Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>PancraGEN™ Genotyping for Risk Assessment of Pancreatic Cancer</th>
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<td>Effective Date:</td>
<td>5/21/2018</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

PancraGEN™ topographic genotyping for risk assessment of pancreatic cancer is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

PancraGEN™ is a molecular anatomic pathology test that combines DNA-molecular analysis with anatomic pathology and clinical data to evaluate the malignant potential of pancreatic cysts. This technology, also known as topographic genotyping, is intended to aid in the risk assessment, treatment decisions (such as whether to undergo surgery), and management course for each patient's unique diagnosis.

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.” A proprietary algorithm combines imaging, cytology, biochemical, and gene mutation results to stratify patients into a risk category of benign, statistically indolent, statistically high risk, or aggressive.

PancraGEN™ test is being proposed for patients who have pancreatic cysts of undetermined malignant potential and is offered, in conjunction with first-line testing or as a second-line test when first-line testing is equivocal. PancraGEN™ is not intended for cases where the cytology is positive for malignancy.

FDA Approval

Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution. PathFinderTG® tests are developed by RedPath Integrated Pathology (Pittsburgh, PA) and are currently performed only at RedPath’s CLIA certified facility. Therefore, these tests are not currently subject to FDA approval.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

Original Effective Date: 5/21/2018

Re-Review Date(s): 2/20/2020 – administrative update; format