PathFinderTG® MOLECULAR TESTING

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

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Description:

Topographic genotyping (TG), also called molecular anatomic pathology, integrates microscopic analysis (anatomic pathology) with molecular tissue analysis.

Interpace Diagnostics, formerly known as RedPath, offers the PancraGEN™ and BarreGEN™ tests that use the PathFinderTG® platform. These molecular tests are intended to be used adjunctively when a definitive pathologic diagnosis cannot be made, because of inadequate specimen or equivocal histologic or cytologic findings. The purpose of the test is to choose appropriate surveillance or surgical strategies.
PathFinderTG MOLECULAR TESTING (cont.)

Criteria:

➢ Genetic testing and/or counseling of an unaffected individual, regardless of risk factors is considered screening and not eligible for coverage.

➢ Genetic testing and/or counseling of an affected individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered not medically necessary and not eligible for coverage.

➢ Molecular testing using the PathFinderTG system for all indications is considered experimental or investigational based upon:
   1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
   2. Insufficient evidence to support improvement of the net health outcome, and
   3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, but are not limited to:

▪ Barrett esophagus
▪ Pancreatic cyst fluid evaluation

Resources:

Resources prior to 10/05/16 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

Literature reviewed 06/16/15. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

PathFinderTG MOLECULAR TESTING (cont.)

Resources: (cont.)


