Protocol

PathFinderTG® Molecular Testing

(20452)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 09/09, 09/10, 07/11, 07/12, 07/13, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel the service is medically necessary.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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.

Background

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 five 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.

Table 1. PathFinderTG® Tests (4)

Test	Description	Specimen Type(s)
PathFinderTG® Pancreas	Uses loss of heterozygosity markers, oncogene mutations, and DNA content abnormalities to stratify patients according to their risk of progression to cancer	Pancreatobiliary fluid/ERCP brush, pancreatic masses, or pancreatic tissue
PathFinderTG® Barrett	Measures the presence and extent of genomic instability and integrates those results with histology	Esophageal tissue
PathFinderTG® Biliary	Uses oncogene mutations and loss of heterozygosity markers to identify whether patients with biliary strictures have a malignant neoplasm or benign reactive disease	Biliary brush/supernatants

Test	Description	Specimen Type(s)
PathFinderTG® Metastases versus Primary Tumors (MvP)	Uses molecular markers and mutations to determine whether concurrent tumors are synchronous primaries or metastatic disease	Slides
PathFinderTG® Glioma	Intended to help differentiate between gliosis and glioma, grade of glioma, and type of malignancy	Not reported

ERCP: endoscopic retrograde cholangiopancreatography.

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 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.

Policy (Formerly Corporate Medical Guideline)

Molecular testing using the PathFinderTG® system is considered **investigational** for all indications including the evaluation of pancreatic cyst fluid, of suspected or known gliomas, and Barrett esophagus.

Medicare Advantage

PathFinderTG® may have potential for coverage by original fee-for-service Medicare for members with pancreatic cysts or masses when the service is provided in a clinical trial. This would be billed to original Medicare not Medicare Advantage. All other indications will be considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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