

## Corporate Medical Policy

### Fecal Pancreatic Elastase-1 Test

**File Name:** fecal\_pancreatic\_elastase\_1\_test  
**Origination:** 8/2009  
**Last CAP Review:** 10/2011  
**Last Review:** 10/2011

**Active policy, no longer scheduled for routine literature review.**

#### Description of Procedure or Service

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Diagnosis of chronic pancreatitis is based on the detection of abnormal structure or function of the diseased pancreas. Pancreatic function tests more accurately determine the presence of chronic pancreatitis than tests of structure, especially for early stage disease. The function tests can be divided into 2 categories: non-invasive and invasive. The invasive tests can reliably detect mild, early chronic pancreatitis, but are only available at a few referral centers and tend to be poorly tolerated by patients. The non-invasive tests are easy to obtain, but tend to perform poorly in patients with early, mild disease. Therefore, no one test is useful in all clinical situations.

Fecal pancreatic elastase-1 test has been proposed as a novel noninvasive test of pancreatic function. Fecal pancreatic elastase is an enzyme produced only in the pancreas with a direct correlation to exocrine pancreatic function. It is minimally degraded during intestinal transit and is concentrated 6-fold in stool compared to duodenal juice. The concentration of fecal elastase in stool measured by ELISA correlates well with duodenal amylase, lipase, and trypsin in both patients with chronic pancreatitis and in control groups. Low fecal pancreatic elastase levels are indicative of exocrine pancreatic insufficiency caused by conditions such as but not limited to: chronic pancreatitis, hereditary pancreatitis, autoimmunologically cause pancreatitis, pancreatic cancer, cystic fibrosis, cholelithiasis, diabetes, and chronic inflammatory bowel disease.

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

#### Policy

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**Active policy, no longer scheduled for routine literature review.**

**Fecal Pancreatic Elastase-1 Testing is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Fecal Pancreatic Elastase-1 Test is covered

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Not applicable.

# Fecal Pancreatic Elastase-1 Test

## When Fecal Pancreatic Elastase-1 Test is not covered

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Fecal pancreatic elastase-1 testing is considered investigational. BCBSNC does **not** cover investigational services.

## Policy Guidelines

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Information to date does not indicate that Pancreatic Elastase-1 testing is standard of care in the United States. The majority of the literature found was related to studies done in Europe. Further clinical studies are needed to determine the clinical utility of this test. Net health outcomes have not been established.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes:* 82656

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Vermeire S, et al. Laboratory markers in IBD: useful, magic, or unnecessary toys? *Gut* 2006;55:426-431.

Genova Diagnostics. CDSA & CDSA 2.0 Support Guide. 2007.

Specialty Matched Consultant review, 2/2009

Senior Medical Director - 7/2009

Fosmark CE. The early diagnosis of chronic pancreatitis. *Clin Gastroenterol Hepatol*. 2008;6(12):1291-1293

Lieb JG, Draganov PV. Pancreatic function testing: here to stay for the 21st century. *World J Gastroenterol* 2008 May 28; 14(20): 3149-3158

Chowdhury RS, Forsmark CE. Review article: pancreatic function testing. *Aliment Pharmacol Ther* 2003; 17: 733-750

## Policy Implementation/Update Information

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| 8/31/09  | New policy written. Reviewed by the Senior Medical Director 7/9/2009. Fecal pancreatic elastase-1 test is considered investigational. BCBSNC does <b>not</b> cover investigational services. Notice given 8/31/2009. Policy effective date 12/7/09. (btw) |
| 6/22/10  | Policy Number(s) removed (amw)  |
| 11/23/10 | Medical Director review. No change to policy statement. References updated. Policy status changed to: "Active policy, no longer scheduled for routine literature review." (adn)   |
| 11/8/11  | Description section updated. Specialty Matched Consultant Advisory Panel review 10/26/11. No change to policy, remains investigational. (adn)   |

# Fecal Pancreatic Elastase-1 Test

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.