

MolDX: Chromosome 1p/19q Deletion Analysis

Noridian Healthcare Solutions, LLC

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Please Note: This is a Proposed LCD.

Proposed LCDs are works in progress and not necessarily a reflection of the current policies or practices. Proposed LCDs in an approval status display on the CMS MCD for public review.

Contractor Information



Contractor Name Noridian Healthcare Solutions, LLC

Contract Number 01112

Contract Type A and B MAC

Associated Contract Numbers (A and B MAC - 01111 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01211 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01311 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01911 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01182 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01212 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01312 - J - E) Noridian Healthcare Solutions, LLC

Proposed LCD Information



Source LCD ID N/A

Proposed LCD ID DL36557

Original ICD-9 LCD ID N/A

Proposed LCD Version 3

Proposed LCD Title **MoldX: Chromosome 1p/19q Deletion Analysis**

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CMS Internet Online Manual Pub. 100-02 (Medicare Benefit Policy Manual), Chapter 15, Section 80, "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests"

**CMS National
Coverage
Policy**

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes"

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §30-Correct Coding Policy

Jurisdiction California - Northern

Coverage Guidance



Indications for testing

Chromosome 1p-/19q- (e.g., glial tumors), deletion analysis is considered medically necessary for the management of following glial tumors:

- Astrocytoma
- Ependymoma
- Oligoastrocytoma (Mixed Glioma)
- Oligodendroglioma
- Optic Glioma
- Gliomatosis Cerebri

Chromosome 1p-/19q-deletion analysis may also be indicated in the diagnosis of neoplasms that exhibit small round cell features (e.g. small glioblastomas and neurocytic tumors)

**Coverage
Indications,
Limitations and/or
Medical Necessity**

Limitations of coverage
Chromosome 1p-/19q- deletion analysis may be accomplished by molecular sequencing (81402) or morphometric analysis (e.g. in situ hybridization (FISH) 88367 or 88368). Physicians with patients who meet the indications of chromosome 1p-/19q testing - may select from one of the following test services:

- 81402 Chromosome 1p-/19q- (e.g., glial tumors), deletion analysis
- 88367 Chromosome 1p-/19q- Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure
- 88373 Chromosome 1p-/19q- Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure

- 88368 Chromosome 1p-/19q- Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure
- 88369 Chromosome 1p-/19q-Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure

Note: Only ONE chromosome 1p-/19q analysis service per patient will be considered reasonable and necessary for tumor management.

Background

The presence of chromosome 1p/19q deletions in gliomas can assist in tumor differentiation, prognosis and treatment plan. Deletion studies specific to the 1p (short arm of chromosome #1) and 19q (long arm of chromosome #9) are performed on tumor tissue to determine if one or both 1p and 19q are deleted.

Over half of oligodendrogliomas have 1p/19q deletions that can help distinguish them from other types of gliomas.³ 1p/19q deletions can differentiate low-grade oligodendrogliomas from oligoastrocytomas.¹

The choice of adjuvant therapy depends on factors including tumor pathology and 1p/19q deletion status. Research observing improved survival has established combined procarbazine, lomustine, and vincristine (PCV) chemotherapy and radiation therapy as the new standard for treating anaplastic oligodendroglioma with the 1p/19q co-deletion.^{2,4,5,6}

Proposed Process Information



Synopsis of Changes	Changes	Fields Changed
Associated Information	Not Applicable	
Sources of Information and Basis for Decision		<ol style="list-style-type: none"> 1. Buckner JC, et al. Phase II trial of procarbazine, lomustine, and vincristine as initial therapy for patients with low-grade oligodendroglioma or oligoastrocytoma: efficacy and associations with chromosomal abnormalities. J Clin Oncol. 2003. 21(2):251-5.

2. Cairncross G, et al. Phase III trial of chemoradiotherapy for anaplastic oligodendroglioma: long-term results of RTOG 9402. *J Clin Oncol.* 2013. 31(3):337-43. doi: 10.1200/JCO.2012.43.2674. Epub.
3. Cairncross JG, et al. Specific genetic predictors of chemotherapeutic response and survival in patients with anaplastic oligodendrogliomas. *J Natl Cancer Inst.* 1998. 90(19):1473-9.
4. Hoang-Xuan K, et al. Temozolomide as initial treatment for adults with low-grade oligodendrogliomas or oligoastrocytomas and correlation with chromosome 1p deletions. *J Clin Oncol.* 2004. 22(15):3133-8.
5. Ino Y, et al. Molecular subtypes of anaplastic oligodendroglioma: implications for patient management at diagnosis. *Clin Cancer Res.* 2001. 7(4):839-45.
6. Kaloshi G, et al. Temozolomide for low-grade gliomas: predictive impact of 1p/19q loss on response and outcome. *Neurology.* 2007. 68(21):1831-6.

	Meeting Date	Meeting Information	State
Open Meetings	02/04/2016	Four Points by Sheraton Hotel 1617 1st Avenue San Diego, CA 92101	American Samoa, California - Entire State, Guam, Hawaii, Nevada, Northern Mariana Islands, California - Northern, California - Southern
Part B MAC Contractor Advisory Committee (CAC) Meetings	02/17/2016	Los Angeles	California - Entire State, California - Northern, California - Southern
	02/12/2016	Honolulu	Hawaii
	02/18/2016	Las Vegas	Nevada
Comment Period Start Date	02/04/2016		
Comment Period End Date	04/10/2016		
Released to Final LCD Date	Not yet released.		

**Reason for
Proposed LCD**

Creation of Uniform LCDs...
Creation of Uniform LCDs With Other MAC Jurisdiction

**Proposed LCD
Contact**

Noridian Healthcare Solutions, LLC JE Part B Contractor Medical
Director(s)
Attention: Draft LCD Comments
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Coding Information



Bill Type Codes 0x TBD

Revenue Codes N/A

Group 1: Paragraph

Group 1: Codes

**CPT/HCPCS
Codes**

81402	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 3 (EG, >10 SNPS, 2-10 METHYLATED VARIANTS, OR 2-10 SOMATIC VARIANTS [TYPICALLY USING NON-SEQUENCING TARGET VARIANT ANALYSIS], IMMUNOGLOBULIN AND T-CELL RECEPTOR GENE REARRANGMENTS, DUPLICATION/DELETION VARIANTS OF 1 EXON, LOSS OF HETEROZYGOSITY [LOH], UNIPARENTAL DISOMY [UPD])
88367	MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), USING COMPUTER-ASSISTED TECHNOLOGY, PER SPECIMEN; INITIAL SINGLE PROBE STAIN PROCEDURE
88368	MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), MANUAL, PER SPECIMEN; INITIAL SINGLE PROBE STAIN PROCEDURE
88369	MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), MANUAL, PER SPECIMEN; EACH ADDITIONAL SINGLE PROBE STAIN PROCEDURE

(LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

88373 MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), USING COMPUTER-ASSISTED TECHNOLOGY, PER SPECIMEN; EACH ADDITIONAL SINGLE PROBE STAIN PROCEDURE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

Does the CPT 30% Coding Rule Apply? No

Group 1: Paragraph

N/A

Group 1: Codes

ICD-10 Codes that Support Medical Necessity

Note: Performance is optimized by using code ranges.

- C71.0 Malignant neoplasm of cerebrum, except lobes and ventricles
- C71.1 Malignant neoplasm of frontal lobe
- C71.2 Malignant neoplasm of temporal lobe
- C71.3 Malignant neoplasm of parietal lobe
- C71.4 Malignant neoplasm of occipital lobe
- C71.5 Malignant neoplasm of cerebral ventricle
- C71.6 Malignant neoplasm of cerebellum
- C71.7 Malignant neoplasm of brain stem
- C71.8 Malignant neoplasm of overlapping sites of brain
- C71.9 Malignant neoplasm of brain, unspecified
- C72.0 Malignant neoplasm of spinal cord

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1: Paragraph

N/A

Group 1: Codes

Note: Performance is optimized by using code ranges.

Additional ICD-10 Information

Associated Documents



Attachments
Related Local Coverage
Documents
Related National Coverage
Documents

There are no attachments for this LCD.

This LCD version has no Related Local Coverage Documents.

This LCD version has no Related National Coverage Documents.