MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Molecular Testing for the Management of Pancreatic Cysts (e.g., PancraGEN Pancreatic Risk Classifier)**
Policy Number	**2.02.39**
Category	**Technology Assessment**
Original Effective Date	**07/17/08**
Committee Approval Date	**03/19/09, 03/18/10, 03/17/11**
Current Effective Date	**12/21/23**
Archived Date	**02/16/12**
Archived Review Date	**01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18, 01/17/19, 01/16/20, 01/21/21, 01/20/22, 01/19/23, 12/21/23**
Product Disclaimer	• *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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment 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, therefore, is considered **investigational** for all indications, including the evaluation of pancreatic cyst fluid, pancreatic masses, or pancreatic tissue.

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

POLICY GUIDELINE

The PancraGEN pancreatic risk classifier was formerly called the Pathfinder TG pancreas test.

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 pancreatic cysts or pancreatic masses and enhance diagnostic tools such as endoscopic ultrasound (EUS) imaging, CEA, cytology and other risk factors by providing more information for use in management decisions.

This test is intended to determine a patient's risk of cancer progression and to assess the best course of treatment. The PancraGEN report categorizes patients into one of four groups: benign, statistically indolent, statistically higher risk, or aggressive. A patient with a benign (low risk) test result may opt for disease surveillance while a patient with an aggressive (high-risk) disease may undergo surgery.

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 at any age, "including those stored in paraffin for over 30 years." As stated on the company website, PancraGEN is a personalized molecular pathology test, that interrogates cumulative oncogene and tumor suppressor gene damage, reporting results in the context of each patient's clinical history, imaging, fluid chemistry, and cytology test results. The manufacturer calls this technique integrated molecular pathology.

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 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, 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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
81479	Unlisted molecular pathology procedure
0313U **(E/I)**	Oncology (pancreas), DNA and mRNA next generation sequencing analysis or 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (i.e., negative, low probability of neoplasia or positive, high probability of neoplasia) (*Includes PanceaSeq Genomic Classifier, Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center*)

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

Based upon our review, PathfinderTG is not addressed in National or Regional Medicare coverage determinations or policies.

However, please refer to the Medicare Managed Care Manual/Chapter 4: Benefits and Beneficiary Protections (Rev.

121, Issued: 04-22-16)/Section 90 National and Local Coverage Determinations/Subsection 90.4.1 MAC with Exclusive Jurisdiction over a Medicare Item or Service:

In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. This generally occurs when there is only one provider of a particular item or service (for example, certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage policy reflected in an LCD issued by the A/B MAC that enrolled the provider and processes all the Medicare claims for that item or service.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326 accessed 11/22/23.