Medical Coverage Policy | PathfinderTG® Molecular Testing

EFFECTIVE DATE: 11|10|2016
POLICY LAST UPDATED: 09|03|2020

OVERVIEW

This policy describes coverage of molecular testing using the PathfinderTG platform (e.g. PancraGEN, BarreGEN).

MEDICAL CRITERIA

BlueCHiP for Medicare

The specific requirements for medical necessity involve:

1. Highly-concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary.
2. Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
   a. A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/ml, suggesting a mucinous cyst, but is not diagnostic.
   b. Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

PRIOR AUTHORIZATION

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Prior authorization is required and is obtained via the online tool for participating providers. See the Related Policies section.

Commercial Products

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

PathfinderTG molecular testing is covered for pancreatic cyst/mass when the medical criteria are met. All PathfinderTG® indications other than pancreatic cyst fluid evaluation are considered not covered due to insufficient data on both analytical and clinical validity.

> **Note:** BCBSRI must follow CMS (Centers for Medicare and Medicaid Services) guidelines, such as National Coverage Determinations or Local Coverage Determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial Products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products

Molecular testing using the PathFinderTG system is considered not medically necessary for all indications including the evaluation of pancreatic cyst fluid, Barrett esophagus, and solid pancreaticobiliary lesions as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND

Commercial

Topographic genotyping, 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. Topographic genotyping may permit pathologic diagnosis when first-line analyses are inconclusive.

RedPath Integrated Pathology (now Interpace Diagnostics) has patented a proprietary platform called PathFinderTG; it provides 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." Interpace currently describes PathFinderTG test called PancraGEN on its website and describes another PathFinder test called BarreGEN™ "as in a "soft launch". As stated on the company website, PancraGEN integrates molecular analyses with first-line results (when these are inconclusive) and pathologist interpretation. The manufacturer calls this technique integrated molecular pathology. Test performance information is not provided on the website.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Patented diagnostic tests (eg, PancraGEN™) are available only through Interpace Diagnostics (Pittsburgh, PA and New Haven, CT; formerly RedPath Integrated Pathology) under the auspices of CLIA. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

For individuals who have pancreatic cysts who do not have a definitive diagnosis after first-line evaluation and who receive standard diagnostic and management practices plus topographic genotyping (PancraGEN molecular testing), the evidence includes retrospective studies of clinical validity and clinical utility. Relevant outcomes are overall survival, disease-specific survival, test validity, change in disease status, morbid events, and quality of life. The best evidence regarding incremental clinical validity comes from the National Pancreatic Cyst Registry report that compared PancraGEN performance characteristics with current international consensus guidelines and provided preliminary but inconclusive evidence of a small incremental benefit for PancraGEN. The analyses from the registry study included only a small proportion of enrolled patients, relatively short follow-up time for observing malignant transformation, and limited data on cases where the PancraGEN results are discordant with international consensus guidelines. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Barrett esophagus who receive standard prognostic techniques plus topographic genotyping (BarreGEN molecular testing), the evidence includes a systematic review. Relevant outcomes are overall survival, disease-specific survival, test validity, change in disease status, morbid events, and quality of life. The systematic review identified no studies relevant to this evidence review. Two observational studies were excluded based on selection criteria because it was unclear whether the test used was specifically BarreGEN or whether the BarreGEN prognostic algorithm was applied for classification. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have solid pancreaticobiliary lesions who do not have a definitive diagnosis after first-line evaluation and who receive standard diagnostic and management practices plus topographic genotyping (PancraGEN molecular testing), the evidence includes 3 observational studies of clinical validity. Relevant

outcomes are overall survival, disease-specific survival, test validity, change in disease status, morbid events, and quality of life. Two of the 3 studies had populations with biliary strictures and the other had a population of patients with solid pancreaticobiliary lesions. The studies reported higher sensitivities and specificities when PancraGEN testing was added to cytology results compared with cytology alone. However, the inclusion of patients in the analysis who may not have solid pancreaticobiliary lesions (those with biliary strictures not caused by solid pancreaticobiliary lesions) limits the interpretation of the results. While preliminary results showed a potential incremental benefit for PancraGEN, further research focusing on patients with solid pancreaticobiliary lesions is warranted. The evidence is insufficient to determine the effects of the technology on health outcomes.

BlueCHiP for Medicare
PathfinderTG® will be considered medically reasonable and necessary when selectively used as an **occasional second-line diagnostic supplement**:
• only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; **AND**
• a decision regarding treatment (e.g. surgery) has NOT already been made based on existing information.

DOCUMENTATION REQUIREMENTS

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.
5. The medical record must clearly indicate the purpose of the Pathfinder TG® test.
6. The medical record should clearly support why and how the first-line diagnostic work-up was insufficient to adequately monitor or manage the pancreatic cyst(s) under evaluation, such that this very specialized second-line PathfinderTG®testing has become necessary.

CODING

BlueCHiP for Medicare and Commercial Products
There is no established CPT or HCPCS code which adequately describes the procedure; therefore, it may be reported using an unlisted CPT code (84999 or 81479)

RELATED POLICIES

Genetic Testing Services
Unlisted Procedures

PUBLISHED

Provider Update, November 2020
Provider Update, October 2019
Provider Update, January 2019
Provider Update, November 2017
Provider Update, December 2016
Provider Update, January 2016
Provider Update, January 2015
Provider Update, September 2013

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