EFFECTIVE DATE: 04/07/2009
POLICY LAST UPDATED: 12/02/2014

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

PRIOR AUTHORIZATION
Prior authorization is not required.

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 CMS (Centers for Medicare and Medicaid Services), 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 as Medicare offers.

Commercial
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.

MEDICAL CRITERIA
None

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 microdissected to increase tumor cell yield for subsequent molecular analysis. TG may permit pathologic diagnosis when first-line analyses are inconclusive.(1)

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."(2) 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."(3) Although the website states that "PathFinderTG® is clinically validated as reported in over 200 peer-reviewed articles," test performance information is not provided.

FDA 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 RedPathIntegrated 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 (ie, 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

BCBSRI participating facilities **ONLY**:
If the decision to send out the specimen is made at least 14 days (i.e., 14 or more days) after discharge, and the specimen arrives at RedPath more than 30 days after discharge, we will allow the specimen to be reported as the date it is received, which would be outside the hospital payment. If it is ordered 13 days or less after discharge **OR** is received 30 days or less after discharge, it is dated as the date of the procedure and is the facility obligation.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable Services Not Medically Necessary and Laboratory tests coverage.

CODING

BlueCHiP for Medicare and Commercial

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

84999

RELATED POLICIES

None

PUBLISHED

Provider Update	Jan 2015
Provider Update	Sep 2013
Provider Update	Jun 2012
Provider Update	Jul 2011
Provider Update	Jul 2010
Provider Update	Aug 2009

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