Local Coverage Determination (LCD): MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) (L37368)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
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LCD Information

Document Information

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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 in immune competent beneficiaries up to 5 bacterial targets which represent the top 90-95% of foodborne infections ([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 addition, when there is a clinical concern for Clostridium difficile colitis, this contractor will cover up to 11 targets if Clostridium difficile is one of the organisms tested for.

Testing for 12 or more organisms will only be covered in critically ill or immunosuppressed patients.

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. 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.

Summary of Evidence

Traditionally, stool testing algorithms required physicians to consider which specific pathogens that might be associated with individual cases of gastroenteritis, and choose a testing scheme that ensured that all the appropriate pathogens were targeted. In the setting of community-acquired diarrheal illness, large foodborne GIP testing panels for parasites and 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.

Travelers with >2 weeks of symptoms, after bacterial pathogens have been ruled out, may require traditional ova and parasite stool examination and/or specific protozoa antigen or molecular testing. Medicare specifies that testing must be reasonable and necessary for the specific needs of a given patient. Large panels that represent a "one size fits all" approach to testing without regard for a patient's medical history, time of year, clinical setting, and patient symptoms are not reasonable and necessary, and thus not a Medicare benefit. A "one size fits all" panel approach is not restricted to specific population subgroups, such as neonates, pediatrics, or adults, does not differential between community-acquired vs traveler source of infection, and does not differentiate the needs of select patient populations such as the ICU patient or immunocompromised patients. In addition, while identification of specific viruses may be of interest in an outbreak or epidemiologically, clinical management is not predicated on viral test results, and are thus not reasonable and necessary.

This contractor recognizes that GIP assays are closed systems, without random access for physician directed, patient-specific testing. However, some laboratories elect to use GIP panel tests but report only the specific tests ordered by the physician. In other words, and the laboratory "blinds" unnecessary test results or utilize disclaimers in their reporting and bill only for the medically necessary test results. Other laboratories report results of all tests in the panel which adds unnecessary cost to the healthcare system when reimbursement is directly related to the number of organisms in the panel. The FDA approved/cleared assays discussed below are comparable with coverage limited to bacterial organisms for acute diarrhea, with justification of medical necessity recorded in the patient's medical record.

Nucleic Acid Amplified Probe Technique (NAAT) for Identification of Microorganisms:

Tests performed by NAAT uses a microorganism's DNA or RNA to directly identify specific bacteria, viruses, and/or protozoa rather than standard microorganism detection techniques such as bacterial culture, microscopy with and without stains, direct fluorescent antibody testing, rapid antigen testing, qualitative and quantitative immunoassay for identification of antigens or toxins from stool and single-plex PCR assays. Multiplex NAAT tests are included in the larger grouping of culture-independent diagnostic tests (CIDT). CIDT includes but is not limited to simplex direct probe and amplified probe techniques. This technology offers same day results in a matter of hours rather than 2-3 days of time-consuming and labor intensive bacterial cultures and immunoassays for processing stool specimens. CIDT are touted as providing a more comprehensive assessment of disease etiology by increasing the diagnostic yield compared with conventional diagnostic tests permitting earlier initiation of appropriate therapeutic agents targeted to the detected pathogen(s), if any, rather than empirical therapy until culture results are available.

CIDT testing is not without its challenges; latent infections or colonization cannot be distinguished from active, clinically significant infections. Additionally, fragments of nucleic acids from dead microorganisms may cloud organism identification, complicating clinical interpretation, and potentially, clinical management. In a CIDT comparative study, mixed infections were identified in 13-21% of positive prospective stool samples compared to only 8.3% by routine (culture/immunoassay/microscopy) methods.[1] In another recent study, 32.9% of the FilmArray GI Panel-positive specimens were found to contain more than one potential pathogen.[2] The significance of detecting coinfections may be difficult to understand, as the clinical implications of specific pathogen combinations are not well documented or understood. Many GI pathogens can be shed asymptomatically or for prolonged periods of time after symptoms subside, further complicating the interpretation of positive results. For example, Salmonella spp. and norovirus can be shed for weeks to months after symptoms subside. Asymptomatic infection with Cryptosporidium spp. or G. lamblia is common in children.[2] High rates of asymptomatic carriage of enteropathogens, often identified as a co-infection in large microbial panels, create diagnostic confusion by the interpreting clinician.[3]

From a public health and epidemiologic point of view, CIDT testing does not provide the culture isolates that are needed for antimicrobial susceptibility testing, serotyping, subtyping and whole genome sequencing that are critical for monitoring trends, detecting clusters of illness and investigating outbreaks. For Salmonella, the inability to

distinguish serotypes will prevent tracking of important changes in incidence by serotype, and markedly limit detection and investigation of outbreaks (not a Medicare benefit). For Shiga toxin producing E. coli (STEC), because identification of serogroups requires culture, it is not known which STEC-positive CIDT result represents 0157 vs non-0157[4].

FDA-approved GIP Assays:

Five 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.,
    - Enterohemorrhagic 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. dysenteriae, S. boydii, S. sonnei and S. flexneri),
    - Vibrio Group (comprised of V. cholera and V. parahaemolyticus),
    - 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 cholerae,
        - 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.

All targeted viruses included in GIPs are more prevalent in young children than in adults. In one study, Sapovirus was detected in 10% of all specimens from children >1 year old and 7.4% of specimens from children between 1 to 5 years of age.[2]

Enteropathogenic E. coli (EPEC), historically associated with developing countries, are known to cause both acute and persistent diarrhea in 2 young children in the US and were identified in one study in 24.8% of all samples collected from children<1 year of age, and 37% of all samples from children between age of 1 and 5 years. EPEC strains can also be found in healthy children and adults, thus confounding its significance when identified in symptomatic children and adults.

Similarly, the interpretation of C. difficile toxin A/B detection is also complicated, especially in children <1 year old. The American Academy of Pediatrics does not recommend routine testing for C. difficile in children <1 year of age and suggests that positive C. difficile results be interpreted with suspicion in children <3 years old[5].

Most recently a publication looking at Syndromic Panel-Based Testing, specifically the multiplex detection of GI pathogens, states that it makes it difficult the interpretation of a positive results in asymptomatic individuals colonized with C. difficile. Patients experiencing diarrhea associated with antecedent of antibiotic or hospitalization are at risk for C. difficile infection; in such cases specific testing for C. difficile is most cost-effective. GIP's detection

of multiple targets has created confusion for healthcare providers that now faced with results that were not previously reported and for which current guidelines provide no direction as to management (treatment, clinical significance or the need for additional or repeat testing)[12].

A meta-analysis (of 10 studies) by NHS in UK found that GIP testing produces a greater number of pathogen-positive findings than conventional testing. It is unclear whether or not these additional "positives" are clinically important. The review identified no robust evidence to inform consequent clinical management of patients. There is considerable uncertainty about cost-effectiveness of GIP panels used to test for suspected infectious gastroenteritis in hospital and community settings. The systemic review and cost-effectiveness model identify uncertainties about the adoption of GIP tests. GIP testing will generally identify pathogens identified by conventional testing, however, these tests also generate considerable additional positive results of uncertain clinical importance[13].

Indications for Foodborne GI Testing

Acute diarrhea, often called gastroenteritis, can be defined as the passage of a greater number of stools of decreased form from the normal lasting < 14 days. Acute diarrhea is generally associated with clinical features of nausea, vomiting, abdominal pain and cramps, bloating, flatulence, fever, passage of bloody stools, tenesmus and fecal urgency. It is the leading cause of outpatient visits, hospitalizations, and lost quality of life occurring domestically and those traveling abroad. The Centers for Disease Control and Prevention (CDC) has estimated 47.8M cases occurring annually in the US with an estimated healthcare cost upwards of US$150M.[6] Detection of microbial pathogens associated with GI disease may be important in certain populations, such as immunocompromised hosts, the critically ill and individuals with prolonged disease that is refractory to treatment.

Over a 20 year period, some foods that have been linked to food-borne outbreaks including milk (Campylobacter), shellfish (Noroviruses), unpasteurized apple cider (Escherichia coli O157:H7), raw and undercooked eggs (Salmonella), fish (ciguatera poisoning), raspberries (Cyclospora); strawberries (Hepatitis A virus); and ready-to-eat meats (Listeria).[7]

Although the etiologic agents responsible for about 80% of GI illnesses are unidentified or otherwise unspecified, Norovirus and Salmonella spp (non-typhoidal) are currently the most commonly identified pathogens associated with food-borne disease in the US and account for 5.5 and 1.0 million cases each year, respectively.[8] Clostridium perfringens, Campylobacter and Staphylococcus aureus follow Norovirus and Salmonella spp. in decreasing frequency in domestically acquired foodborne illnesses. Healthcare- and antibiotic-associated diarrhea is also problematic, with the major causative pathogen being toxin-producing Clostridium difficile[9]. In the US, >300,000 cases of C. difficile are diagnosed annually, with associated costs of >$1 billion.

In 2015, the number and incidence of confirmed infections per 100,000 population were reported for Salmonella (15.89), Campylobacter (12.97), Shigella (5.53), Cryptosporidium (3.31), Shiga-toxin producing Escherichia coli (STEC) non-O157 (1.64), STEC O157 (.95), Vibrio (0.39), Yersinia (0.29), Listeria (0.24) and Cyclospora (0.13).[4] Among confirmed infections, the vast majority were diagnosed only by culture. Compared with incidence in 2012-2014, the incidence of confirmed infections was significantly higher for STEC non-O157 (40% increase) and Cryptosporidium (57% increase). No significant changes were observed in 2015 for other pathogens compared with the previous 3-year averages. In addition to the 20,107 confirmed cases of infection, there were 3,112 positive CIDT case reports. In general, the incidence of most foodborne bacterial pathogens and for Cryptosporidium is highest among children aged <5, except for Listeria and Vibrio for which the highest incidence is among persons aged ≥ 65 years.[10]

Many episodes of acute diarrhea are self-limited and require fluid replacement and supportive care. Oral rehydration is indicated for patients who are mildly to moderately dehydrated. IV fluids may be required for more severe dehydration. Routine use of antidiarrheal agents is not recommended because many of these agents have potentially

serious adverse effects, particularly in infants and young children. Antimicrobial therapy is warranted only for patients with severe disease or for individuals with immune systems are severely weakened from medications and other illnesses.[11]

Laboratory testing algorithms for infectious causes of diarrhea generally agree that testing is NOT warranted for community-acquired diarrhea of <7 days duration without signs or symptoms of severe (fever, bloody diarrhea, dysentery, severe abdominal pain, dehydration, hospitalization and immunocompromised state) disease. In general, when community-acquired diarrhea persists for ≥7 days, or the diarrhea is travel-related, or there are signs/symptoms of severe disease, GIP testing may be warranted. Additional directed testing may be indicated if the GIP results are negative and diarrhea persists. No additional testing is indicated for GIP-positive result unless the clinical pictures changes. Clostridium difficile molecular testing is warranted on health-care associated diarrhea with onset after the 3rd inpatient day or after recent antibiotic use.

Analysis of Evidence
(Rationale for Determination)

Level of Evidence

Quality of Evidence: Moderate

Strength of Evidence: Moderate

Weight of Evidence: Moderate

Summary Medicare Coverage Decision:

GIP testing is limited to no more than 5 bacterial pathogen targets when not testing for Clostridium difficile. Testing for 6-11 pathogens is covered when there is a clinical concern for Clostridium Difficile colitis, and Clostridium difficile is one of the pathogens being tested.

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. Travelers with >2weeks of symptoms, after bacterial pathogens have been ruled out, may require traditional ova and parasite stool examination and/or specific protozoa antigen or molecular testing. Large panels inclusive of 11 viruses and protozoa are not reasonable and necessary for community-acquired diarrheal illness. There is no Medicare benefit for GIP testing for national, state or local agency tracking of diarrheal outbreaks, for epidemiologic purposes, or to confirm another etiologic test result. Once the target etiology of an outbreak is identified, subsequent patient testing is generally not indicated and patients are managed empirically. However, if the clinical presentation varies from the outbreak prototype, a specific test for the causative 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 community tracking or surveillance.

Limitations

A GIP test **panel** is a single service with a single unit of service (UOS =1). A panel cannot be unbundled and billed as individual components regardless of the fact that the GIP test reports multiple individual pathogens and/or targets. The panel is a closed system performed on a single platform, and as such, is a single test panel with multiple components (UOS=1). If C. difficile is not included in a GIP panel, testing for C. difficile may be reasonable and necessary when ordered in addition to a GIP bacterial pathogen panel and supported by documentation in the medical record.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type.Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

These codes are covered

Group 1 Codes:

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

CODE	DESCRIPTION
	TECHNIQUE, MULTIPLE TYPES OR SUBTYPES, 6-11 TARGETS

Group 2 Paragraph:

This code is covered in beneficiaries with immunodeficiency

Group 2 Codes:

CODE	DESCRIPTION
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

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

One of the following diagnosis codes must be on the claim to bill for 87505. To bill for 87506, the claim must contain A04.71 or A04.72 plus at least one other code from the list.

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
A01.00	Typhoid fever, unspecified
A02.0	Salmonella enteritis
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
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohemorrhagic Escherichia coli infection
A04.5	Campylobacter enteritis
A04.6	Enteritis due to Yersinia enterocolitica
A04.71	Enterocolitis due to Clostridium difficile, recurrent

ICD-10 CODE	DESCRIPTION
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent
A04.8	Other specified bacterial intestinal infections
A05.0	Foodborne staphylococcal intoxication
A05.1	Botulism food poisoning
A05.2	Foodborne Clostridium perfringens [Clostridium welchii] intoxication
A05.3	Foodborne Vibrio parahaemolyticus intoxication
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
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
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
D81.3	Adenosine deaminase [ADA] 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
D81.819	Biotin-dependent carboxylase deficiency, unspecified
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome

ICD-10 CODE	DESCRIPTION
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
D82.9	Immunodeficiency associated with major defect, unspecified
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
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D84.9	Immunodeficiency, unspecified
D89.0	Polyclonal hypergammaglobulinemia
D89.1	Cryoglobulinemia
D89.2	Hypergammaglobulinemia, unspecified
D89.3	Immune reconstitution syndrome
D89.40	Mast cell activation, unspecified
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
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified

ICD-10 CODE	DESCRIPTION
D89.9	Disorder involving the immune mechanism, unspecified
Y92.239	Unspecified place in hospital as the place of occurrence of the external cause
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

Group 2 Paragraph:

To bill for 87507, one of the following diagnoses must be on the claim.

Group 2 Codes:

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
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers

ICD-10 CODE	DESCRIPTION
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.3	Adenosine deaminase [ADA] 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
D81.819	Biotin-dependent carboxylase deficiency, unspecified
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
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
D82.9	Immunodeficiency associated with major defect, unspecified
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
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D84.9	Immunodeficiency, unspecified
D89.0	Polyclonal hypergammaglobulinemia
D89.1	Cryoglobulinemia
D89.2	Hypergammaglobulinemia, unspecified

ICD-10 CODE	DESCRIPTION
D89.3	Immune reconstitution syndrome
D89.40	Mast cell activation, unspecified
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
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
D89.9	Disorder involving the immune mechanism, unspecified
Y92.239	Unspecified place in hospital as the place of occurrence of the external cause
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

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
02/11/2019	R2	12/21/2018: Removal of verbiage 'in addition to a diagnosis code from Group 1' from Group 2 Paragraph per Palmetto GBA.	• Creation of Uniform LCDs With Other MAC Jurisdiction

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
02/11/2019	R1	LCD revised to add E. histolytica, Adenovirus 40/41 and Vibrio cholera under **FDA approved GIP Assays** for **Luminex's xTAG Gastroenterology Pathogen Panel (GPP)** Target identified.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Typographical Error

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A56207 - Response to Comments: MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs)
LCD(s)
DL37368 - MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 12/26/2018 with effective dates 02/11/2019 - N/A
Updated on 12/20/2018 with effective dates 02/11/2019 - N/A
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Keywords

- 87505
- 87506
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- Foodborne
- Gastrointestinal
- Multiplex
- Nucleic Acid
- Amplification
- NAATs