

**EFFECTIVE DATE:** 01 | 01 | 2016

**POLICY LAST UPDATED:** 11 | 03 | 2015

## OVERVIEW

This policy describes the coverage of molecular testing for the indications of pancreatic cyst/mass where diagnostic evaluations are inconclusive.

## MEDICAL CRITERIA

### BlueCHiP for Medicare

PathfinderTG® molecular testing is only medically necessary for pancreatic cyst/mass where diagnostic evaluations are inconclusive.

## PRIOR AUTHORIZATION

### BlueCHiP for Medicare

Prior authorization is required and is obtained via the online tool for participating providers. See the Related Policies section.

## Commercial Products

Not applicable

## POLICY STATEMENT

### BlueCHiP for Medicare

PathfinderTG molecular testing is only medically necessary for pancreatic cyst/mass where diagnostic evaluations are inconclusive.

**Note:** Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

## Commercial Products

Molecular testing using the PathFinderTG system is considered **not medically necessary** for all indications including the evaluation of pancreatic cyst fluid and of suspected or known gliomas, and Barrett esophagus as there is inadequate peer reviewed data to support its use.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

## BACKGROUND

The patented PathFinderTG test is a molecular test intended to be used adjunctively when a definitive pathologic diagnosis cannot be made, because of inadequate specimen or equivocal histologic or cytologic findings. RedPath Integrated Pathology (Pittsburgh, PA), the test provider, states that PathFinderTG

produces mutational profiles to help physicians resolve complex diagnostic dilemmas in patients who are at risk of cancer.

Topographic genotyping (TG), also called molecular anatomic pathology, integrates microscopic analysis (anatomic pathology) with molecular tissue analysis. Under microscopic examination of tissue and other specimens, areas of interest may be identified and micro-dissected to increase tumor cell yield for subsequent molecular analysis. TG may permit pathologic diagnosis when first-line analyses are inconclusive.

RedPath Integrated Pathology has patented a proprietary platform, called PathFinderTG, to provide 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.” RedPath currently offers 5 PathFinderTG tests (listed and briefly described in Table 1). As stated on the company website PathFinderTG integrates molecular analyses with first-line results (when these are inconclusive) and pathologist interpretation to provide “clinically valid and useful diagnostic and prognostic information.”<sup>(3)</sup> Although the website states that “PathFinderTG is clinically validated as reported in over 200 peer-reviewed articles,” test performance information is not provided.

### **Regulatory Status**

These patented diagnostic tests are available only through RedPath Integrated Pathology (Pittsburgh, PA). The PathFinderTG Molecular Test is not subject to review by the U.S. Food and Drug Administration (FDA) because it is a laboratory-developed test (LDT) conducted only at RedPath Integrated Pathology’s licensed laboratory. Laboratories performing LDTs must be licensed for high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). RedPath is licensed under CLIA.

Information regarding coding and individual consideration of Medicare claims for this test was released in a provider bulletin from Highmark Medicare Services in June 2007 (available online at: <https://secure.highmark.com/ldap/medicalpolicy/wpa-highmark/printerfriendly/L-83-001.html>). Because the RedPath laboratory is located in Pennsylvania, all Medicare claims for this test would be processed by Highmark Medicare Services. The CPT code suggested by Highmark Medicare Services for this test is code 84999 – unlisted chemistry procedure.

### **Ongoing Clinical Trials**

A search of online site, ClinicalTrials.gov, using the search terms “RedPath” and “PathFinder” identified 1 active study of PathFinderTG in patients with biliary stricture (NCT02000999). Washington State University is sponsoring an observational study to compare the diagnostic utility of brush cytology plus florescence in situ hybridization or free DNA analysis performed at RedPath. Estimated enrollment is 110 adults with bile duct stricture who are undergoing endoscopic retrograde cholangiopancreatography (ERCP). Expected completion is December 2016.

Evidence reviewed for 3 representative uses of PathFinderTG has significant limitations, as discussed. Demonstrating the utility of a test for diagnostic and prognostic purposes or to predict therapeutic response requires that results accurately inform clinical decision making in a manner leading to a net health benefit defined by clinical outcomes. Results also must be clearly reproducible, as shown by applying the test (with prior-defined cutoff points) to independent samples for validation. Because the impact of this technology on health outcomes is unknown and because outcomes with this technology compared with existing alternatives (i.e., incremental value) are unknown, PathFinderTG testing is considered not medically necessary for Commercial products for all indications, including evaluation of pancreatic cyst fluid, suspected/known gliomas, and Barrett esophagus.

### **BlueCHiP for Medicare**

PathfinderTG Technology is covered as a “reasonable and necessary” service specifically and only for the indications of pancreatic cyst/mass where diagnostic evaluations are inconclusive.

As a requirement for coverage, RedPath Integrated Pathology will maintain and populate a Medicare-specific database of all Medicare patients for which PathfinderTG Technology is utilized as a diagnostic tool. This information collection will begin no later than January 1, 2011, and include at least the following information:

- Patient's Medicare Identifiers (Medicare #, DOB)
- Date of PathfinderTG service
- Date sample collected
- Results of Cytology
- CEA values
- Results of Ultrasound/CT Studies
- PathfinderTG results

## **CODING**

### **BlueCHiP for Medicare and Commercial Products**

There is no established CPT or HCPCS code which adequately describes the procedure; to report use the following unlisted CPT code:

**84999**

## **RELATED POLICIES**

Preauthorization via online tool for Genetic Testing

## **PUBLISHED**

Provider Update, January 2016

Provider Update, January 2015

Provider Update, September 2013

Provider Update, June 2012

Provider Update, July 2011

Provider Update, July 2010

Provider Update, August 2009

## **REFERENCES**

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2. U.S. Patent #7,014,999. Finkelstein et al. March 21, 2006. Topographic genotyping. [http://patft.uspto.gov/netacgi/nphParser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnethtml%2FPTO%2Fsearchadv.htm&r=16&f=G&l=50&d=PTXT&S1=\(redpath+AND+specimen\)&OS=redpath+AND+specimen&RS=\(redpath+AND+specimen\)](http://patft.uspto.gov/netacgi/nphParser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnethtml%2FPTO%2Fsearchadv.htm&r=16&f=G&l=50&d=PTXT&S1=(redpath+AND+specimen)&OS=redpath+AND+specimen&RS=(redpath+AND+specimen)). Accessed April 30, 2015

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4. Centers for Medicare and Medicaid Services (cms.gov) Local Coverage Determination (LCD): Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (L34864) [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34864&ContrId=323&ver=5&ContrVer=1&CntrctrSelected=323\\*1&Cntrctr=323&s=45&DocType=Active&LCntrctr=295\\*1&bc=AggAAAIAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34864&ContrId=323&ver=5&ContrVer=1&CntrctrSelected=323*1&Cntrctr=323&s=45&DocType=Active&LCntrctr=295*1&bc=AggAAAIAAAAAA%3d%3d&)

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