

Corporate Medical Policy

PathFinderTG® Molecular Testing

File Name:	pathfindertg_molecular_testing
Origination:	1/2009
Last CAP Review:	3/2012
Next CAP Review:	3/2013
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Description of Procedure or Service

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.” RedPath, the test provider, suggests that the PathFinderTG® results provide useful and definitive diagnostic and prognostic information and reliably 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. PCR)
- DNA sequencing to identify oncogenic mutations
- Integrating 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 described by the company 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.

Some of the tests RedPath offers (e.g., 1p/19q loss, microsatellite instability) are offered by other laboratories as single clinical tests. The remainder of the tests they offer (e.g., KRAS point mutation and loss-of-heterozygosity [LOH] panels) are typically performed in research settings. The aim of PathFinderTG® testing is to integrate molecular findings into the pathology diagnosis.

This patented diagnostic test is available only through RedPath Integrated Pathology (Pittsburgh, PA). The PathFinderTG® Molecular Testing 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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

PathFinderTG® Molecular Testing is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When PathFinderTG Molecular Testing is covered

Not applicable.

When PathFinderTG Molecular Testing is not covered

Molecular testing using the PathFinderTG® system is considered **investigational** for all indications including, but not limited to, the evaluation of pancreatic cyst fluid and of suspected or known gliomas.

Policy Guidelines

The evidence reviewed for 2 representative uses 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 prior-defined cutoff points) to independent samples for validation. The impact of this technology on health outcomes and the outcomes of this technology compared with existing alternatives (i.e., incremental value) are not known.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: There is no specific HCPCS or CPT code for this technology.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

PathFinderTG® Molecular Testing

Scientific Background and Reference Sources

- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.52, 4/9/2008
Senior Medical Director Review - 12/10/2008
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.52, 4/24/2009
Specialty Matched Consultant Advisory Panel – 5/2010
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.52, 6/19/2010
Specialty Matched Consultant Advisory Panel – 3/2011
- BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.52, 6/9/2011
Specialty Matched Consultant Advisory Panel – 3/2012

Policy Implementation/Update Information

- 2/16/09 New policy implemented. "Molecular testing using the PathFinderTG® system is considered **investigational** for all indications including but not limited to the evaluation of pancreatic cyst fluid and of suspected or known gliomas." Reviewed with the Senior Medical Director 12/10/2008. Notification given 2/16/2009. Policy effective 5/18/2009. (btw)
- 6/22/10 Policy Number(s) removed. (amw)
- 7/6/10 Specialty Matched Consultant Advisory Panel review 5/24/2010. Updated "Description" section. No change to policy intent. References added. btw
- 4/26/11 Specialty Matched Consultant Advisory Panel Review March 30, 2011. No change to policy intent. References added. (btw)
- 8/16/11 Reference added. (btw)
- 4/17/12 Specialty Matched Consultant Advisory Panel 3/21/2012. No change to policy. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.