of Tennessee

Policy

Reimbursement Policy

Pancreatic Enzyme Testing for Acute Pancreatitis

I. Policy Description

Pancreatitis is an inflammation of pancreatic tissue and can be either acute or chronic. Pancreatic enzymes, including amylase, lipase, and trypsinogen, can be used to monitor the relative health of the pancreatic tissue. Damage to the pancreatic tissue, including pancreatitis, can result in elevated pancreatic enzyme concentrations whereas depressed enzyme levels are associated with exocrine pancreatic insufficiency.[1,2]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals presenting with signs and symptoms of acute pancreatitis (see Note 1), measurement of serum lipase **MEETS COVERAGE CRITERIA**.

2) Measurement of serum lipase **DOES NOT MEET COVERAGE CRITERIA** in any of the following situations:
   a) For individuals with an established diagnosis of acute **or** chronic pancreatitis.
   b) More than once per visit.
   c) For asymptomatic individuals during a general exam without abnormal findings.

3) When ordered for anything other than analysis of pancreatic cyst fluid, measurement of serum amylase **DOES NOT MEET COVERAGE CRITERIA.**

4) For the diagnosis, assessment, prognosis, and/or determination of severity of acute pancreatitis, measurement of serum or urine trypsin/trypsinogen/TAP (trypsinogen activation peptide) **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

5) For the diagnosis, assessment, prognosis, and/or determination of severity of acute pancreatitis, measurement of the following biomarkers **DOES NOT MEET COVERAGE CRITERIA**:
   a) C-Reactive Protein (CRP)
   b) Interleukin-6 (IL-6)
   c) Interleukin-8 (IL-8)
   d) Procalcitonin

6) For individuals presenting with signs and symptoms of acute pancreatitis (see Note 1), measurement of urinary amylase concentration for the initial diagnosis of acute pancreatitis **DOES NOT MEET COVERAGE CRITERIA**.

7) For all other situations or conditions not described above, measurement of serum lipase **DOES NOT MEET COVERAGE CRITERIA.**

NOTES:

Note 1: Signs and symptoms of acute pancreatitis:[3,4]

- Mild to severe epigastric pain that begins slowly or suddenly (may spread to the back in some patients)
- Nausea
- Vomiting
- Tender to palpitation of epigastrium
- Abdominal distention
- Hypoactive bowel sounds
- Fever
- Rapid pulse
- Tachypnea
- Hypoxemia
- Hypotension
- Anorexia
- Diarrhea
- Cullen sign
- Grey Turner sign

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National

Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82150	Amylase
83519	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, by radioimmunoassay (eg, RIA)
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
83529	Interleukin-6 (IL-6)
83690	Lipase
84145	Procalcitonin (PCT)
86140	C-reactive protein

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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VI. Revision History

Revision Date	Summary of Changes
06/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review necessitated the following changes in coverage criteria: Removed amylase from CC1 and CC2. Measurement of amylase is no longer allowed for the diagnosis of acute pancreatitis. Results in new CC3: "3) When ordered for anything other than analysis of pancreatic cyst fluid, measurement of serum amylase DOES NOT MEET COVERAGE CRITERIA." New CC3 results in removal of amylase from former CC6, now CC7.