



# SelectHealth Medical Policies

## Pathology Policies

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## PANCRAGEN™ MOLECULAR DIAGNOSTIC TEST FOR EVALUATION OF PANCREATIC CYSTS

Policy # 603

Implementation Date: 11/29/16  
Review Dates: 12/21/17, 12/4/18, 12/16/19  
Revision Dates: 1/24/17

**Disclaimer:**

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare/CMS), and SelectHealth Community Care (Medicaid/CHIP) plans. Refer to the “Policy” section for more information.

**Description**

Pancreatic cysts may be detected in over 2% of patients who undergo abdominal imaging for unrelated reasons, and this frequency increases with age.

Most pancreatic cystic neoplasms (PCNs) are detected incidentally when abdominal imaging is performed for other indications. PCNs account for more than 50% of pancreatic cysts, even in patients with a history of pancreatitis. The first step in evaluating a cyst is to obtain magnetic resonance imaging (MRI) with magnetic resonance cholangiopancreatography (MRCP). Cross-sectional imaging is obtained to determine if there are features present that can identify the specific cyst type and to determine if there are any findings that increase the risk of malignancy (large cyst > 3 cm, a solid component within the cyst, main pancreatic duct dilation). Endoscopic ultrasound with fine-needle aspiration (EUS-FNA) provides high-quality imaging of the pancreas and the opportunity to sample pancreatic lesions, which increases diagnostic accuracy. The addition of intraductal EUS may also increase diagnostic accuracy but is not part of the routine evaluation of pancreatic cysts.

Once a cyst has been aspirated, it undergoes analysis of any fluid obtained. This includes cytology, CEA level, and amylase along with genetic testing for KRAS, GNAS, and sometimes other markers. In some instances, these markers are indeterminate and a decision to either monitor the cyst with periodic imaging based on established guidelines, or surgical intervention, must be undertaken with less certainty as to the true necessity of this invasive intervention.

PancraGEN™ (Interpace Diagnostics LLC, Parsippany, NJ), formerly Pathfinder TG (RedPath Diagnostics) is a laboratory test that integrates cytological, fluid chemistry (CEA, amylase), imaging, and DNA analysis into 4 diagnostic categories that works to help stratify the risk of malignancy, particularly in cysts with indeterminate features. On a DNA level, PancraGEN measures the quantity, quality, and level of DNA damage (specifically, the presence and clonality of loss of heterozygosity mutations (LOH) next to tumor suppressor genes and oncogene point mutations) that is causally responsible for pancreatic cancer. PancraGEN measures 15 genetic markers which are distributed across 10 chromosomal regions including KRAS and GNAS.

Cyst fluid chemistry (i.e., CEA, amylase), imaging, levels of atypia, and cellularity are abstracted from the patients' records provided by the managing physician. Parameters of these initial tests are used along with the results of DNA analysis to compute a malignancy risk estimate in an attempt to help guide surgery.

**Commercial Plan Policy**

SelectHealth **does NOT cover PancraGEN molecular diagnostic test for evaluation of pancreatic cysts as it is considered unproven.**

### PancaGEN™ Molecular Diagnostic Test for Evaluation of Pancreatic Cysts, continued

#### SelectHealth Advantage (Medicare/CMS) (Preauthorization Required)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the SelectHealth Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

#### SelectHealth Community Care (Medicaid/CHIP) (Preauthorization Required)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the SelectHealth Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

#### Summary of Medical Information

Two systematic reviews and 14 primary studies were identified that met inclusion criteria for this review. Data on > 1,500 samples have been reported in the literature since 2006. The majority of the literature on PancaGEN or Pathfinder (as this test was previously known) was related to the clinical validity of the test, namely, the test's ability to accurately profile tissue samples versus cytology, cyst fluid, or other standard means of cyst assessment. All the studies that noted sensitivity and specificity showed that the test has higher of the latter than the former with specificities ranging from 75% to 100%. Of the 14 primary studies, only 1 paper (Das et al.) discussed the health economics of the test and identified the noteworthy number needed to treat of 56. Similarly, only 2 papers (Kowalski and Loren et al.) discussed the potential clinical utility of the study showing that use of the test may improve patient surveillance.

In general, the literature shows some measure of clinical validity but fails to prove the clinical utility of the test (e.g., altering treatment plans, improving morbidity and mortality, improving progression-free survival, etc.). Given that the test has an average specificity of 88%, the lack of clinical utility data, limited follow-up periods in the literature, and evidence of improved outcomes resulting from use of PancaGEN, the current body of evidence is not sufficient to draw meaningful conclusions regarding the clinical usefulness of the test.

#### Billing/Coding Information

##### CPT CODES

|              |  |
|--------------|--|
| <b>81479</b> | Unlisted molecular pathology procedure |
| <b>84999</b> | Unlisted chemistry procedure           |

##### HCPCS CODES

No specific codes identified

##### Key References

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### PancaGEN™ Molecular Diagnostic Test for Evaluation of Pancreatic Cysts, continued

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