

Subject: Serum Amylase Testing**Guideline #:** CG-LAB-16**Status:** Reviewed**Publish Date:** 01/03/2024**Last Review Date:** 11/09/2023

Description

This document addresses the use of laboratory testing of the digestive enzyme serum amylase. Serum amylase is no longer the standard of care in evaluating an individual for pancreatitis as serum lipase is considered a more sensitive test for this disease.

Clinical Indications

Not Medically Necessary:

Serum amylase testing is considered **not medically necessary** for acute and chronic pancreatitis and all other conditions.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Not Medically Necessary:

CPT

82150

For the following code **when specified as serum testing for amylase:**

Amylase [when specified as serum amylase testing]

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Amylase and lipase are digestive enzymes normally released from the acinar cells of the exocrine pancreas into the duodenum. Following injury to the pancreas, these enzymes are released into the circulation, along with other enzymes, such as elastase, and trypsin. As each enzyme is cleared from the bloodstream at varying rates, the sensitivity of blood samples measuring enzyme levels is dependent on timing (Shah, 2018).

While amylase is primarily released by the pancreas, it is also released by the salivary glands, as well as negligible amounts by adipose tissue, the gonads, fallopian tubes, intestinal tract and skeletal muscles (Ismail, 2017). The measure of total amylase includes both α -amylase from the salivary glands and different macro-amylase molecules (Smith, 2005). The pancreas and the salivary glands release different isoenzymes of amylase; these different isoenzymes can be identified using monoclonal antibodies. The measurement of pancreatic amylase enzymes is associated with improved sensitivity and specificity, however pancreatic amylase levels have been "largely disregarded" and laboratories continue to report total amylase levels (Ismail, 2017).

Every year in the United States, approximately 275,000 hospital admissions are attributed to acute pancreatitis. Gallstones and alcohol are the most common causes of acute pancreatitis, causing about 70% of all acute pancreatitis cases. Individuals with acute pancreatitis are at higher risk of developing chronic pancreatitis, with one-third to one-half of affected individuals developing chronic pancreatitis (Forsmark, 2016).

Guidelines from the American Gastroenterological Association (AGA) (2018) and the American College of Gastroenterology (ACG) (Tenner, 2013) contain similar criteria for diagnosing acute pancreatitis. At least 2 of 3 criteria must be met for this diagnosis: abdominal pain consistent with acute pancreatitis, biochemical evidence of pancreatitis (i.e., amylase or lipase elevated > 3 times the upper limit of normal), and/or radiographic evidence of pancreatitis on cross-sectional imaging.

The ACG further defines its recommendation regarding laboratory testing noting:

Because of limitations in sensitivity, specificity, and positive and negative predictive value, serum amylase alone cannot be used reliably for the diagnosis of AP (acute pancreatitis) and serum lipase is preferred.

Serum lipase is now the preferred test due to its improved sensitivity for a longer period of time (Shah, 2018). The sensitivity of amylase compared to lipase in the diagnosis of acute pancreatitis ranges between 45% to 87% and 64% to 100% respectively. The specificities of both tests range from 92% to 99% (Ismail, 2017). The prolonged elevation of lipase compared to amylase creates a wider diagnostic window. In acute pancreatitis, amylase can rise rapidly within the first 12 hours of the onset of symptoms and returns to baseline within 3 to 5 days (Matull, 2006). Lipase, however, usually peaks at 24 hours with serum concentrations remaining elevated for 8-14 days. This makes it far more useful than amylase when the clinical presentation or testing has been delayed for more than 24 hours.

Amylase levels can be affected by other comorbid conditions, such as hypertriglyceridemia, other abdominal inflammatory conditions, salivary gland pathologies, renal impairment or macroamylasemia. Lipase levels are not affected by hypertriglyceridemia, but may be affected by other abdominal inflammatory conditions or renal insufficiencies (Matull, 2006). Amylase concentrations may also be normal in alcohol-induced acute pancreatitis (ACG, 2013). In those with acute pancreatitis, amylase levels have not been shown to be a reliable predictor of disease severity (Hong, 2017). In summary, lipase levels are affected by fewer comorbid conditions, and there is no advantage in evaluating both amylase and lipase levels.

A number of studies have reported that improved sensitivity is obtained when using lipase level testing to diagnose acute pancreatitis. These studies indicate that lipase testing should replace amylase testing or testing for both enzymes when acute pancreatitis is

suspected (Chase, 1996; Gomez, 2012; Keim, 1998; Koizumi, 2006; Orebaugh, 1994; Smith, 2005; Treacy, 2001).

Definitions

Acute pancreatitis: This form of pancreatitis occurs suddenly, soon after the pancreas becomes damaged or irritated.

Chronic pancreatitis: This form of pancreatitis occurs when an individual has a permanently damaged or scarred pancreas. It is a slowly progressive form of pancreatitis which may take years to develop.

Pancreatitis: An inflammation of the pancreas.

References

Peer Reviewed Publications:

1. Banks PA, Bollen TL, Dervenis C, et al; Acute Pancreatitis Classification Working Group. Classification of acute pancreatitis--2012: revision of the Atlanta classification and definitions by international consensus. *Gut*. 2013; 62(1):102-111.
2. Chase CW, Barker DE, Russell WL, Burns RP. Serum amylase and lipase in the evaluation of acute abdominal pain. *Am Surg*. 1996; 62(12):1028-1033.
3. Forsmark CE, Vege SS, Wilcox CM. Acute pancreatitis. *N Engl J Med*. 2016; 375(20):1972-1981.
4. Gomez D, Addison A, De Rosa A, et al. Retrospective study of patients with acute pancreatitis: is serum amylase still required? *BMJ Open*. 2012; 2(5):e001471.
5. Hao S, Wu Y, Kang Y, Niu X, Zhu G, Huang W. A single-center analysis of primary nephrotic syndrome with acute pancreatitis in children. *Medicine (Baltimore)*. 2020; 99(27):e21056.
6. Hong W, Geng W, Chen B, et al. Predictors of acute pancreatitis with low elevation of serum amylase. *Ther Clin Risk Manag*. 2017; 13:1577-1584.
7. Ismail OZ, Bhayana V. Lipase or amylase for the diagnosis of acute pancreatitis? *Clin Biochem*. 2017; 50(18):1275-1280.
8. Keim V, Teich N, Fiedler F, et al. A comparison of lipase and amylase in the diagnosis of acute pancreatitis in patients with abdominal pain. *Pancreas*. 1998; 16(1):45-49.
9. Matull WR, Pereira SP, O'Donohue JW. Biochemical markers of acute pancreatitis. *J Clin Pathol*. 2006; 59(4):340-344.
10. Orebaugh SL. Normal amylase levels in the presentation of acute pancreatitis. *Am J Emerg Med*. 1994; 12(1):21-24.
11. Smith RC, Southwell-Keely J, Chesher D. Should serum pancreatic lipase replace serum amylase as a biomarker of acute pancreatitis? *ANZ J Surg*. 2005; 75(6):399-404.
12. Sutton PA, Humes DJ, Purcell G, et al. The role of routine assays of serum amylase and lipase for the diagnosis of acute abdominal pain. *Ann R Coll Surg Engl*. 2009; 91(5):381-384.
13. Treacy J, Williams A, Bais R, et al. Evaluation of amylase and lipase in the diagnosis of acute pancreatitis. *ANZ J Surg*. 2001; 71(10):577-582.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Crockett SD, Wani S, Gardner TB, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guideline on Initial Management of Acute Pancreatitis. *Gastroenterology*. 2018; 154(4):1096-1101.
2. Tenner S, Baillie J, DeWitt J, Vege SS; American College of Gastroenterology. American College of Gastroenterology guideline: management of acute pancreatitis. *Am J Gastroenterol*. 2013; 108(9):1400-1415; 1416.

Websites for Additional Information

1. Association for Diagnostics & Laboratory Medicine. Amylase. Last reviewed June 2020. Available at: <https://www.aacc.org/advocacy-and-outreach/optimal-testing-guide-to-lab-test-utilization/a-f/amylase#order>. Accessed on August 28, 2023
2. National Institute of Diabetes and Digestive and Kidney Diseases. Pancreatitis. Available at: <https://www.niddk.nih.gov/health-information/digestive-diseases/pancreatitis>. Accessed on August 28, 2023.
3. The National Pancreas Foundation. Acute Pancreatitis. Available at: <https://pancreasfoundation.org/pancreas-disease/acute-pancreatitis/>. Accessed on August 28, 2023.

History

| Status | Date | Action |
|----------|------------|---|
| Reviewed | 11/09/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion and Websites for Additional Information section. |
| Reviewed | 11/10/2022 | MPTAC review. Updated References sections. |
| Reviewed | 11/11/2021 | MPTAC review. Updated Discussion and References sections. |
| New | 11/05/2020 | MPTAC review. Initial document development. |

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Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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