

Genetic Testing- Topographic Genotyping (MA Only)

Policy Number: MP-027 Last Review Date: 05/09/2019 Effective Date: 07/01/2019

Policy

Evolent Health considers **Topographic Genotyping (TG)** medically necessary when both of following indications are met:

- 1. Cystic lesions and masses of the pancreas when cytology is suspicious for cancer
- 2. Documentation of specific reasons for the additional testing, including how results will change patient management of their disease

Limitations

- 1. TG testing (PathfinderTC®) is not intended for "first-line" pathology analysis
- 2. RedPath® Diagnostics (PathfinderTG®) for Topographic Genotyping will be considered an out-of-network provider

Background

Topographic Genotyping (TG) is a cancer diagnostic testing mechanism combining pathologic study with molecular analyses of microdissected tissue. TG is claimed to enhance the ability to provide more specific diagnostic information and ultimately help guide cancer treatment decisions. The Centers for Medicare and Medicaid (CMS) describes this type of diagnostic method as an alternative to standard pathologic analyses which can provide inconclusive information at times. Loss-of-heterozygostiy based topographic genotyping and other molecular analyses are combined in a patented technology known as PathfinderTG [®]. This testing is approved by Clinical Laboratory Improvement Amendments (CLIA) & the College of American Pathologists (CAP).

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
81479	Unlisted molecular pathology procedure
84999	Unlisted chemistry procedure

Variations

Topographical Genotyping is considered Experimental and Investigational for all products except Medicare. All PathfinderTG® indications other than pancreatic cyst fluid evaluation are considered investigational and are therefore not considered medically reasonable and necessary due to insufficient data on both analytical and clinical validity.

References



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- Cai G, Siddiqui U, Aslanian H, et al. Molecular analysis of pancreatic cyst fluid: correlation with cytologic diagnosis and surgical follow-up. CT USCAP; March 23, 2010. http://redpathip.com/files/pdf/abstracts-posters/2010/Molecular%20Analysis%20of%20Pancreatic%20Cyst%20Fluid%20Cyrelation%20with%20Cytologic%20Diagnosis%20and%20Surgical%20Follow-Up.pdf
- Centers for Medicare and Medicaid Services (CMS). Local Coverage
 Determination (LCD). No. L34864 Loss-of-Heterozygosity Based Topographic
 Genotyping with PathfinderTG®, (Contractor: Novitas Solutions, Inc). Revision
 Effective Date: 01/04/2016. <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-det
- Department of Health and Human Services. Agency for Healthcare Research and Quality (AHRQ): A systematic review of loss-of-heterozygosity based topographic genotyping with PathfinderTG®, Technology Assessment Report, Project ID: GEND0308, March 1, 2010. http://www.cms.gov/determinationprocess/downloads/id68ta.pdf
- 4. Gress TM. Commentary: Molecular diagnosis of pancreatobiliary malignancies in brush cytologies of biliary strictures. GUT 2004; 53(12):1727-1729. doi:10 1136/gut.2004.046177. http://gut.bmj.com/content/53/12/1727.full
- 5. Hayes GTE Report. PathFinderTG Test for Pancreatic Cancer. Published Date: 12/07/2009. Annual Review Date: 11/08/2013.
- Khalid A, Pal R, Sasatomi E, et al. Use of microsatellite marker loss of heeterozygosity in accurate diagnosis of pancreaticobiliary malignancy from brush cytology samples. GUT 2004: 53:1860-1865. http://gut.bmj.com/content/53/12/1860.full.pdf+html
- 7. Mohan D, Finkelstein SD, Swalsky PA, et al. Microdissection genotyping of gliomas: therapeutic and prognostic considerations, Mod Pathol 2004 Nov. 17(11):1346-1358.
 - http://www.nature.com/modpathol/journal/v17/n11/full/3800194a.html
- Panarelli NC, Sela R, Schreiner AM, et al. Commercial molecular panels are of limited utility in the classification of pancreatic cystic lesions. Am J Surg Pathol. 2012 Oct;36(10):1434-1443. doi: 10.1097/PAS.0b013e31825d534a. http://www.ncbi.nlm.nih.gov/pubmed/22982886
- 9. Pitman MB, Lewandrowski K, Shen J, et al. Pancreatic Cysts: preoperative diagnosis and clinical management. Cancer Cytopathol. 2010 Feb 25; 118(1):1-13. https://www.ncbi.nlm.nih.gov/pubmed/20043327
- 10. RedPath Integrated Pathology Inc. Overview: PathFinder TG™ Accessed: 04/21/2019 . http://redpathip.com/physicians/overview



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- 11. Sasatomi E, Finkelstein SD, Woods JD, et al. Comparison of accumulated allele loss between primary tumor and lymph node metastasis in Stage II non-small cell lung carcinoma. Implications for the timing of lymph node metastasis ad prognostic value. Cancer Res 2002; 62(9):2681-2689. http://cancerres.aacrjournals.org/content/62/9/2681.full.pdf+html
- 12. Watanabe I, Hasebe T, Sasaki S, et al. Advanced pancreatic ductal cancer: fibrotic focus and beta-catenin expression correlate with outcome. Pancreas 2003 May; 26(4):326-333. http://www.ncbi.nlm.nih.gov/pubmed/12717263

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