

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	MOLECULAR TESTING for the MANAGEMENT of PANCREATIC CYSTS or BARRETT ESOPHAGUS (e.g.,PancraGEN® Pancreatic Risk Classifier)
Policy Number	2.02.39
Category	Laboratory Test
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

Based upon our criteria and review of the peer-reviewed literature, molecular testing using the Pathfinder TG® system (e.g.,PancraGEN® pancreatic risk classifier) has not been medically proven to be effective and is considered **investigational** for all indications including the evaluation of pancreatic cyst fluid.

Refer to Corporate Medical Policy # 11.01.03 Experimental or Investigational Services.

DESCRIPTION

The patented PancraGEN® pancreatic risk classifier is a proprietary integrated molecular pathology test that assesses the cumulative DNA mutations in key oncogenes and tumor suppressor genes associated with pancreatic cancer. PancraGEN® can help assess risk of malignancy in patients with cysts and enhance diagnostic tools such as EUS imaging, CEA, cytology and other risk factors by providing more information for use in management decisions. PanDNA is the molecular technology that drives PancraGEN®. It identifies cumulative DNA abnormalities in pancreatic cysts. Using well-established molecular markers, PanDNA can help inform patient management when used in the context of clinical features, imaging, and cytology results.

Interpace Diagnostics has patented a proprietary platform called PathFinderTG®; it provides mutational analyses of patient specimens. The patented technology permits analysis of tissue specimens of any size, “including minute needle biopsy specimens,” and any age, “including those stored in paraffin for over 30 years. As stated on the company website, PancraGEN® integrates molecular analyses with first-line results (when these are inconclusive) and pathologist interpretation. The manufacturer calls this technique integrated molecular pathology. Test performance information is not provided on the website.

RATIONALE

For individuals with pancreatic cysts who do not have a definitive diagnosis after first-line evaluation and who receive standard diagnostic and management practices plus topographic genotyping (PancraGEN® molecular testing), the evidence includes retrospective studies of clinical validity and clinical utility. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, change in disease status, morbid events, and quality of life. The best evidence regarding incremental clinical validity comes from the National Pancreatic Cyst Registry report, which compared PancraGEN® performance characteristics with current international consensus guidelines and provided

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preliminary but inconclusive evidence of a small incremental benefit for PancraGEN®. The analyses from the registry study included only a small proportion of enrolled patients, relatively short follow-up time for observing malignant transformation and limited data on cases where the PancraGEN® results were discordant with international consensus guidelines. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
81479	Unlisted molecular pathology procedure

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HCPCS Codes

Code	Description
	No specific code

ICD10 Codes

Code	Description
	Investigational for all diagnosis codes

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*Key Article

KEY WORDS

Molecular anatomic pathology, PathFinder, RedPath, Topographic genotyping, Pancregen

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for gene expression analysis for Molecular Testing for the Management of Pancreatic Cysts. However, effective 01/04/16 the Medicare Part-B carrier for New Jersey, Novitas Solutions, Inc, established a favorable local Coverage Decision for Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG®. This covers most of Medicare beneficiaries in all 50 states since the Interpace reference laboratory in Parsippany, New Jersey is within the sole jurisdiction of NHIC for purposes of Part-B coverage. Please refer to https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34864&ver=42&CtrctrSelected=324*1&Ctrctr=324&s=38&DocType=Active&bc=AAgAAAQBAAAA&