KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Integrated Molecular Pathology

- Loss-of-Heterozygosity Topographic Genotyping with PathfinderTG®
- PancraGEN

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: Molecular Diagnostic Tests (MDT) (L36256)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Integrated Molecular Pathology (Topographic Genotyping) - PathFinderTG (A-0632) MCG* guideline for medical necessity determinations. This test is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider
- Genetics consult if applicable & requesting provider is not a geneticist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Pathologic analysis of tissue samples is central to the diagnosis of cancer; however, there are some instances when these results may by inconclusive. Pathfinder TG® is a molecular DNA-based cancer diagnostic test that can aid diagnosis when pathology results are inconclusive. The Pathfinder TG® test uses a method known as topographic genotyping that combines pathology and molecular analysis using specific genetic marker panels to identify acquired mutations in a variety of difference types of cancer.

PancraGEN description

PancraGEN is a DNA-based, integrated molecular pathology test that evaluates the risk of pancreatic cancer in pancreatic cysts. This test can help choose adequate surveillance strategies or surgical options for patients with pancreatic cysts (https://pancragen.com/).

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PancraGEN is a personalized test, that interrogates cumulative oncogene and tumor suppressor gene damage, reporting results in the context of each patient's clinical history, imaging, fluid chemistry and cytology test results. Offering added clarity about the biologic behavior of a pancreatic cyst, PancraGEN provides an overall prognostic assessment that helps inform the best step forward when determining which patients are suited for surveillance vs. surgical intervention (https://pancragen.com/power-of-pancragen/). The test provides high positive predictive value (PPV) for malignancy and can inform surveillance and surgical decisions when first-line results have clinical uncertainty. It determines high and low malignancy potential within pancreatic cysts, masses, and ductal strictures.

PancraGEN identifies the quality and quantity of DNA in cyst fluid (giving those high levels of intact DNA are associated with actively dividing cells), oncogenes (KRAS and GNAS point mutations), tumor suppressor gene mutations (loss of heterozygosity).
PancraGEN is offered by Interpace Biosciences.

PancraGEN can help answer the following questions: 1) Is this cyst benign or aggressive today? 2) What is the likelihood that the cyst will progress to cancer? 3) How do I monitor this patient and what do I do next?

Medical Technology Assessment Committee (MTAC)

Pathfinder TG®

06/18/2012: MTAC REVIEW

Evidence Conclusion: Analytic validity - No studies were identified that evaluated the analytic validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Clinical validity- Fifteen retrospective studies with methodological limitations were identified that evaluated the clinical validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®. Details on patient characteristics, treatments, clinical definitions, and statistical methods were limited. Additionally, only 3 studies had more than 50 patients and it is possible that these publications analyzed the same patient population. There is insufficient high-quality evidence to determine the clinical validity of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Clinical utility - No studies were identified that evaluated the clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG® (AHRQ 2010). Conclusion:
There is insufficient evidence to determine the analytic validity, clinical validity, and clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®.
Articles: The literature search revealed a 2010 AHRQ technology assessment that evaluated the analytic validity, clinical validity, and clinical utility of loss-of-heterozygosity based topographic genotyping with Pathfinder TG®. Studies were excluded if they had less than 25 subjects. No relevant articles were identified after the 2010 ARHQ review. The following technology assessment was selected for review: Trikalinos TA, Terasawa T, Raman G et al. A systematic review of loss-of-heterozygosity based topographic genotyping with PathfinderTG®. AHRQ Technology Assessment Program (Project ID GEND0308). March 2010. See Evidence Table.

The use of Pathfinder TG® does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

PancraGEN

01/09/2023: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the clinical value and utility of pancragen.
Articles: PubMed was searched through 12/7/2022 with the search terms pancragen, pathfinder tg, redpath, and topographic genotyping with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
81479	Unlisted molecular pathology procedure
With diagnosis codes	
K86.2	Cyst of pancreas

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K86.3	Pseudocyst of pancreas

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/03/2012	07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 03/04/2014[MDCRPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	03/04/2014

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/20/2023	Added MTAC review for PancraGen.

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