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Re: Draft Local Coverage Determination: MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) (DL37330)

Dear Drs. Almas and Jeter:

Thank you for this opportunity to respond to your draft local coverage determination regarding MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) (DL37330). The Association for Molecular Pathology (AMP), American Society for Microbiology (ASM), Association of Public Health Laboratories, (APHL), College of American Pathologists (CAP), Infectious Diseases Society of America (IDSA), American Gastroenterological Association (AGA), and Pan American Society for Clinical Virology (PASCV), representing multiple areas of practice, have collaborated to present the most thorough analysis for your draft local coverage determination. The members of the six organizations developing these comments are subject matter experts in diagnosis and treatment of the gastrointestinal conditions covered by this policy and its possible implementation will directly impact their practices. We are submitting joint comments because our organizations share the same concerns regarding this draft local coverage determination (LCD). Furthermore, to assist Palmetto, this letter provides specific recommended LCD language changes on medical necessity followed by supporting commentary and literature evaluations. In addition, there is a recommended configuration of ICD-10 codes, which support this medical necessity language.

We recommend modifying the paragraph titled "DL37330 Coverage Indications, Limitations, and/or Medical Necessity" to read as follows:

(Please note: strikethrough font indicates recommended deletion of original draft LCD language; blue font indicates recommended additions)

> This contractor will provide limited coverage for Gastrointestinal Pathogen (GIP) molecular assays identified by multiplex nucleic acid amplification tests (NAATs), and

will limit GIP coverage ~~up to 5 bacterial targets which represent~~ to the top 90-95% of foodborne infectious agents ~~*([incidence of infection per 100,000 population]in decreasing incidence): Salmonella [15.89]; Campylobacter [12.97]; Shigella [5.53]; Cryptosporidium [3.31]; Shiga toxin producing E. coli (STEC) non-O157 [1.64] and STEC O157 [.95]. In immune competent individuals, most people with Cryptosporidium, a parasitic disease, will recover without treatment. The pathogens in some of the GIP panels are determined by the manufacturers that make them, and do not represent specific pathogens that cause a common age-based syndrome, or represent organisms that commonly are found in a specific sample type, patient population or reflect community acquired foodborne infections.*~~ considered medically necessary for therapeutic decision making. These infectious agents include *Salmonella*, *Campylobacter*, *Shigella*, Shiga toxin- producing *E. coli* (STEC) non-O157 and STEC O157, as well as enterotoxigenic *E. coli*, enteropathogenic *E. coli*, enteroaggregative *E. coli*, *Clostridium difficile*, *Yersinia enterocolitica*, *Vibrio parahaemolyticus*, *Giardia*, *Cryptosporidium*, norovius, rotavirus, and enteric adenoviruses. Diarrheal illnesses pose a considerable diagnostic challenge, where the history, presenting signs and symptoms, and other features are often non-specific but effective therapy requires precise microbial identification. This clinical need has led to a new generation of diagnostic panels that cover this broad range of likely infectious etiologies. In addition, a vulnerable subset of patients, including the immunocompromised and the elderly, is particularly prone to complications. Although immune competent individuals may recover from some infections without treatment, the elderly have diminished immune function and a greater risk of mortality from GI infections. This contractor recognizes that patients may benefit from rapid diagnosis and early intervention (e.g., antibiotic therapy). Due to the substantial overlap in clinical signs and symptoms exhibited by patients with acute GI infections, the diagnostic approach and rapid analysis offered by broad GIP molecular assays, rather than the step-by-step sequential approach of single target assays, may be considered medically necessary. In the infrequent, if not rare, situations where clinical features of the patient's presentation indicate a specific microbial etiology and/or therapy, traditional culture methods or single target molecular assay rather than a broad GIP should be used. Because of the unique clinical circumstances of immune compromised patients, ICU patients, and HIV positive patients with diarrhea, GIP testing for bacteria, virus and parasite testing may be indicated, and thus a Medicare benefit.

We recommend modifying the paragraph titled "DL37330 Summary Medicare Coverage Decision" to read as follows:

(Please note: strikethrough font indicates recommended deletion of original draft LCD language; blue font indicates recommended additions)

~~*GIP testing is limited to no more than 5 bacterial pathogen targets. Testing for viral etiologies is not reasonable and necessary because these GI diseases are generally self-limited, virus specific therapies are not available, and patients are managed by supportive care and hydration.*~~ GIP testing is limited to the minimum number of targets needed for therapeutic decision making. The following clinical indications and

contraindications characterize the role of GIP testing:

INDICATED:

1. Individuals with moderate-to-severe symptoms associated with acute diarrhea
2. Individuals with dysentery
3. Individuals with acute diarrhea lasting > 7 days
4. Immunocompromised individuals with acute diarrhea

NOT INDICATED:

- Immunocompetent individuals with mild diarrhea, particularly of ≤ 7 days duration
- Individuals in whom the clinical presentation of acute diarrhea suggests a specific microbial etiology

Physicians should follow current American College of Gastroenterology (ACG) clinical guidelines. A broad GIP molecular panel (with 6-22 targets) is indicated when a patient presents with a clinical scenario and overlapping symptoms consistent with multiple possible microbiological etiologies. When the patient history and clinical presentation suggest a specific microbial etiology and/or therapy, a broad GIP with more than 5 infectious targets is not indicated.

Although viral infections may be self-limiting, this contractor considers GIP molecular assays including GI viruses (such as norovirus) to be medically necessary to guide initial patient management through best supportive care including hydration and to avoid the use of antibiotics associated with secondary *Clostridium difficile* infection.

For patients in long-term care facilities, GIP molecular panels containing viruses (norovirus, rotavirus, and enteric adenoviruses) are reasonable and necessary because results inform individual patient management decisions such as isolation of the patient (which may increase risk of unrecognized delirium) , and decisions regarding appropriate use of antibiotic therapy.

Travelers with > 2 weeks of symptoms, after bacterial pathogens have been ruled out, may require traditional ova and parasite stool examination and/or specific protozoal antigen or molecular testing. Large panels including ~~*viruses and*~~ protozoa are not reasonable and necessary for usual community-acquired diarrheal illness.

There is no Medicare benefit to the use of GIP testing for national, state, or local agency tracking of diarrheal outbreaks, for epidemiologic purposes, or to confirm another etiologic test result. Once the etiology of an outbreak is identified, subsequent patient testing is generally not indicated and patients are managed empirically. However, if the clinical presentation of an individual patient varies from the outbreak prototype, a specific test for the etiologic organism may be indicated. The Medicare benefit is specifically for the clinical identification and management of disease for a given beneficiary. The Medicare benefit does not extend for purposes of the family or for community tracking or surveillance.

Rationale for the Above Language

We are supportive of Palmetto's proposal to cover Gastrointestinal Pathogen (GIP) molecular assays identified by multiplex nucleic acid amplification tests. While we agree codes for up to five bacterial targets are applicable, we also believe that additional targets should be included, and that there are clinical scenarios where more than five targets are medically necessary. The draft LCD lists five bacterial targets that will be eligible for GIP coverage: *Salmonella*; *Campylobacter*; *Shigella*; *Cryptosporidium*; and Shiga toxin-producing *Escherichia coli* (STEC) O157 and non-O157. Several clinical studies have demonstrated that these targets are insufficient to identify the top 90-95 percent of pathogens that may cause diarrhea in patients (Buss, *et al.,* 2015).

Testing for more than five infectious targets is necessary in order to achieve a diagnosis rate of 90-95 percent of pathogens. Restriction of testing to five prioritized bacterial targets would likely miss the majority of pathogens responsible for gastrointestinal infections in the elderly. In a prospective study published by the Infectious Diseases Society of America (IDSA), *Salmonella*, *Campylobacter*, *Shigella*, and STEC (O157 and non-O157) accounted for less than half of the gastrointestinal pathogens detected in adults up to 98 years of age with diarrhea. The other pathogens detected included enterotoxigenic *E. coli*, enteropathogenic *E. coli*, enteroaggregative *E. coli*, *Clostridium difficile*, *Yersinia enterocolitica*, *Vibrio parahaemolyticus, Aeromonas* sp., *Entamoeba histolytica, Giardia*, *Cryptosporidium*, adenovirus, astrovirus, calicivirus, and rotavirus **(**Svenungsson, et al., 2000). Additionally, in a separate study published by the American Society for Microbiology, *Salmonella*, *Campylobacter*, *Shigella*, and STEC (O157 and non-O157) accounted for only 24% of the GI pathogens detected in patients 65 years of age or older. At least three other pathogens were frequently detected in these patients (Buss, et al., 2015).

American College of Gastroenterology (ACG) clinical guidelines recommends the use of broad GIP panels. Due to the substantial overlap in clinical signs and symptoms exhibited by patients with acute GI infections, a broad diagnostic approach may be required. ACG clinical guidelines recognize that "as symptoms of acute diarrhea are protean, attempts to diagnose etiologic agents or classes by symptoms are subjective at best and fraught with imprecision due to overlap in symptoms. Although features of the clinical presentation may be useful in distinguishing bacteria from protozoan causes they are often unreliable indicators of the likely pathogen responsible." Consequently, infectious diarrhea is the second most highly-ranked syndrome in need of improved diagnostics (Blaschke et al., 2015). This is the precise rationale that makes the use of broad multiplex GI panels in clinical practice a necessity (Riddle et al., 2016).

ACG clinical guidelines also recognize the specific advantages provided by more comprehensive NAATs analysis for therapeutic decision-making over other diagnostic approaches. ACG guidelines state that "it is now possible using culture-independent molecular techniques to identify a multitude of bacterial, protozoan and viral diarrheal pathogens including some not commonly identified in clinical laboratories. Diarrheal disease by definition has a broad range of potential pathogens particularly well suited for multiplex molecular testing. "Molecular diagnostic tests can provide a more comprehensive assessment of disease etiology by increasing the diagnostic yield compared with conventional diagnostic tests." (Riddle et al., 2016). This advantage is important for therapeutic decision-making since elderly persons are at an increased risk for severe illness and complications from infectious diarrhea, and benefit from

therapeutic intervention, similar to patients with defined congenital or acquired immunocompromising conditions (Guerrant et al., 2001, Chen et al., 2015, Jagai et al., 2014, Hall et al., 2012). Testing more than five bacterial targets is necessary since alternative diagnoses other than the prioritized "5 targets" (i.e. *Salmonella, Campylobacter, Shigella*, *Cryptosporidium*, Shiga toxin producing *E.coli*), have been shown to benefit from specific therapy (see specific examples below).

1. *Cryptosporidium parvum*: Prolonged symptoms can occur even in immune-competent hosts. A randomized clinical trial study of nitazoxanide demonstrated the efficacy of anti-parasitic treatment in shortening the duration of symptoms and oocyst shedding (Rossignol et al., 2001, Dupont 2016).
2. *Clostridium difficile*: Delays in diagnosis are common and are associated with poor outcomes to treatment. Oral vancomycin can shorten the duration of symptoms (Guerrero et al., 2011).
3. Enteropathogenic/Enteroaggregative *E.coli* Infections in older adults respond to specific antimicrobial treatment (Nataro et al., 2006; Thorén et al., 1980; Wanke et al., 1998; Glandt et al., 1999).
4. Enterotoxigenic *E.coli*: Fluoroquinolone therapy can reduce the duration of symptoms in patients with enterotoxigenic *E.coli* from a mean of 3 days to 1 day (Mattila et al., 1993).
5. *Yersinia enterocolitica:* Symptoms including chronic diarrhea in patients up to 94 years of age can be readily treated with fluoroquinolones (Saebø et al. 1992., Gayraud et al., 1993).
6. *Vibrio:* Fluoroquinolone therapy confers clinical and microbiological response in patients with gastrointestinal *Vibrio* infections. (Butler et al., 1993)
7. *Giardia* – Albendazole and metronidazole improve symptoms and shorten duration of parasite shedding. (Grandados et al., 2012)
8. Amoebic dysentery: Effective options for treatment include metronidazole, tinidazole and secnidazole. (Marie and Petri. 2013.)
9. *Cyclospora:* Treatment reduces the duration of symptoms and parasite shedding in prolonged diarrhea in both immunocompetent and immunocompromised hosts (Hoge et al., 1995).

A comprehensive review of persistent diarrhea by the Journal of the American Medical Association (JAMA) emphasizes the challenges of a broad differential diagnosis, which includes enteropathogenic *E. coli,* enteroaggregative *E. coli*, *Clostridium difficile, Aeromonas, Campylobacter, Salmonella, Shigella,* norovirus, *Entamoeba histolytica, Giardia, Cryptosporidium* and *Cyclospora* (Dupont 2016). This review states that "Culture-independent sequencing diagnostic methods are now available and include a multiplex approach that allows a number of bacterial, viral and parasitic enteropathogens to be detected in a single test simultaneously. These methods are faster and have greater sensitivity than culture-based methods facilitating identification of the many pathogens that must be considered when trying to find the cause of persistent diarrhea." There are an estimated 226,000 foodborne illnesses among U.S. adults ≥ 65 years of age, resulting in approximately 9,700 hospitalizations and 500 deaths, underscoring the burden of foodborne illness in older adults and the need for rapid diagnosis and treatment in this population.

There is evidence that using GIP assays with more than five targets would benefit patients due to the resulting incidental findings. Compelling data suggest that an incidental finding of *C.*

difficile is beneficial, however *C. difficile* is one of the bacterial targets omitted from the draft LCD. Infections due to *C. difficile* are a significant issue for patients in long-term care facilities. A study of a long-term care facility operated by the Department of Veterans Affairs found that delays in diagnosis for *C. difficile* are common and associated with poorer outcomes of treatment (Guerrero et al., 2011). IDSA found that *C .difficile* is the main contributor to gastroenteritis-associated deaths, largely accounting for the increasing trend, with norovirus being the second most common pathogen, often as a co-infection with *C. difficile* (Hall et al., 2012). A lack of clinical suspicion can result in the under-diagnosis of *C. difficile* infection in the community setting (Reigadas et al., 2015). Growing evidence indicates that a substantial burden of *C. difficile* infection is community-acquired, and some of these patients lack traditional risk factors, such as antibiotic exposure or recent hospitalization (Khanna et al., 2012). In the population-based study by Khanna et al., 41% of definite *C. difficile* infection cases were found to be community-acquired, and nearly one-quarter of these cases had no history of recent antibiotic use. **We recommend coverage for GIP assays with more than five targets to include *C. difficile* testing to reflect current practice and improve care for patients.**

Further evidence that patients benefit from incidental detection of unsuspected pathogens is provided by a study that found that routine utilization of a multiplex molecular panel (BioFire Diagnostics, Salt Lake City, UT) for diagnosis, would have led to more rapid detection of a cyclosporiasis outbreak. In the clinical microbiology laboratory, *Cyclospora* testing is typically conducted using a specifically ordered, modified-acid-fast-stained fecal smear. Prior to the recognition of and during the early stages of the cyclosporiasis outbreak, de-identified specimens that tested positive for *Cyclospora* using the FilmArray GI panel in the research study were undetected by the clinical laboratory because modified acid-fast staining had not been not ordered by clinicians. As the medical community became aware of the outbreak, direct analysis of stools for *Cyclospora* became a common practice, and stool specimens enrolled in the clinical study later in the outbreak timeline were more likely to have had *Cyclospora* testing ordered. Routine utilization of NAAT tests consisting of more than five targets as a diagnostic tool would have led to more rapid detection of the cyclosporiasis outbreak, since *Cyclospora* would have been detected before anyone was specifically looking for this parasite (Buss et al., 2013).

The testing of more than five bacterial targets is a significant benefit for immunocompromised patients, including those who are elderly. Immunocompromised individuals are more susceptible to infection with enteric pathogens and are more likely to develop more severe illness and complications. The spectrum of etiologies in normal and immunocompromised hosts is similar (Guerrant et al., 2001), and gastrointestinal pathogens can cause prolonged diarrhea in both immunocompetent and immunocompromised hosts (Hoge et al., 1995, Rossignol et al.2001). One study found that the effects of aging on the immune system manifest at multiple levels that include reduced production of B and T cells in bone marrow and thymus and diminished function of mature lymphocytes in secondary lymphoid tissues. As a result, elderly individuals do not respond to immune challenges as well as the young, qualifying them as immunocompromised (Montecino-Rodriguez et al., 2013). Not expanding the infectious targets beyond those prioritized in this draft LCD may cause infections to be overlooked in susceptible patients, delaying effective treatment. Identifying and treating these patients in a timely manner would greatly benefit Medicare beneficiaries and by extension would also benefit the Medicare program as a whole. Use of this testing strategy leads to actionable diagnoses for Medicare beneficiaries.

It is our recommendation that this draft LCD should be updated to recognize that > 5 targets

must be tested to reach the LCD's stated goal of covering 90-95% of foodborne infections. The LCD should reflect ACG guidelines, which endorse the use of broad GIP panels of > 5 targets and recognize that many of the pathogens detected by multiplex assays have specific treatments that can benefit patients. Clinical scenarios require GIP molecular assays that consist of > 5 targets and are medically necessary for management of Medicare patients with compromised immune systems (which includes the elderly). Patients tested using GIP assays with more than five targets also benefit from incidental findings such as *C. difficile*. Coverage for actionable diagnoses beyond the 5 targets listed in this draft LCD will greatly benefit Medicare patients and improve their healthcare outcomes.

The experts from our organizations who reviewed this policy believe Palmetto's view of actionable pathogens for gastrointestinal diseases is too narrow. There are other pathogens common in the Medicare population that affect the correct diagnosis and therapeutic decision-making of providers. Acute gastroenteritis is a significant cause of morbidity and mortality in the elderly.

Diagnosis of viruses that cause gastroenteritis is medically necessary since they are associated with higher morbidity/mortality rates in the elderly and medical intervention is available. Noroviruses are the leading cause of acute gastroenteritis in the United States and are a frequent cause of outbreaks in long-term care facilities (Wikswo et al., 2015, White et al., 2016). Norovirus is responsible for 10-20% of gastroenteritis hospitalizations and 10-15% of all-cause gastroenteritis deaths in older adults. Individuals 65 years of age and older are at increased risk of severe outcomes, longer length-of-stay and higher costs with attributable mortality rates 200% higher than other patient groups (Lindsay et al., 2015, Belliot et al., 2014). Although norovirus is the most common cause of gastroenteritis outbreaks in long-term care institutions, a substantial percentage of the outbreaks can also be attributed to rotavirus and enteric adenoviruses (Gaspard et al., 2015, Gerber et al. 2011). Older adults that live in retirement communities and long-term care facilities are disproportionately affected by complications of norovirus infection. Norovirus is commonly included in GIP panels but is not listed among those covered in the draft LCD's narrow listing of covered targets. Pathogens like norovirus have specific treatment and infection control implications that can benefit patients and public health.

A correct diagnosis of norovirus affects therapeutic decision-making (*i.e.*, is intervention or prescribing antibiotics necessary?) For example, NAATs allowed for more rapid recognition of norovirus and *C. difficile* infections in elderly patients, in whom diarrhea is often initially incorrectly attributed to laxative use (Salmona et al., 2016). In this situation, a diagnosis is required before the patients are managed by supportive care and hydration. A diagnosis of a viral infection may also prevent the unnecessary use of antibiotics. This approach may, in turn, reduce the rate of *C. difficile* infections associated with antibiotic therapy, and is anticipated to result in cost savings for the Medicare program. A study published by ASM has shown that antibiotic exposure and *C. difficile* infection are closely related (Wenisch et al., 2014). The policy fails to consider the potential benefits to beneficiaries provided by NAATs that exclude or include a diagnosis with specific infection control implications (e.g., norovirus, *C. difficile).* The CDC recommends isolation of patients with norovirus, EPA-approved disinfection procedures, and use of personal protective equipment including masks with eye shields for at least 2 weeks after clinical resolution. This is important, as contact precautions may increase the incidence of delirium and other adverse events for the Medicare beneficiary (Day et al. 2012; Croft et al. 2015). The use of sensitive diagnostic assays can allow accurate case identification, prevent secondary transmission to other Medicare beneficiaries and benefit patients by avoiding

unnecessary contact isolation in those who are not infected (Mattner et al., 2015). **Based on this evidence, we recommend that Palmetto provide coverage for testing of norovirus.** This change would greatly benefit Medicare beneficiaries and by extension benefit the Medicare program as a whole.

As published evidence has shown, the elderly are at increased risk from gastroenteritis but Medicare beneficiaries also include a smaller patient population that is less than 65 years of age (e.g., disabled individuals, patients with amyotrophic lateral sclerosis [ALS] or end stage renal disease). It is essential that any policies regarding coverage for GIP adequately serve the entirety of the Medicare population and ensure that all are properly accounted for under any policy decisions**. It is our recommendation that the draft LCD be revised to recognize that viral pathogens may cause gastrointestinal infections in patients of all ages, and that the Medicare population is at increased risk for complications, hospitalization, and death from these infections.**

Coding

The proposed policy lists ICD-10 codes, A01.00-A05.3 as the only codes that are used to support medical necessity. The ICD-10 coding system contains detailed disease classification pertaining to gastrointestinal infections, many codes of which are relevant to the draft policy that is proposed. We contend that there are more than 80 ICD-10 codes that should be included in this proposed policy. We request that additional ICD-10 codes be added to this policy including, but not limited to, the following list:

CODE	DESCRIPTOR
A00.0	Cholera due to Vibrio cholerae 01, biovar cholerae
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
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
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
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
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
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 exanthem
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
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
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
A09	Infectious gastroenteritis and colitis, unspecified
B99.8	Other and unspecified infectious diseases
B99.9	Unspecified infectious disease
R19.7	Diarrhea, unspecified
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
Z94.7	Corneal transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status

We respectfully ask that you consider these comments, which were prepared by expert panels including members of AMP, APHL, ASM, CAP, IDSA, AGA, and PASCV who provide services to Medicare beneficiaries covered by Palmetto. Without hesitation, we are willing to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Tara Burke, AMP 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,

American Gastroenterological Association
American Society for Microbiology
Association for Molecular Pathology
Association of Public Health Laboratories
College of American Pathologists
Infectious Diseases Society of America
Pan American Society for Clinical Virology

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