



LCD L31144 - Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG[®] Posted for Notice

Contractor Information

Contractor Name:

Highmark Medicare Services, Inc.

Contractor Number:

12102, 12202, 12302, 12501, 12301, 12201, 12401, 12402, 12101, 12502

Contractor Type:

MAC Part A & B

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LCD Information

LCD Database ID Number

L31144

LCD Title

Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG[®] Posted for Notice

Contractor's Determination Number

L31144

AMA CPT/ADA CDT Copyright Statement

CPT codes, descriptions and other data only are copyright 2009 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology, (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Primary Geographic Jurisdiction

Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware

Oversight Region

Central Office

Original Determination Effective Date

For services performed on or after 11/05/2010

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

Evaluating tissue samples pathologically is crucial to the diagnosis and treatment of patients with malignancy. At times, standard pathologic analyses provide inconclusive information. Combining pathologic study with molecular analyses of microdissected tissue, is claimed to enhance the ability to provide more specific diagnostic information, to help guide treatment decisions. These testing combinations are generally known as topographic genotyping.

More specifically, loss-of-heterozygosity based topographic genotyping and other molecular analyses are combined in a patented technology known as PathfinderTG[®]. Recently, a Technology Assessment Report prepared by the Tufts Evidence-Based Practice Center, for the Agency for Healthcare Research and Quality (AHRQ), reviewed the existing scientific literature for PathfinderTG[®].

The Technology Assessments conclusions noted insufficient studies measuring whether the use of PathfinderTG[®] Technology would improve patient relevant clinical outcomes. Questions raised included whether PathfinderTG[®] results affected diagnostic evaluation or treatment decisions.

However, during the comment period for the draft LCD, Highmark Medicare Services received extensive comments from physicians and providers from across the country, many from distinguished, highly reputable universities and physicians specifically on their use and results of the PathfinderTG[®] Technology very specifically for patients with pancreatic cysts where "traditional" fluid chemistry and/or cytology evaluations were inconclusive. Several institutions provided their own research results of their use of PathfinderTG[®] Technology specifically for patients with pancreatic cysts where fluid chemistries and/or cytology evaluations were inconclusive.

As a result, PathfinderTG[®] Technology will be covered as a "reasonable and necessary" service specifically and only for the indications of pancreatic cyst/mass where diagnostic evaluations are inconclusive under "Coverage with Appropriateness Development," in keeping with the Social Security Act Section 1862(a)(1)(A) allowance for "Coverage with Appropriateness Development."

As a requirement for this "Coverage with Appropriateness Development," the provider of the Loss-of Heterozygosity Based Topographic Genotyping with PathfinderTG[®] will maintain and populate a Medicare-specific database of all Medicare patients for which PathfinderTG[®] Technology is utilized as a diagnostic tool. This information collection will begin no later than January 1, 2011, and include at least the following information:

- Patient's Medicare Identifiers (Medicare #, DOB)
- Date of PathfinderTG[®] service
- Date sample collected
- Results of Cytology
- Results of Ultrasound / CT Studies

- CEA values
- PathfinderTG[®] results

This information will be maintained while preserving patient confidentiality and will be provided to Medicare every six months. This information will be matched with Medicare claims information to assist in developing appropriateness criteria in future, based upon longitudinal review of the impact of this study on the clinical outcomes of the individual patients. All other indications will be considered investigational and therefore not eligible for coverage due to insufficient data on the clinical utility and efficacy beyond pancreatic cyst/mass evaluation.

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Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x	Hospital Inpatient (Including Medicare Part A)
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999	Not Applicable
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CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT) codes*.

84999	UNLISTED CHEMISTRY PROCEDURE
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ICD-9 Codes that Support Medical Necessity

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

577.0 -	ACUTE PANCREATITIS - UNSPECIFIED DISEASE OF PANCREAS
577.9	

Diagnoses that Support Medical Necessity

Pancreatic Cyst; Pancreatic Mass

ICD-9 Codes that DO NOT Support Medical Necessity

All other ICD-9-CM codes not listed above.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

All other diagnoses except Pancreatic Cyst / Pancreatic Mass.

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Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and 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 record must include the physician or non-physician practitioner responsible for and providing the care of the patient.
3. The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. The date of service for laboratory specimens

According to the Medicare Internet Only Manual; 100-04 Claims Processing; Chapter 16, Section 40.8 and 42 CFR §414.510, the date of service for laboratory tests is as follows:

General Rule:	The date of service (DOS) of the test shall be the date the specimen was collected.	
Variation:	If a specimen is collected over a period that spans two calendar days, then the DOS shall be the date the collection ended.	
Exceptions:	DOS for tests performed on stored specimens	
	In the case of a test performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test must be the date the test was performed <u>only if</u> :	
	<ul style="list-style-type: none"> • The test is ordered by the patient's physician 14 days following the date of the patient's discharge from hospital; • The specimen was collected while the patient was undergoing a hospital surgical procedure; • It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted; • The results of the test do not guide treatment provided during the hospital stay; <u>AND</u> • The test was reasonable and medically necessary for the treatment of illness. 	
	If the specimen was stored for more than 30 calendar days before testing, the specimen was considered to have been archived and the DOS of the test must be the date the specimen was obtained from storage.	

Appendices

N/A

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Sources of Information and Basis for Decision

Highmark Medicare Services is not responsible for the continued viability of websites listed.

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.

Pitman MB, Lewandrowski K, Shen J, et al. Pancreatic Cysts: Preoperative Diagnosis and Clinical Management. *Cancer Cytopathol.* 2010 Feb 25;118(1):1-13.

Shen J, Brugge WR, Dimaio CJ, et al. Molecular Analysis of Pancreatic Cyst Fluid: A Comparative Analysis with Current Practice of Diagnosis. *Cancer Cytopathol.* 2009;117(3):217-27.

Trikalinos TA, Terasawa T, Raman G, Ip S, Lau J. A Systematic Review of Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG®: *Technology Assessment Report.* Rockville, MD: Agency for Healthcare Research and Quality, US Dept of Health and Human Services; 2010.

Other Contractor(s)' Policies

Highmark Medicare Services Contractor Medical Directors

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Directors. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

CAC Distribution: 05/20/2010

Start Date of Comment Period

05/20/2010

End Date of Comment Period:

07/13/2010

Start Date of Notice Period

09/20/2010

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Revision History

Revision History Number

L31144

Revision History Explanation

Date	Policy #	Description
09/20/2010	L31144	LCD posted for notice. LCD to become effective on 11/05/2010.
05/20/2010	DL31144	Original LCD posted for comment.

Last Reviewed On

09/17/2010

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

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