



March 24, 2017

Olatokunbo Awodele, M.D, MPH  
2525 No. 117th Avenue,  
Suite 200  
Omaha, NE 68164  
policycomments@wpsic.com

Re: Draft Coverage Determination: MOLDX: Chromosome 1p/19q Deletion Analysis (DL37009)

Dear Dr. Awodele,

Thank you for the opportunity to comment on WPS' proposed local coverage determination policy (LCD) for MolDX: Chromosome 1p/19q deletion analysis (DL37009). The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide

We are submitting joint comments because at this time both of our organizations share the same concerns regarding this draft LCD, and, as such, we request that WPS consider the joint recommendations outlined in this letter.

We support your decision to provide coverage for 1p/19q deletion analysis under certain circumstances; however we request that you consider the following addition to coverage.

### **Limitations of Coverage**

Additional clinical indications beyond those listed in the draft LCD may require more than one 1p/19q assay per patient. For example, recurrent oligodendrogliomas often exhibit histologic features of astrocytic gliomas as a result of therapeutic interventions raising the possibility of an oligoastrocytoma, a tumor with a worse prognosis.

Also, small biopsies of treated sites (areas which have received prior therapy) can produce histologic features of astrocytic hyperplasia that can be confused with recurrent tumor. In such instances, 1p/19q- testing is indicated, as distinguishing recurrent tumor versus treatment response is of obvious diagnostic and therapeutic significance. Needle biopsies after treatment may demonstrate features similar to those of an oligoastrocytoma, raising questions about the original diagnosis versus treatment effect where tumor is gone and replaced by benign reactive changes. The presence of a 1p/19q co-deletion is diagnostic of a significantly different tumor type. Oligodendroglioma with 1p/19q co-deletion is a diagnostic marker used to guide therapy, not a prognostic marker. As such, it should be covered in these circumstances.

**Request:** The following language be added to "Limitations of Coverage" section: "Exceptions include clinical scenarios whereby repeat testing of 1p/19q may be required to inform appropriate therapeutic decision-making, with the appropriate medical record documentation specifically demonstrating why repeat testing is indicated.

## CPT/HCPCS Codes

We request that you consider coverage for the following CPT codes, which are commonly used in the course of common lab practice to evaluate the 1p/19q co-deletion:

- 81406 Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenetic array analysis for neoplasia)
- 88374 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure
- 88377 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure

The 81406 CPT code will be used by labs that evaluate the 1p/19q co-deletion using micro-array technology, a well-documented method for evaluating deletion events in tumor cells. The 88374 (computer-assisted FISH) and 88377 (manual FISH) CPT code will be used by labs that evaluate the 1p/19q co-deletion using semi-quantitative morphometric fluorescence in situ hybridization, which is probably the most popular method for evaluating large chromosome-level deletion events in tumor cells. These "quantitative multiplex" FISH codes are required in order to quantitatively evaluate the ratio of the deleted 1p and 19q chromosome arms in comparison to the control 1q and 19p chromosome arms.

**Request:** We request that you consider coverage for the following ICD-10 codes which are not any of the specific tumor types that are known to be positive for the 1p/19q deletion, but rather are non-specific "rule out" diagnoses that often require specialized testing (including 1p/19q) to definitively exclude the specific 1p/19q-associated diagnoses detailed above. Coverage is thus requested for the diagnoses listed below where a negative test result will also be useful to assign an accurate diagnosis and inform the most appropriate therapy.

- C72.9 Malignant neoplasm of central nervous system, unspecified
- C79.31 Secondary malignant neoplasm of brain
- C79.32 Secondary malignant neoplasm of cerebral meninges
- D33.0 Benign neoplasm of brain, supratentorial
- D33.1 Benign neoplasm of brain, infratentorial
- D33.2 Benign neoplasm of brain, unspecified
- D43.0 Neoplasm of uncertain behavior of brain, supratentorial
- D33.7 Benign neoplasm of other specified parts of central nervous system
- D33.9 Benign neoplasm of central nervous system, unspecified
- D43.0 Neoplasm of uncertain behavior of brain, supratentorial
- D43.1 Neoplasm of uncertain behavior of brain, infratentorial
- D43.2 Neoplasm of uncertain behavior of brain, unspecified
- D43.8 Neoplasm of uncertain behavior of other specified parts of central nervous system
- D43.9 Neoplasm of uncertain behavior of central nervous system, unspecified
- D49.6 Neoplasm of unspecified behavior of brain
- G93.89 Other specified disorders of brain
- G93.9 Disorder of brain, unspecified
- G94 Other disorders of brain in diseases classified elsewhere
- H47.611 Cortical blindness, right side of brain
- H47.612 Cortical blindness, left side of brain
- H47.619 Cortical blindness, unspecified side of brain
- H47.631 Disorders of visual cortex in (due to) neoplasm, right side of brain
- H47.632 Disorders of visual cortex in (due to) neoplasm, left side of brain
- H47.639 Disorders of visual cortex in (due to) neoplasm, unspecified side of brain
- Z85.841 Personal history of malignant neoplasm of brain
- Z86.011 Personal history of benign neoplasm of the brain

We thank WPS for the opportunity to comment on DL37009. We respectfully ask that you consider these comments which were prepared by a consortium of providers in the WPS jurisdiction. who provide service to Medicare beneficiaries covered by WPS.

We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Tara Burke, AMP Policy Analyst, at [tburke@amp.org](mailto:tburke@amp.org) or Nonda Wilson, CAP Manager, Economic and Regulatory Affairs, at [nwilson@cap.org](mailto:nwilson@cap.org).

Sincerely,

Association for Molecular Pathology  
College of American Pathologists