



Easy Choice Health Plan, Inc.

Harmony Health Plan of Illinois, Inc.

Missouri Care, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare Health Insurance of Arizona, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of South Carolina, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Windsor Health Plan

Windsor Rx Medicare Prescription Drug Plan

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

Policy Number: HS-155

Original Effective Date: 2/18/2010

**Revised Date(s): 2/18/2011; 2/2/2012;
6/7/2012; 6/6/2013; 6/5/2014**

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.

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. *Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.*

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.

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.

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

There is insufficient evidence in published, peer-reviewed, scientific literature to demonstrate that topographic genotyping or the PathFinderTG (RedPath Integrated Pathology Inc., Pittsburgh) 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. 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 been established through well-designed clinical trials.

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Topographic genotyping using the PathFinderTG® and other molecular tests **is considered a covered benefit for the indications of 577.2 pancreatic cyst/mass.**

Centers for Medicaid and Medicare Services (2012)

Evaluating tissue samples pathologically is crucial to the diagnosis and treatment of patients with malignancy. At times, standard pathologic analyses provide inconclusive information. Combining pathologic study with molecular analyses of microdissected tissue, is claimed to enhance the ability to provide more specific diagnostic information, to help guide treatment decisions. These testing combinations are generally known as topographic genotyping.

More specifically, loss-of-heterozygosity based topographic genotyping and other molecular analyses are combined

in a patented technology known as PathfinderTG®. Recently, a Technology Assessment Report prepared by the Tufts Evidence-Based Practice Center, for the Agency for Healthcare Research and Quality (AHRQ), reviewed the existing scientific literature for PathfinderTG®.

The Technology Assessments conclusions noted insufficient studies measuring whether the use of PathfinderTG® Technology would improve patient relevant clinical outcomes. Questions raised included whether PathfinderTG® results affected diagnostic evaluation or treatment decisions. However, during the comment period for the draft LCD, Contractor received extensive comments from physicians and providers from across the country, many from distinguished, highly reputable universities and physicians specifically on their use and results of the PathfinderTG® Technology very specifically for patients with pancreatic cysts where “traditional” fluid chemistry and/or cytology evaluations were inconclusive. Several institutions provided their own research results of their use of PathfinderTG® Technology specifically for patients with pancreatic cysts where fluid chemistries and/or cytology evaluations were inconclusive.

As a result, PathfinderTG® Technology **will be covered as a “reasonable and necessary” service specifically and only for the indications of 577.2 pancreatic cyst/mass** where diagnostic evaluations are inconclusive under “Coverage with Appropriateness Development,” in keeping with the Social Security Act Section 1862(a)(1)(A) allowance for “Coverage with Appropriateness Development.”

CODING

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

84999 Unlisted Chemistry Procedure

89240 Unlisted Miscellaneous Pathology Test; Professional Component

HCPCS Codes - No applicable codes

ICD-9-CM Procedure Codes - No applicable codes

Draft ICD-10-PCS Codes – No applicable codes

ICD-9-CM Diagnosis Codes

577.2 Cyst and pseudocyst of pancreas

Draft 2013 ICD-10-CM Diagnosis Codes

K86.2 Cyst of pancreas

K86.3 Pseudocyst of pancreas

*Current Procedural Terminology (CPT) 2014 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Directory. (2009, December 7). PathFinderTG® (pancreatic cancer) [updated on November 8, 2013]. Retrieved from <http://www.hayesinc.com>
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.
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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. Agency for Healthcare Research and Quality. (2010). Technology assessment: a systematic review of loss-of-heterozygosity based on topographic genotyping with PathFinderTG®. Retrieved from <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id68ta.pdf>
2. Centers for Medicare and Medicaid Services. (2012, April). Local coverage determination for loss-of-heterozygosity based topographic genotyping with PathFinderTG ® (L31144). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>
3. National Comprehensive Cancer Network. (2014). NCCN clinical practice guidelines in oncology™: pancreatic adenocarcinoma (V.1.2014). Retrieved from <http://www.nccn.org>

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
6/5/2014	<ul style="list-style-type: none">• Approved by MPC. No changes.
6/6/2013	<ul style="list-style-type: none">• Approved by MPC. No changes.
6/7/2012	<ul style="list-style-type: none">• Approved by MPC. Coverage is offered per CMS guidelines (as of 4/2012).
2/2/2012	<ul style="list-style-type: none">• Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
2/18/2011	<ul style="list-style-type: none">• Approved by MPC.