



**PATHFINDER TG® MOLECULAR TESTING
(TOPOGRAPHIC GENOTYPING)
HS-155**



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**PathFinderTG®
Molecular Testing
(Topographic Genotyping)**

Policy Number: HS-155

Original Effective Date: 2/18/2010

Revised Date(s): 2/18/2011; 2/2/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

The RedPath Integrated Pathology (Pittsburgh, PA) PathFinderTG test is not a single test, but rather, is an advanced pathology service that includes microdissection, selection of regions to be analyzed, analysis of these regions using a variety of molecular tests (topographic genotyping), and expert pathologist interpretation of the results along with what is known about the particular case.

Description of Use for Pancreatic Cancer

The PathFinderTG test for pancreatic cancer examines 17 different genetic markers. The precise description of these markers is proprietary; however, it is known that there are 2 markers in each of the chromosome regions 1p, 3p, 5q, 9p, 10q, and 17p; and 1 marker in each of the chromosome regions 12p, 17q, 18q, 21q, and 22q. The genetic marker at chromosome region 12p is the Kirsten rat sarcoma viral oncogene homolog (*KRAS*) gene; however, the sequence variant analysis performed on this gene is not described. The PathFinderTG test combines the results of testing of the 17 genetic markers to produce 3 criteria of *KRAS* sequence variant status, loss of heterozygosity, and a determination of DNA quality. Depending on whether a pancreatic cyst is considered positive or negative for these 3 criteria, it is classified as benign nonmucinous, benign mucinous, or malignant. According to RedPath Integrated Pathology, the PathFinderTG test is suitable for molecular analysis of pancreatic cysts where the results of traditional pathology analysis are unclear.

Cost Analysis

The list price of the PathFinderTG test for pancreatic cancer is \$4000 to \$4500, depending on specimen type.

Summary Statement

There is insufficient evidence in the published, peer-reviewed, scientific literature to demonstrate that topographic genotyping or the PathFinderTG® (RedPath Integrated Pathology Inc., Pittsburgh, PA) can be used as methods to assist in the diagnosis or management of individuals with cancer when microscopic analysis and staining fail to provide a definitive diagnosis. This testing has not been adequately compared with established testing methods and impact on health outcomes is not known at this time. The clinical utility of topographic genotyping and the PathfinderTG® in the diagnosis and management of cancer has not yet been established through well-designed clinical trials.

POSITION STATEMENT

Topographic genotyping using the PathFinderTG® and other molecular tests **is considered experimental and investigational** for all indications and is NOT a covered benefit.

CODING

Non-Covered CPT®* Codes for Topographic genotyping using the PathFinderTG® and other molecular tests

84999	Unlisted Chemistry Procedure
84999-26	Unlisted Chemistry Procedure; Professional Component
84999-TC	Unlisted Chemistry Procedure; Technical Component
88321	Consultation and report on referred slides prepared elsewhere
88323	Consultation and report on referred material requiring preparation of slides
88325	Consultation; comprehensive with review of records and specimens, with report on referred material
89240	Unlisted Miscellaneous Pathology Test



89240-26 Unlisted Miscellaneous Pathology Test; Professional Component
89240-TC Unlisted Miscellaneous Pathology Test; Technical Component

ICD-9-CM Procedure Codes - No applicable codes

HCPCS Codes - No applicable codes

Non-Covered ICD-9-CM Diagnosis Codes - All diagnosis are non-covered

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

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2. Shen, J., Brugge, W.R., Dimaio, C.J., & Pitman, M.B. (2009). Molecular analysis of pancreatic cyst fluid: a comparative analysis with current practice of diagnosis. *Cancer Cytopathology*, 117(3), 217-227.
3. Sreenarasimhaiah, J., Lara, L.F., Jazrawi, S.F., Barnett, C.C., & Tang, S.J. (2009). A comparative analysis of pancreas cyst fluid CEA and histology with DNA mutational analysis in the detection of mucin producing or malignant cysts. *Journal of Oncology Practice*, 10(2), 163-168.
4. Zolotarevsky, E., Al Mohajer, M., Kwon, R.S., & et al. (2008). DNA mutational analysis versus cytology with and without fluid CEA level in the diagnosis of mucinous cystic lesions of the pancreas: a multicenter study. *Gastroenterology*, 134(4), A56-A57.

Government Agencies, Professional and Medical Organizations

1. National Comprehensive Cancer Network. (2009, March 26). NCCN clinical practice guidelines in oncology™: pancreatic adenocarcinoma (V.1.2009). Retrieved from <http://www.nccn.org>

HISTORY AND REVISIONS

Date	Action
2/2/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
2/18/2011	• Approved by MPC.