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 (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG 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. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

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 test 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.

Centers for Medicaid and Medicare Services (2015)

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.

**POSITION STATEMENT**

**Applicable To:**
- Medicaid – Hawaii
- Medicare – California (Easy Choice) and Hawaii

**Exclusions**

PathfinderTG® is not considered medically necessary if any of the following apply:

1. All PathfinderTG® indications other than pancreatic cyst fluid evaluation are considered investigational and are therefore not considered medically reasonable and necessary due to insufficient data on both analytical and clinical validity.
2. Image guided needle aspiration of the pancreatic cyst or cystic component of a mass lesion or dilated duct demonstrate definitive diagnosis of malignancy by cytology
3. Cytology not showing malignancy, but meets AGA guidelines to reach a definitive diagnosis of benign disease. Lesions must be:
   A. Under 1 cm
   B. Lack a solid component
   C. Lack concerning cytology features
   D. Lack main pancreatic duct dilatation of > 1 cm in diameter with absence of abrupt change in duct diameter
   E. Have fluid CEA level not exceeding 5 ng/ml

**Coverage**

PathfinderTG® is considered medically necessary when all of the following criteria are met:

1. Highly-concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary; **AND**,  
2. Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
   A. A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/ml, suggesting a mucinous cyst, but is not diagnostic; **OR**,
B. Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

**CODING**

**CPT® Codes**
- 84999 Unlisted Chemistry Procedure
- 89240 Unlisted Miscellaneous Pathology Test

**HCPCS Codes** - No applicable codes

**ICD-10-PCS Codes** – No applicable codes

**ICD-10-CM Diagnosis Codes**
- K86.2 Cyst of pancreas
- K86.3 Pseudocyst of pancreas

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**


**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

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<th>Date</th>
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<td>12/7/2017</td>
<td>Approved by MPC. Updated CMS criteria and LCD. Policy changed to applicable to HI and CA or</td>
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<td>1/12/2017</td>
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<td>7/5/2015</td>
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