

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.027.MH
Last Review Date: 05/27/2021
Effective Date: 08/01/2021

MP.027.MH – Genetic Testing- Topographic Genotyping

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Topographic Genotyping (TG)** medically necessary for the following indications:

TG testing is covered 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-heterozygosity 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
84999	Unlisted chemistry procedure

The following code(s) require prior authorization:

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81479	Unlisted molecular pathology procedure
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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

1. 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. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34864&ver=42&Date=02%2F01%2F2020&DocID=L34864&bc=hAAAAAgAAAA&>
2. 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>
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4. Khalid A, Pal R, Sasatomi E, et al. Use of microsatellite marker loss of heterozygosity in accurate diagnosis of pancreatobiliary malignancy from brush cytology samples. GUT 2004; 53:1860-1865. <http://gut.bmj.com/content/53/12/1860.full.pdf+html>
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9. 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>

Archived Referenes

1. Hayes GTE Report. PathFinderTG Test for Pancreatic Cancer. Published Date: 12/07/2009. Annual Review Date: 11/08/2013. Archived: January 7, 2015.

Disclaimer:

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