

CONCERT INFECTIOUS DISEASE: GASTROENTEROLOGY TESTING

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

OVERVIEW

This policy addresses the use of tests for gastrointestinal (GI) pathogens, including *Helicobacter pylori* (*H. pylori*), as well as amylase, lipase, liver function panels, and blood-based non-invasive liver fibrosis.

For additional information see the [Rationale and References](#) section.

Note: Please see *Concert Genetic Testing: Gastroenterology* for genetic and molecular gastroenterologic testing criteria.

POLICY REFERENCE TABLE

Criteria Sections	Example Tests (Labs)	Support
Gastrointestinal Pathogen Panel Tests		
Syndromic Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets	Enteric Bacterial Panel by PCR (Cleveland Clinic Laboratories)	Rationale/References
	Gastrointestinal Pathogen Panel, Real-Time PCR (Quest Diagnostics)	

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<u>Criteria Sections</u>	Example Tests (Labs)	Support
Syndromic Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets	The BioFire® FilmArray® Gastrointestinal (GI) Panel	Rationale/References
	GI assay (Gastrointestinal Pathogen with ABR) (Lab Genomics LLC)	
<u>Helicobacter pylori (H. pylori) Tests</u>		
Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests	Helicobacter pylori Breath Test (Mayo Clinic Laboratories)	Rationale/References
	Helicobacter pylori Stool Antigen (LabCorp)	
Helicobacter pylori (H. pylori) Antibody Tests	Helicobacter pylori Antibody, IgG, Serum (University of Michigan Laboratories)	Rationale/References
<u>Pancreatitis</u>		
Amylase Tests	Amylase (LabCorp)	Rationale/References
Lipase Tests	Lipase, Fluid (ARUP Laboratories)	Rationale/References
<u>Noninvasive Liver Disease Tests</u>		
Liver Function Panel Tests	Hepatic Function Panel (ARUP Laboratories)	Rationale/References
Blood-based Noninvasive Liver Fibrosis Screening Tests	Liver Fibrosis FIB-4 (LabCorp)	Rationale/References
	Liver Fibrosis, Fibrosis-4 (FIB-4) Index Panel (Quest Diagnostics)	

CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific tests noted below are **medically necessary** when meeting the related criteria:

GASTROINTESTINAL PATHOGEN PANEL TESTS

Syndromic Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets

- I. Syndromic/multiplex gastrointestinal pathogen panels with 11 or Fewer targets are considered **medically necessary** when:
 - A. The member/enrollee presents in the outpatient setting with suspected infectious [gastroenteritis](#), **AND**
 - B. The member/enrollee has at least one of the following:
 1. Immunocompromised status (e.g., HIV/AIDS, immunosuppression therapy, primary immunodeficiency), **OR**
 2. Recent travel to/contact with travelers from an infectious diarrheal disease-endemic area, **OR**
 3. Dysentery (presence of blood or mucus in stool), **OR**
 4. Fever, **OR**
 5. Dehydration, **OR**
 6. Abdominal pain/tenderness, **OR**
 7. Bacteremia, **OR**
 8. Diarrhea persisting longer than 7 days, **OR**
 9. [Symptoms of enteric fever](#) (i.e., Typhoid/paratyphoid fever), **AND**
 - C. Results of the testing will influence the member/enrollee's clinical management.
- II. Syndromic/multiplex gastrointestinal pathogen panels with 11 or fewer targets are considered **medically necessary** once per incident of diarrheal disease, or no more than

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once per 14-day period.

- III. Current evidence does not support syndromic/multiplex gastrointestinal pathogen panels with 11 or fewer targets for all other indications.

Syndromic Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets

- I. Syndromic/multiplex gastrointestinal pathogen panels with 12 or more targets are considered **medically necessary** when:
 - A. The member/enrollee presents in the outpatient setting with suspected infectious [gastroenteritis](#), **AND**
 - B. The member/enrollee has at least one of the following:
 - 1. Immunocompromised status (e.g., HIV/AIDS, immunosuppression therapy, primary immunodeficiency), **OR**
 - 2. Recent travel to/contact with travelers from an infectious diarrheal disease-endemic area, **OR**
 - 3. Bacteremia, **OR**
 - 4. [Symptoms of enteric fever](#) (i.e., Typhoid/paratyphoid fever), **AND**
 - C. Results of the testing will influence the member/enrollee's clinical management.
- II. Syndromic/multiplex gastrointestinal pathogen panels with 12 or more targets are considered **medically necessary** once per incident of diarrheal disease, or no more than once per 14-day period.
- III. Current evidence does not support syndromic/multiplex gastrointestinal pathogen panels with 12 or more targets for all other indications.

HELICOBACTER PYLORI (H. pylori) TESTS

Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests

- I. *H. pylori* urea breath or stool antigen tests are considered **medically necessary** when:
 - A. The member/enrollee is receiving a test-of-cure after treatment for *H. pylori* infection, **OR**

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B. The member/enrollee is 17 years of age or younger, **AND**

1. Has gastric or duodenal ulcers and/or erosions, **OR**
2. Has a [first-degree relative](#) with gastric cancer, **OR**

C. The member/enrollee is 18 years of age or older, **AND**

1. Is symptomatic (i.e., has current or past signs/symptoms of *H. pylori* infection), **AND**

a) Has at least one of the following:

- 1) Active peptic ulcer disease (PUD), **OR**
- 2) Low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma, **OR**
- 3) Unexplained iron deficiency (ID) anemia despite an appropriate evaluation, **OR**
- 4) Idiopathic thrombocytopenic purpura (ITP), **OR**
- 5) Personal history of endoscopic resection of early gastric cancer (EGC), **OR**
- 6) Personal history of gastric premalignant conditions (including atrophic gastritis, intestinal metaplasia, and dysplasia), **OR**
- 7) Personal history of gastric adenocarcinoma, **OR**
- 8) Personal history of gastric adenomas or hyperplastic polyps, **OR**
- 9) Personal history of autoimmune gastritis, **OR**
- 10) Past history of PUD, **AND**

(a) Previous cure of *H. pylori* infection has **NOT** been documented, **OR**

11) Dyspepsia, **AND**

- (a) Is younger than 60 years of age, **AND**
- (b) Does **NOT** have dyspepsia alarm features (e.g., vomiting, dysphagia, unintended weight loss, gastrointestinal bleeding, palpable mass or

lymphadenopathy), **AND**

(c) Has [uninvestigated dyspepsia](#), **OR**

2. Is asymptomatic (i.e., does **NOT** have current or past signs/symptoms of *H. pylori* infection), **AND**
 - a) At least one of the following:
 - 1) The member/enrollee is initiating prophylactic low-dose aspirin (e.g., following a major cardiovascular event), **OR**
 - 2) The member/enrollee is initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID), **OR**
 - 3) Has a [first-degree relative](#) with gastric cancer, **OR**
 - 4) Has a hereditary syndrome associated with an increased risk for gastric cancer, **OR**
3. Is at increased risk for *H. pylori* infection (e.g., household member with *H. pylori* infection, race or ethnicity associated with high prevalence of *H. pylori* infection/incidence of gastric cancer, or immigration from a region with high incidence of gastric cancer).

II. Current evidence does not support *H. pylori* urea breath or stool antigen tests for all other indications, including, but not limited to:

- A. For the evaluation of average risk individuals with GERD or hyperemesis gravidarum.
- B. Children and adolescents with functional abdominal pain or short stature.

***Helicobacter pylori* (*H. pylori*) Antibody Tests**

- I. Current evidence does not support *H. pylori* antibody tests for all indications.

PANCREATITIS

Amylase Tests

- I. Amylase tests are considered **medically necessary** when:
 - A. The member/enrollee has a pancreatic cyst, **OR**
 - B. The member/enrollee has a transplanted pancreas, **OR**

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- C. The member/enrollee has a diagnosis or [signs/symptoms of an eating disorder](#).
- II. Current evidence does not support the use of amylase tests for all other indications, including for evaluation of suspected pancreatitis.

Lipase Tests

- I. Lipase tests are considered **medically necessary** when:
 - A. The member/enrollee has signs/symptoms of one of the following:
 - 1. Acute pancreatitis, **OR**
 - 2. Cyclic Vomiting Syndrome (CVS), **OR**
 - 3. Blockage of the pancreatic duct, **OR**
 - 4. Development of a pancreatic pseudocyst, **OR**
 - B. The member/enrollee has a pancreatic cyst, **OR**
 - C. The member/enrollee has a transplanted pancreas.
- II. Current evidence does not support the use of lipase tests for all other indications.

NONINVASIVE LIVER DISEASE TESTS

Liver Function Panel Tests

- I. Liver function panel testing is considered **medically necessary** when:
 - A. The member/enrollee has [signs/symptoms of liver dysfunction](#), **OR**
 - B. The member/enrollee has increased [risk factors for liver dysfunction](#), **OR**
 - C. The member/enrollee had previously abnormal liver chemistries.
- II. Current evidence does not support liver function panel testing for routine screening purposes, including for annual evaluation of asymptomatic members/enrollees with no increased [risk factors for liver dysfunction](#).

Blood-based Noninvasive Liver Fibrosis Screening Tests

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- I. Blood-based noninvasive liver fibrosis screening tests (e.g., [Fibrosis-4 index \(FIB-4\)](#), [NAFLD Fibrosis Score \(NFS\)](#), AST to Platelet Ratio Index (APRI)) are considered **medically necessary** when:
 - A. The member/enrollee has at least one of the following:
 1. [Signs/symptoms or a diagnosis of chronic liver disease](#), **OR**
 2. Abnormal liver chemistries, **OR**
 3. Hepatic steatosis on imaging, **OR**
 4. Prediabetes/type 2 diabetes mellitus, **OR**
 5. Features of metabolic syndrome (e.g. dyslipidemia, obesity), **OR**
 6. Significant alcohol consumption, **OR**
 7. A [first-degree relative](#) with metabolic associated steatohepatitis (MASH) (formerly, nonalcoholic steatohepatitis [NASH]) cirrhosis.
- II. Current evidence does not support the use of blood-based noninvasive liver fibrosis screening tests (e.g., FIB-4, NFS, APRI) for all other indications.

RATIONALE AND REFERENCES

Syndromic/Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets

American College of Gastroenterology (ACG)

ACG makes the following general recommendations in their 2016 guidelines regarding diagnostic testing for suspected diarrheal infections:

- Stool diagnostic studies may be used if available in cases of dysentery, moderate-to-severe disease, and symptoms lasting >7 days to clarify the etiology of the patient's illness and enable specific directed therapy. (Strong recommendation, very low level of evidence).

The guideline acknowledges the benefit of multiplex molecular testing for diarrheal disease, but does not provide specific guidance regarding recommended panel content.

“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” (p. 606).

Regarding repeat testing for persistent symptoms, the ACG guideline states:

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- Serological and clinical lab testing in individuals with persistent diarrheal symptoms (between 14 and 30 days) is not recommended (Strong recommendation, very low level of evidence) (p. 611).

Riddle MS, DuPont HL, Connor BA. ACG Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults. *Am J Gastroenterol*. 2016;111(5):602-622. doi:10.1038/ajg.2016.126

Infectious Diseases Society of America (IDSA)

In their 2017 guidelines for infectious diarrhea, the IDSA stated the following: “Although the majority of diarrheal illnesses are self-limited and identification of the infectious etiology often has little value to these individual patients, for certain infections, an organism-specific diagnosis is important to guiding clinical management. However, testing all patients with acute diarrhea for these pathogens would be inefficient... Restricting testing to patients with bloody stools, fever, or abdominal tenderness can increase the likelihood of identifying a bacterial pathogen” (p. e60).

The IDSA outlines several highly specific clinical recommendations regarding diagnostic evaluation for specific pathogens and/or testing methods based on the presentation of a patient with suspected infectious diarrhea. They also summarize many exposures or conditions and the pathogens associated with each (Table 2, p. e48).

Among these pathogen associations, no exposures or situations included are associated with more than 11 pathogens, outside of “travel to a resource-challenged country”. Additionally, the guideline recommends considering a “broader set of bacterial, viral, and parasitic agents” for patients with immunocompromisation/AIDS, suspected disease outbreak (for the purposes of public health coordination), and suspected enteric fever or diarrhea with bacteremia (p. e47).

Shane AL, Mody RK, Crump JA, Tarr PI, Steiner TS, Kotloff K, Langley JM, Wanke C, Warren CA, Cheng AC, Cantey J, Pickering LK. 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80. PMID: 29053792; PMCID: PMC5850553. doi:10.1093/cid/cix669.

Syndromic/Multiplex Gastrointestinal Pathogen Panels with 12 or More Targets

American College of Gastroenterology (ACG)

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- Stool diagnostic studies may be used if available in cases of dysentery, moderate-to-severe disease, and symptoms lasting >7 days to clarify the etiology of the patient’s illness and enable specific directed therapy. (Strong recommendation, very low level of evidence)

The guideline acknowledges the benefit of multiplex molecular testing for diarrheal disease, but does not provide specific guidance regarding recommended panel content.

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Shane AL, Mody RK, Crump JA, Tarr PI, Steiner TS, Kotloff K, Langley JM, Wanke C, Warren CA, Cheng AC, Cantey J, Pickering LK. 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. *Clin Infect Dis*. 2017 Nov 29;65(12):e45-e80. PMID: 29053792; PMCID: PMC5850553. doi:10.1093/cid/cix669.

Helicobacter pylori (H. pylori) Urea Breath or Stool Antigen Tests

American College of Gastroenterology (ACG)

In their 2024 guidelines, the ACG recommends testing for and treating *H. pylori* infection for all indications listed in Table 4:

- Prior or active peptic ulcer disease
- History of marginal zone B-cell lymphoma (MALT type)
- Uninvestigated dyspepsia in any patient under the age of 60 years, or between 45-50 years of age for patient populations at high risk for gastric cancer
- Functional dyspepsia

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- Individuals age 18 years or older who share a household with someone who has a positive non-serological test for *H. pylori*
- Patients who are taking long-term NSAIDS
- Patients who are starting long-term treatment for low-dose aspirin
- Unexplained iron deficiency anemia
- Idiopathic thrombocytopenic purpura (autoimmune condition)
- Current or prior diagnosis of gastric premalignant conditions (examples include: atrophic gastritis, intestinal metaplasia, and dysplasia)
- Current or prior history of resection of early gastric cancer
- Current or prior history of gastric adenocarcinoma
- Current or prior history of gastric adenomas or hyperplastic polyps
- Individuals with a first-degree relative with a history of gastric cancer
- Individuals who are at increased risk for gastric cancer due to factors such as: belonging to certain non-White racial or ethnic groups¹, those immigrating from a region with a high incidence of gastric cancer, and hereditary cancer syndromes associated with a higher risk for gastric cancer
- Current or prior history of autoimmune gastritis (p. 1735)

Additionally, they recommend that patients receive a test-of-cure via urea breath test, fecal antigen test, or biopsy-based test at least 4 weeks after completion of treatment for *H. pylori* infection (p. 1742).

¹There is a documented disparity in age-standardized incidence rates of noncardia cancer in the United States. Rates in many non-White races and ethnicities are at least doubled compared to those in non-Hispanic whites, including Asian, Black, Hispanic, and American Indian individuals. (p. 1735) The prevalence of *H. pylori* infection is also disproportionately distributed by race and ethnicity in the United States, with higher rates observed in Black and Hispanic populations compared to the non-Hispanic White population (p. 1733).

Chey WD, Howden CW, Moss SF, et al. ACG clinical guideline: treatment of *Helicobacter pylori* infection. *Am J Gastroenterol*. 2024;119(9):1730-1753. doi:10.14309/ajg.0000000000002968

European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)

The following recommendations from the updated joint ESPGHAN/NASPGHAN guidelines for management of *Helicobacter pylori* infection in children and adolescents (2023) are pertinent to the testing of children and adolescents for *H. pylori* infection (see publicly available guideline for full list of recommendations):

- Testing for *H. pylori* is recommended for children with gastric or duodenal ulcers and/or erosions.
- Noninvasive testing for *H. pylori* is suggested for children with a history of gastric cancer in a first-degree relative.
- Diagnostic testing for *H. pylori* infection in children with functional abdominal pain is not indicated.

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- Non-invasive testing for *H. pylori* infection as part of the initial investigation in children with iron deficiency anemia is recommended against.
- Testing for *H. pylori* infection when investigating causes of chronic immune thrombocytopenic purpura (ITP) is suggested against.
- Testing for *H. pylori* infection when investigating causes of short stature is recommended against (p. 761).

Additionally, the authors note that current evidence indicates that *H. pylori* infection is asymptomatic in children, outside of peptic ulcer disease and/or erosions. Therefore, noninvasive testing to detect infection is not indicated. They conclude that there is no evidence to support a “test and treat” strategy in children (p. 760).

Homan M, Jones NL, Bontems P, et al. Updated joint ESPGHAN/NASPGHAN guidelines for management of Helicobacter pylori infection in children and adolescents (2023). J Pediatr Gastroenterol Nutr. 2024;79(3):758-785. doi:10.1002/jpn3.12314

Helicobacter pylori (*H. pylori*) Antibody Tests

American College of Gastroenterology (ACG)

In their 2024 guidelines, the ACG recommends that serum *H. pylori* antibody tests should not be used post-treatment to establish a patient’s status, as these antibody levels can be detectable for a significant period of time (months or years) even if *H. pylori* has been successfully eradicated (p. 1742). Aside from this statement, the 2024 guideline does not include a discussion of testing methodologies, instead referring to previous clinical practice guidelines (p. 1731).

The guideline acknowledged a rare appropriate indication for *H. pylori* antibody testing in patients with documented peptic ulcer disease; however, they further state that the ideal test is one that can differentiate between active/current and past infection: "Ideally, tests which identify active infection such as a urea breath test, fecal antigen test, or when endoscopy is performed, mucosal biopsy-based testing should be utilized" (p. 216).

Chey WD, Howden CW, Moss SF, et al. ACG clinical guideline: treatment of Helicobacter pylori infection. Am J Gastroenterol. 2024;119(9):1730-1753. doi:10.14309/ajg.0000000000002968

European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)

The updated joint ESPGHAN/NASPGHAN guidelines for management of Helicobacter pylori infection in children and adolescents (2023) include a recommendation against the use of antibody-based tests for *H. pylori* in serum, whole blood, urine, and saliva, in the clinical setting (p. 762, table 1).

Homan M, Jones NL, Bontems P, et al. Updated joint ESPGHAN/NASPGHAN guidelines for management of Helicobacter pylori infection in children and adolescents (2023). J Pediatr Gastroenterol Nutr. 2024;79(3):758-785. doi:10.1002/jpn3.12314

Amylase Tests

American Academy of Family Physicians (AAFP)

In the publication, “Rapid Evidence Review: Pancreatitis” (2022), the AAFP includes the Choosing Wisely recommendation against the use of amylase tests in the case of suspected acute pancreatitis. Lipase is preferred over total and pancreatic amylase for the initial diagnosis of acute pancreatitis (p. 44).

Oppenlander KE, Chadwick C, Carman K. Acute Pancreatitis: Rapid Evidence Review. *Am Fam Physician*. 2022;106(1):44-50.

In the AAFP article, “Eating Disorders in Primary Care: Diagnosis and Management” (2021), amylase measurement is recommended for those with a suspected or diagnosed eating disorder (p. 26). Characteristics of eating disorders, as defined above, are outlined in table 1 (p. 23).

Klein D, Sylvester J, Schvey N. Eating Disorders in Primary Care: Diagnosis and Management. *Am Fam Physician*. 2021;103(1):22-32.

American College of Gastroenterology (ACG)

In the publication, “ACG Guidelines: Management of Acute pancreatitis” (2024) the authors conclude that due to poor sensitivity and negative predictive value, serum amylase cannot be used reliably for the diagnosis of acute pancreatitis. Serum lipase is preferred. It is further noted that amylase may remain within normal range after an acute pancreatic event. Serum lipase is more specific and remains elevated longer than amylase following disease presentation. In absence of abdominal pain consistent with acute pancreatitis, elevations of amylase and lipase fail to predict the development of acute pancreatitis (p. 420-421).

Tenner S, Vege SS, Sheth SG, et al. American College of Gastroenterology Guidelines: Management of Acute Pancreatitis. *Am J Gastroenterol*. 2024;119(3):419-437. doi:10.14309/ajg.0000000000002645

In the article, “ACG Clinical Guideline: Diagnosis and Management of Pancreatic Cysts” (2018), the authors suggest that assessment of cyst fluid amylase levels can be helpful, as very low levels (<250 IU/l) exclude a pseudocyst in 98% of cases (p. 471). Excluding a pseudocyst is clinically useful because pseudocysts do not require surveillance or treatment when they are asymptomatic, as they have no malignant potential (p. 465).

Elta GH, Enestvedt BK, Sauer BG, Lennon AM. ACG Clinical Guideline: diagnosis and management of pancreatic cysts. *Am J Gastroenterol*. 2018;113(4):464-479. doi:10.1038/ajg.2018.14

Rao

There are no formally established, universally accepted guidelines for clinical surveillance after pancreas transplantation. However, assessment of pancreatic enzymes and metabolic markers is

In the clinical practice resource, Pancreas Transplantation Treatment & Management, the authors state that following pancreas transplant, patients are monitored for the lifetime of the transplanted organ for signs of infection and rejection. Testing can include electrolytes, complete blood count, blood urea nitrogen (BUN) and serum creatinine, glucose, serum amylase and lipase, immunosuppressive drug blood levels, and surveillance for CMV, Epstein-Barr virus, and BK virus infection.

Rao J. Pancreas Transplantation Treatment & Management. MedScape. Updated April 13, 2022.
<https://emedicine.medscape.com/article/429408-treatment#d10>

Lipase Tests

American College of Gastroenterology (ACG)

In the publication, “ACG Guidelines: Management of Acute Pancreatitis” (2024), the authors recommend measuring lipase for laboratory diagnosis of acute pancreatitis. Once the diagnosis is established, repeat analysis of lipase is not recommended. Monitoring lipase levels is not useful in predicting severity, assessing prognosis, or aiding clinical decision-making (p. 420-421).

Tenner S, Vege SS, Sheth SG, et al. American College of Gastroenterology Guidelines: Management of Acute Pancreatitis. The American Journal of Gastroenterology. 2024;119(3):419-437. doi:10.14309/ajg.0000000000002645

American Gastroenterological Association (AGA)

In the publication, “AGA Clinical Practice Update on Diagnosis and Management of Cyclic Vomiting Syndrome: Commentary” (2024), the basic workup for uninvestigated, episodic vomiting should include assessment of lipase (p. 809).

Signs and symptoms of cyclical vomiting syndrome can include recurrent episodes of acute-onset vomiting lasting less than 7 days, occasional vomiting, changes in cognition/affect, nausea, dyspepsia, bowel urgency, acute diarrhea or constipation, abdominal pain, headache, excessive sweating, shakiness, and flushing (p. 805-806).

Levinthal DJ, Staller K, Venkatesan T. AGA Clinical Practice Update on Diagnosis and Management of Cyclic Vomiting Syndrome: Commentary. Gastroenterology. 2024;167(4):804-811.e1. doi:10.1053/j.gastro.2024.05.031

American Academy of Family Physicians (AAFP)

In the publication, “Rapid Evidence Review: Pancreatitis” (2022), the AAFP includes the Choosing Wisely recommendation that lipase is preferred over total and pancreatic amylase for the initial diagnosis of acute pancreatitis. Assessment should not be repeated to monitor disease prognosis. Repeat testing should only be considered when the patient has signs and symptoms of persisting pancreatic or peripancreatic inflammation, blockage of the pancreatic duct, or development of a

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pancreatic pseudocyst (p. 44-45).

Oppenlander KE, Chadwick C, Carman K. Acute Pancreatitis: Rapid Evidence Review. Am Fam Physician. 2022;106(1):44-50.

American College of Gastroenterology (ACG)

In the publication, “ACG Clinical Guideline: Diagnosis and Management of Pancreatic Cysts” (2018), the authors suggest that when pancreatic cyst diagnosis is uncertain, fine needle aspirate and assessment of cyst fluid can be helpful in excluding a pseudocyst. They state that pseudocyst aspirates usually have very high cyst fluid lipase or amylase. Excluding a pseudocyst is clinically useful because pseudocysts do not require surveillance or treatment when they are asymptomatic, as they have no malignant potential (p. 465).

Elta GH, Enestvedt BK, Sauer BG, Lennon AM. ACG Clinical Guideline: diagnosis and management of pancreatic cysts. Am J Gastroenterol. 2018;113(4):464-479. doi:10.1038/ajg.2018.14

Rao

There are no formally established, universally accepted guidelines for clinical surveillance after pancreas transplantation. However, assessment of pancreatic enzymes and metabolic markers is routinely performed to monitor for complications.

In the clinical practice resource, “Pancreas Transplantation Treatment & Management”, the authors state that following pancreas transplant, patients are monitored for the lifetime of the transplanted organ for signs of infection and rejection. Testing can include electrolytes, complete blood count, blood urea nitrogen (BUN) and serum creatinine, glucose, serum amylase and lipase, immunosuppressive drug blood levels, and surveillance for CMV, Epstein-Barr virus, and BK virus infection.

Rao J. Pancreas Transplantation Treatment & Management. MedScape. Updated April 13, 2022.
<https://emedicine.medscape.com/article/429408-treatment#d10>

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

In the publication “Pancreatitis” (2017) the NIDDK lists the following symptoms of acute pancreatitis: abdominal pain, back pain, fever, nausea, vomiting, fast heart rate, swollen/tender abdomen. Signs and symptoms of chronic pancreatitis include abdominal pain, back pain, fever, nausea, vomiting, diarrhea, greasy/foul-smelling stools, and weight loss. Severe pancreatitis may involve any of the above and/or shortness of breath and jaundice.

National Institute of Diabetes and Digestive and Kidney Diseases. Pancreatitis: Symptoms & Causes of Pancreatitis. Last update November 2017. Available at: <https://www.niddk.nih.gov/health-information/digestive-diseases/pancreatitis/symptoms-causes>

In the 2022 publication “Biliary Obstruction”, the authors list the following signs and symptoms of blockage of the pancreatic duct: right upper quadrant abdominal pain, fever, nausea and vomiting, weight loss, jaundice, clay-colored or alcoholic stools, dark urine, pruritus, loss of appetite, diarrhea, fever, elevated heart rate, distress, pallor, scleral icterus, palmar erythema, signs of malnutrition, hepatomegaly/splenomegaly, presence of ascites, palpable mass, stigmata of cirrhosis, lower extremity edema.

Coucke EM, Akbar H, Kahloon A, et al. Biliary Obstruction. [Updated 2022 Nov 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK539698/>

Misra and Sood

In the 2023 publication “Pancreatic Pseudocyst”, the authors describe the signs and symptoms of pancreatic pseudocysts as generally nonspecific and that these symptoms may present only vaguely as abdominal pain, nausea, and/or vomiting.

Misra D, Sood T. Pancreatic Pseudocyst. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK557594/>

Liver Function Panel Tests

American College of Gastroenterology (ACG)

The ACG Guideline on the evaluation of abnormal liver chemistries (2017) states that there are many valid reasons to perform a liver function panel/liver chemistry panel, including:

- To confirm a previously abnormal result
- Workup for a broad range of conditions, such as acute or chronic hepatitis (including viral hepatitis), alcohol-associated liver disease, hereditary hemochromatosis, autoimmune hepatitis, Wilson’s disease, alpha-1 antitrypsin deficiency, primary biliary cholangitis and primary sclerosing cholangitis
- Evaluation for damage due to certain medications, cancer, autoimmune diseases, hyperthyroidism, hypothyroidism, thyrotoxicosis, myxedema, celiac disease, cholelithiasis, intrahepatic cholestasis of pregnancy, acute fatty liver of pregnancy, pre-eclampsia, and exacerbation of other chronic primary liver disorders due to pregnancy, and some tick-borne illnesses.

Kwo PY, Cohen SM, Lim JK. ACG Clinical Guideline: Evaluation of Abnormal Liver Chemistries. Am J Gastroenterol. 2017;112(1):18-35. Accessed December 2, 2024. Available at: https://journals.lww.com/ajg/fulltext/2017/01000/acg_clinical_guideline_evaluation_of_abnormal.13.aspx
doi:10.1038/ajg.2016.517.

American Association for the Study of Liver Diseases (AASLD)

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According to the AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease (2023), general population-based screening for MASLD (formerly NAFLD) is not advised.

Rinella M E, Neuschwander-Tetri B A, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023 May;77(5):1797-1835.
doi:10.1097/HEP.0000000000000323

Centers for Medicare & Medicaid Services (CMS)

In the local coverage determination policy Hepatic (Liver) Function Panel (L33907), CMS states that hepatic panel function testing is not considered medically reasonable or necessary when performed during annual physical examinations or other routine screening situations without signs, symptoms or illnesses which indicate medical necessity.

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination (LCD). Hepatic (Liver) Function Panel. (L33907). Revision effective date: September 7, 2025. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33907&ver=15>

Tholey

Additional signs, symptoms and risk factors for liver dysfunction, as defined above, are outlined in the Merck Manual chapter (2023) “Evaluation of the Patient With a Liver Disorder”.

Tholey D. Evaluation of the Patient With a Liver Disorder. Merck Manual. 2023. Accessed April 25, 2025. Available at: <https://www.merckmanuals.com/professional/hepatic-and-biliary-disorders/approach-to-the-patient-with-liver-disease/evaluation-of-the-patient-with-a-liver-disorder>

Blood-based Noninvasive Liver Fibrosis Screening Tests

American Association for the Study of Liver Diseases (AASLD)

According to the AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease (2023), general population-based screening for MASLD (formerly NAFLD) is not advised. Targeted screening of populations at increased risk for advanced liver disease is advised to identify and manage those with clinically significant fibrosis risk. All patients with hepatic steatosis or clinically suspected MASLD based on the presence of obesity and metabolic risk factors (e.g., obesity, dyslipidemia) should undergo primary risk assessment with FIB-4. High-risk individuals, such as those with type 2 diabetes mellitus, medically complicated obesity, family history of cirrhosis, or more than mild alcohol consumption, should be screened for advanced fibrosis. First-degree relatives of patients with metabolic associated steatohepatitis or MASH (formerly known as NASH) cirrhosis should be offered screening for advanced hepatic fibrosis (p. 1806-1808).

Rinella M E, Neuschwander-Tetri B A, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and

American Association for the Study of Liver Diseases (AASLD)

The AASLD Practice Guideline on blood based noninvasive liver disease assessment of hepatic fibrosis and steatosis (2024), recommends using simple blood-based noninvasive liver disease assessments (NILDA) such as APRI or Fibrosis-4 Index (FIB-4) in adult patients with chronic HBV and HCV to assess fibrosis stage prior to antiviral therapy, compared to no test at all (p. 9). It is also noted that NILDA tests should not be used to follow progression or monitor stability or regression in chronic liver disease (p. 16).

In pediatric patients with chronic liver disease, AASLD suggests the use of simple, cost-effective, and readily available blood based NILDA, such as APRI or FIB-4, for the detection of advanced fibrosis (F3-4) (p. 25).

Sterling RK, Patel K, Duarte-Rojo A, et al. AASLD Practice Guideline on blood-based noninvasive liver disease assessment of hepatic fibrosis and steatosis. Hepatology. Published online March 15, 2024.
doi:10.1097/HEP.0000000000000845

American College of Gastroenterology (ACG)

The ACG Guideline on alcohol-associated liver disease (2024) includes the following recommendation regarding the use of noninvasive tests for assessing fibrosis severity in individuals with alcohol-associated liver disease:

- “Noninvasive blood and/or radiological tests (NITs) should be used to assess the severity of fibrosis in persons with asymptomatic ALD [alcohol-associated liver disease]. FIB-4 score, a blood-based marker, and hepatic transient elastography are best initial NITs of fibrosis among persons with ALD.”

Jophlin LL, Singal AK, Bataller R, et al. ACG Clinical Guideline: Alcohol-Associated Liver Disease. Am J Gastroenterol. 2024;119(1):30-54. doi:10.14309/ajg.00000000000002572

DEFINITIONS

1. **Gastroenteritis** is characterized by vomiting and/or diarrhea.
2. **Symptoms of enteric fever** include high fever, abdominal pain, constipation followed by diarrhea (sometimes bloody), rash characterized by flat "rose spots" on abdomen and chest, confusion due to fever, hepatosplenomegaly, GI bleed/perforation. Travel is also a risk factor to consider in patients presenting with fever or flu-like illness after travel or contact with a traveler from endemic areas.
3. **Uninvestigated dyspepsia** refers to dyspepsia that has not already been evaluated via investigations such as upper GI endoscopy.

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4. **Close relatives** include first, second, and third degree blood relatives:
 - a. **First-degree relatives** are parents, siblings, and children
 - b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings
 - c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins
5. **Close relatives** include first, second, and third degree blood relatives on the same side of the family:
 - a. **First-degree relatives** are parents, siblings, and children
 - b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings
 - c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins
6. **Signs/symptoms of an eating disorder** include food restriction/avoidance, bingeing and/or purging, body image distortion, intense fear of gaining weight or being “fat”, misuse of laxatives or diuretics, significant unexplained weight loss, and nutritional deficiencies due to inadequate food intake.
7. **Signs/symptoms of liver dysfunction** can include jaundice, right upper quadrant abdominal pain/tenderness, anemia, thrombocytopenia, unexplained bleeding or bruising, loose/fatty stools, unexplained fatigue, abdominal swelling, edema, itching, anorexia and nausea or vomiting.
8. **Risk factors for liver dysfunction** can include significant alcohol consumption, high risk sexual practices, cancer, recreational drug use, prescription drugs with potential for liver toxicity (e.g., anti-epileptics, statins, NSAIDs, corticosteroids), environmental exposure to liver toxicants, biliary ductal obstruction or disease, certain autoimmune diseases, obesity, infection with hepatitis viruses or other pathogens associated with liver dysfunction, dyslipidemia, and personal or family history of certain disorders such as Wilson disease, Celiac disease, hemochromatosis, and alpha-1 antitrypsin deficiency.
9. **Signs/symptoms or diagnosis of chronic liver disease** are often absent or very mild especially in early stages. When they do occur, pain in the upper right abdomen, weight loss, enlarged spleen, jaundice, abdominal swelling, and abnormal bruising are among the most common.
10. **Fibrosis-4 index (FIB-4)** is a blood test that calculates the probability of advanced liver fibrosis based on AST, ALT, platelets, and age.

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11. **NAFLD fibrosis score (NFS)** is a blood test that calculates the probability of advanced liver fibrosis based on AST, ALT, albumin, age, body mass index (BMI), platelet count, and presence of impaired fasting glucose (IFG) or diabetes.

CPT® Codes	Description
82965	Glutamate dehydrogenase
83009	Helicobacter pylori, blood test analysis for urease activity, non-radioactive isotope (eg, C-13)
83013	Helicobacter pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13)
83014	Helicobacter pylori; drug administration
86060	Antistreptolysin 0; titer
86486	Skin test; unlisted antigen, each
86590	Streptokinase, antibody
86609	Antibody; bacterium, not elsewhere specified
86625	Antibody; Campylobacter
86628	Antibody; Candida
86635	Antibody; Coccidioides
86638	Antibody; Coxiella burnetii (Q fever)
86641	Antibody; Cryptococcus
86671	Antibody; fungus, not elsewhere specified
86674	Antibody; Giardia lamblia
86677	Antibody; Helicobacter pylori
86689	Antibody; HTLV or HIV antibody, confirmatory test (eg, Western Blot)
86711	Antibody; JC (John Cunningham) virus
86713	Antibody; Legionella
86720	Antibody; Leptospira
86723	Antibody; Listeria monocytogenes
86727	Antibody; lymphocytic choriomeningitis
86735	Antibody; mumps
86738	Antibody; mycoplasma
86753	Antibody; protozoa, not elsewhere specified
86759	Antibody; rotavirus
86762	Antibody; rubella
86765	Antibody; rubeola
86768	Antibody; Salmonella

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86771	Antibody; Shigella
86784	Antibody; Trichinella
86790	Antibody; virus, not elsewhere specified
86793	Antibody; Yersinia
87015	Concentration (any type), for infectious agents
87040	Culture, bacterial; blood, aerobic, with isolation and presumptive identification of isolates (includes anaerobic culture, if appropriate)
87045	Culture, bacterial; stool, aerobic, with isolation and preliminary examination (eg, KIA, LIA), Salmonella and Shigella species
87046	Culture, bacterial; stool, aerobic, additional pathogens, isolation and presumptive identification of isolates, each plate
87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87071	Culture, bacterial; quantitative, aerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool
87073	Culture, bacterial; quantitative, anaerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool
87075	Culture, bacterial; any source, except blood, anaerobic with isolation and presumptive identification of isolates
87076	Culture, bacterial; anaerobic isolate, additional methods required for definitive identification, each isolate
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only
87084	Culture, presumptive, pathogenic organisms, screening only; with colony estimation from density chart
87101	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
87102	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; other source (except blood)
87103	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; blood
87106	Culture, fungi, definitive identification, each organism; yeast
87107	Culture, fungi, definitive identification, each organism; mold
87109	Culture, mycoplasma, any source
87116	Culture, tubercle or other acid-fast bacilli (eg, TB, AFB, mycobacteria) any source, with isolation and presumptive identification of isolates
87118	Culture, mycobacterial, definitive identification, each isolate
87140	Culture, typing; immunofluorescent method, each antiserum
87143	Culture, typing; gas liquid chromatography (GLC) or high pressure liquid chromatography (HPLC) method
87147	Culture, typing; immunologic method, other than immunofluorescence (eg, agglutination grouping), per antiserum

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87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed
87153	Culture, typing; identification by nucleic acid sequencing method, each isolate (eg, sequencing of the 16S rRNA gene)
87154	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets
87158	Culture, typing; other methods
87164	Dark field examination, any source (eg, penile, vaginal, oral, skin); includes specimen collection
87168	Macroscopic examination; arthropod
87169	Macroscopic examination; parasite
87172	Pinworm exam (eg, cellophane tape prep)
87176	Homogenization, tissue, for culture
87177	Ova and parasites, direct smears, concentration and identification
87181	Susceptibility studies, antimicrobial agent; agar dilution method, per agent (eg, antibiotic gradient strip)
87184	Susceptibility studies, antimicrobial agent; disk method, per plate (12 or fewer agents)
87185	Susceptibility studies, antimicrobial agent; enzyme detection (eg, beta lactamase), per enzyme
87186	Susceptibility studies, antimicrobial agent; microdilution or agar dilution (minimum inhibitory concentration [MIC] or breakpoint), each multi-antimicrobial, per plate
87187	Susceptibility studies, antimicrobial agent; microdilution or agar dilution, minimum lethal concentration (MLC), each plate (List separately in addition to code for primary procedure)
87188	Susceptibility studies, antimicrobial agent; macrobroth dilution method, each agent
87190	Susceptibility studies, antimicrobial agent; mycobacteria, proportion method, each agent
87205	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87206	Smear, primary source with interpretation; fluorescent and/or acid fast stain for bacteria, fungi, parasites, viruses or cell types
87207	Smear, primary source with interpretation; special stain for inclusion bodies or parasites (eg, malaria, coccidia, microsporidia, trypanosomes, herpes viruses)
87209	Smear, primary source with interpretation; complex special stain (eg, trichrome, iron hemotoxylin) for ova and parasites
87210	Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps)
87220	Tissue examination by KOH slide of samples from skin, hair, or nails for fungi or ectoparasite ova or mites (eg, scabies)
87230	Toxin or antitoxin assay, tissue culture (eg, Clostridium difficile toxin)
87250	Virus isolation; inoculation of embryonated eggs, or small animal, includes observation and dissection

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87252	Virus isolation; tissue culture inoculation, observation, and presumptive identification by cytopathic effect
87253	Virus isolation; tissue culture, additional studies or definitive identification (eg, hemabsorption, neutralization, immunofluorescence stain), each isolate
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus
87255	Virus isolation; including identification by non-immunologic method, other than by cytopathic effect (eg, virus specific enzymatic activity)
87269	Infectious agent antigen detection by immunofluorescent technique; giardia
87272	Infectious agent antigen detection by immunofluorescent technique; cryptosporidium
87299	Infectious agent antigen detection by immunofluorescent technique; not otherwise specified, each organism
87300	Infectious agent antigen detection by immunofluorescent technique, polyvalent for multiple organisms, each polyvalent antiserum
87301	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; adenovirus enteric types 40/41
87324	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Clostridium difficile toxin(s)
87328	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; cryptosporidium
87329	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; giardia
87335	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Escherichia coli 0157
87336	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Entamoeba histolytica dispar group
87337	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Entamoeba histolytica group
87338	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; Helicobacter pylori, stool

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87339	Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; <i>Helicobacter pylori</i>
87385	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; <i>Histoplasma capsulatum</i>
87425	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; rotavirus
87427	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Shiga-like toxin
87430	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; <i>Streptococcus</i> , group A
87449	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; not otherwise specified, each organism
87451	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; polyvalent for multiple organisms, each polyvalent antiserum
87493	Infectious agent detection by nucleic acid (DNA or RNA); <i>Clostridium difficile</i> , toxin gene(s), amplified probe technique
87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87500	Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, <i>enterococcus</i> species van A, van B), amplified probe technique
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, <i>Clostridium difficile</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>Shigella</i> , norovirus, <i>Giardia</i>), 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, <i>Clostridium difficile</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>Shigella</i> , norovirus, <i>Giardia</i>), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets

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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
87551	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, amplified probe technique
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique
87561	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
87797	Infectious agent detection by nucleic acid (DNA or RNA); not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87802	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B
87803	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Clostridium difficile toxin A
87899	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; not otherwise specified
87900	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)
87910	Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus
87999	Unlisted microbiology procedure
89055	Leukocyte assessment, fecal, qualitative or semiquantitative

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0107U	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	02/24
Added “lab” to title. Removed CPT and ICD-10 codes from policy reference table. Added CPT code table and moved the “coding implications” section.	02/24	
Corrected coding descriptions in CPT table; removed 0369U. Corrected policy number from CG.CP.MP.104 to CG.CP.MP.04.	03/24	
Annual review. Added policy number to header. Minor rewording with no clinical significance. For Syndromic/Multiplex Gastrointestinal Pathogen Panels with 11 or Fewer Targets: Changed policy statement from “may be considered medically necessary” to “are considered medically necessary.” Added 87650 and 0369U to Coding Table.	11/24	02/25
Annual review. Changed “Gastroenterologic” in policy name to “Gastroenterology.” Added new criteria, coding and background/rationale for: Amylase Tests, Lipase Tests, Liver Function Panel Tests, and Blood-based Noninvasive Liver Fibrosis Screening Tests. Reformatted background/rationale section to also include references. Added criteria I.B.1, I.B.2, C.1.6, C.1.7, C.1.8, C.1.9 to H.pylori section. Added CPT codes 82965, 83009, 86060, 86486, 86590, 86609, 86625, 86628, 86635, 86638, 86641, 86671, 86674, 86689, 86711, 86713, 86720, 86723, 86727, 86735, 86738, 86753, 86759, 86762, 86765, 86768, 86771, 86784, 86790, 86793, 87015, 87040, 87045, 87046, 87070, 87071, 87073, 87075, 87076, 87077, 87081, 87084, 87101, 87102, 87103, 87106, 87107, 87109, 87116, 87118, 87140, 87143, 87147, 87149, 87150, 87153, 87154, 87158, 87164, 87168, 87169, 87172, 87176, 87177, 87181, 87184, 87185, 87186, 87187, 87188, 87190, 87205, 87206, 87207, 87209, 87210, 87220, 87230, 87250, 87252, 87253, 87254, 87255, 87269, 87272, 87299, 87300, 87301, 87324, 87328, 87329, 87335, 87336, 87337, 87385, 87425, 87427, 87430, 87449, 87451, 87802, 87803, 87899, 87900, 87905, 87910, 87999, 89055, 0107U. Updated last review date and copyright dates.	1/26	1/26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care

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professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions

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expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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