if the patient worsens, to detect possible other etiologies. Additionally, it may be appropriate to test with a different GIP panel if there is suspicion of a false positive on the initial panel because

symptoms or epidemiological evidence is not consistent with the result. As such, First Coast and Novitas should revise the third point of the limitations as follows:

3. *Repeat testing utilizing the same ~~or a different~~ GIP panel within seven days during the same episode of diarrhea by the same or different provider.*

ICD-10 Codes

We request the following additional ICD-10 codes be added to the local coverage articles DA56638 and DA56642:

A00.0 Cholera due to Vibrio cholerae 01, biovar cholera
A01.00 Typhoid fever, unspecified
A01.1 Typhoid meningitis
A01.2 Typhoid fever with heart involvement
A01.3 Typhoid pneumonia
A01.4 Typhoid arthritis
A02.0 Salmonella enteritis
A02.1 Salmonella sepsis
A02.20 Localized salmonella infection, unspecified
A02.22 Salmonella pneumonia
A02.8 Other specified salmonella infections
A02.9 Salmonella infection, unspecified
A03.0 Shigellosis due to Shigella dysenteriae
A03.1 Shigellosis due to Shigella flexneri
A03.2 Shigellosis due to Shigella boydii
A03.3 Shigellosis due to Shigella sonnei
A03.8 Other shigellosis
A03.9 Shigellosis, unspecified
A04.0 Escherichia coli enteropathogenic
A04.1 Escherichia coli enterotoxigenic
A04.2 Escherichia coli enteroinvasive
A04.3 Escherichia coli enterohemorrhagic
A04.4 Escherichia coli enteroaggregative
A04.5 Escherichia coli
A04.6 Yersinia enterocolitica
A04.7 Clostridium difficile
A04.9 Bacterial intestinal infection, unspecified
A05.0 Foodborne staphylococcal intoxication
A05.1 Botulism food poisoning
A05.2 Foodborne Clostridium perfringens [Clostridium welchii] intoxication
A05.3 Foodborne Vibrio parahaemolyticus intoxication
A05.4 Foodborne Bacillus cereus intoxication
A05.5 Foodborne Vibrio vulnificus intoxication
A05.8 Other specified bacterial foodborne intoxications
A05.9 Bacterial foodborne intoxication, unspecified
A06.0 Acute amebic dysentery
A07.1 Giardiasis [lambliasis]
A07.2 Cryptosporidiosis
A07.8 Other specified protozoal intestinal diseases
A08.0 Rotaviral enteritis
A08.2 Adenoviral enteritis
A08.11 Acute gastroenteropathy due to Norwalk agent
A08.19 Acute gastroenteropathy due to other small round viruses
A08.31 Calicivirus enteritis
A08.32 Astrovirus enteritis
A08.39 Other viral enteritis
A08.8 Other specified intestinal infections

A09 Infectious gastroenteritis and colitis, unspecified
A28.2 Extraintestinal yersiniosis
A49.1 Methicillin susceptible Staphylococcus aureus infection, unspecified site
A49.2 Methicillin resistant Staphylococcus aureus infection, unspecified site
A49.3 Mycoplasma infection, unspecified site
A49.9 Bacterial infection, unspecified
A87.0 Enteroviral meningitis
A87.8 Other viral meningitis
A87.9 Viral meningitis, unspecified
A88.8 Other specified viral infections of central nervous system

B08.4 Enteroviral vesicular stomatitis with exanthema
B15.0 Hepatitis A with hepatic coma
B15.9 Hepatitis A without hepatic coma
B19.0 Unspecified viral hepatitis with hepatic coma
B19.9 Unspecified viral hepatitis without hepatic coma
B33.8 Other specified viral diseases
B34.1 Enterovirus infection, unspecified
B34.9 Viral infection, unspecified
B95.0 Streptococcus, group A, as the cause of diseases classified elsewhere
B95.1 Streptococcus, group B, as the cause of diseases classified elsewhere
B95.2 Enterococcus as the cause of diseases classified elsewhere
B95.3 Streptococcus pneumoniae as the cause of diseases classified elsewhere
B95.4 Other streptococcus as the cause of diseases classified elsewhere
B95.5 Unspecified streptococcus as the cause of diseases classified elsewhere
B95.6 Staphylococcus aureus as the cause of diseases classified elsewhere
B95.7 Other staphylococcus as the cause of diseases classified elsewhere
B95.8 Unspecified staphylococcus as the cause of diseases classified elsewhere
B96.1 Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere
B96.2 Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.3 Hemophilus influenzae [H. influenzae] as the cause of diseases classified elsewhere
B96.4 Proteus (mirabilis) (morganii) as the cause of diseases classified elsewhere
B96.5 Pseudomonas (aeruginosa) (mallei) (pseudomallei) as the cause of diseases classified elsewhere
B96.6 Bacteroides fragilis [B. fragilis] as the cause of diseases classified elsewhere
B96.7 Clostridium perfringens [C. perfringens] as the cause of diseases classified elsewhere
B96.81 Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere
B96.82 Vibrio vulnificus as the cause of diseases classified elsewhere
B96.89 Other specified bacterial agents as the cause of diseases classified elsewhere
B97.0 Adenovirus as the cause of diseases classified elsewhere
B97.10 Unspecified enterovirus as the cause of diseases classified elsewhere
B97.11 Coxsackievirus as the cause of diseases classified elsewhere
B97.12 Echovirus as the cause of diseases classified elsewhere
B97.89 Other viral agents as the cause of diseases classified elsewhere
B99.8 Other and unspecified infectious diseases
B99.9 Unspecified infectious disease

K52.0 Gastroenteritis and colitis due to radiation
K52.1 Toxic gastroenteritis and colitis
K52.2 Allergic and dietetic gastroenteritis and colitis
K52.81 Eosinophilic gastritis or gastroenteritis
K52.82 Eosinophilic colitis
K52.89 Other specified noninfective gastroenteritis and colitis
K52.9 Noninfective gastroenteritis and colitis, unspecified

Z51.11: Encounter for antineoplastic chemotherapy (i.e. associated with chemotherapy-induced immunosuppression)

Thank you again for the opportunity to review and comment on this draft LCD. We respectfully ask that you consider these comments, which were prepared by subject matter experts including members of AMP, APHL and CAP who provide services to Medicare beneficiaries covered by First Coast and Novitas. Should you have additional questions or require our expertise, please direct your correspondence to Sarah Thibault-Sennett, Director, Public Policy & Advocacy at sthibaultsennett@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org.

Sincerely,

Association for Molecular Pathology
Association of Public Health Laboratories
College of American Pathologists