Medical Coverage Policy |

PathFinderTG® Molecular

EFFECTIVE DATE: 04/07/2009
POLICY LAST UPDATED: 08/06/2013

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 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 as there is inadequate peer reviewed data to support its use.

MEDICAL CRITERIA

None

BACKGROUND

The patented PathFinderTG® test is a molecular test to be used adjunctively in cases in which a definitive pathologic diagnosis cannot be rendered on a tissue or cytology specimen, either due to inadequate specimen or equivocal histologic or cytologic findings. This approach may be referred to as molecular anatomic pathology. PathFinderTG® results claim to provide diagnostic and prognostic information and predict treatment response for multiple organ systems.

The test involves the following steps:

- Manual microdissection to identify and procure abnormal cells from existing pathology specimens
- DNA extraction and amplification (e.g., polymerase chain reaction [PCR])
- DNA sequencing to identify oncogenic mutations

• Integration of this molecular information with the cytologic or histologic findings provided by the pathologist of record to provide a definitive diagnosis

For some specimens such as fluid aspirates, DNA is extracted from the fluid, since there may be little or no cellular content. The molecular testing consists of applying panels of molecular markers previously defined for each organ system or clinical question.

Potential uses include determining reactive versus neoplastic lesions, benign versus malignant lesions, biologically indolent versus aggressive tumors, which premalignant lesions will or will not progress into cancer, whether a synchronous or metachronous tumor represents metastatic spread or a new primary, and expected responses to treatment for various tumors. RedPath proposes that PathFinderTG® is appropriate in clinical practice when the results will alter clinical decision-making.

This patented diagnostic test is only available 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.
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

Since the RedPath laboratory is located in Pennsylvania, all Medicare claims for this test will be processed by Highmark Medicare Services. The CPT code suggested by Highmark Medicare Services for this test (which also appears on a test requisition form on the company website) is code 84999 – unlisted chemistry procedure.

For Commercial products:
The evidence reviewed for this test has significant limitations. 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 must also be clearly reproducible, as shown by applying the test (with a priori defined cutoff points) to independent samples for validation. Because the impact of this technology on health outcomes is not known and because outcomes with this technology compared with existing alternatives (i.e., incremental value) are not known, the PathFinderTG® testing is considered not medically necessary for all indications, including evaluation of pancreatic cyst fluid and evaluation of suspected/known gliomas.

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, Subscriber Agreement for applicable Services Not Medically Necessary and Laboratory tests coverage.

CODING

As there is no established CPT or HCPCS code which adequately describes the procedure the provider should file the following for BlueCHiP for Medicare and Commercial products:

84999

RELATED POLICIES

None

PUBLISHED

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

REFERENCES

Blue Cross and Blue Shield Association: The Medical Policy Reference Manual (MPRM) Policy: 2.04.52 PathFinderTG® Molecular Testing Reviewed with literature search/May 2013.

Highmark Medicare Services, LCD L31144 - Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® Posted for Notice

http://www.redpathip.com/documents/HMSLCDL31144PathFinderTG.pdf

U.S. Department of Health and Human Services: AHRQ. A Systematic Review on RedPathTG® Diagnostics.

http://www.ahrq.gov/clinic/ta/comments/redpath/

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