

LCD for Cytogenetic Studies (L26684)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

05102, 05202, 05302, 05402

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L26684

LCD Title

Cytogenetic Studies

Contractor's Determination Number

PATH-527

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CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

Medicare National Coverage Determinations (NCD) Manual, 100-3, Section 190.3

Oversight Region

Region I
Region X

Original Determination Effective Date

For services performed on or after 02/01/2008

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 08/01/2009

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

Cytogenetics is the study of chromosomes by light or fluorescent microscopy. Cytogenetic testing is used to study an individual's chromosome makeup. The term karyotyping refers to the arrangement of nucleus chromosomes in order from the largest to the smallest to analyze their number and structure. Cytogenetic testing involves the determination of chromosome number and structure; variations in either can produce numerous physical abnormalities. With cytogenetic testing, the total chromosome count is determined first, followed by the sex chromosome complement and then by any abnormalities. A normal karyotype of chromosomes consists of a pattern of 22 pairs of autosomal chromosomes and a pair of sex chromosomes: XY for the male and XX for the female. A plus (+) or minus (-) sign indicates, respectively, a gain or loss of chromosomal material.

Specimens for cytogenetic analysis can be obtained for routine analysis from the peripheral blood, in which case T lymphocytes are examined; from amniotic fluid for culture of amniocytes; from trophoblastic cells from the chorionic villus; from bone marrow; from solid tumors, and from cultured fibroblasts, usually obtained from a skin biopsy. Enough cells must be examined so that the chance of missing a cytogenetically distinct cell line (a situation of mosaicism) is statistically low. For most clinical indications, 20 mitoses are examined and counted under direct microscopic visualization, and two are photographed or digitalized and karyotypes are prepared. Observation of aberrations usually prompts more extended scrutiny, and in many cases, further analysis of the original culture.

Per Medicare National Coverage Determinations (NCD) Manual, 100-3, Section 190.3:

"Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of the following conditions:

- Genetic disorders (e.g., mongolism) in a fetus; (See the Medicare Benefit Policy Chapter 15, "Covered Medical and Other Health Services," 20.1)
- Failure of sexual development; or
- Chronic myelogenous leukemia.
- Acute leukemias, lymphoid (FAB L1-L3), myeloid (FAB M0-M7) and unclassified; or
- Myelodysplasia." (End of Quote)

The above quotation obligates the carrier to cover the listed diagnoses but does not limit coverage to that list. Further, genetic disorders and failure of sexual development involve chromosomal abnormalities that are stable over time, and, accordingly, payment for cytogenetic studies for these abnormalities will be allowed once per lifetime. This is in contrast to the malignancies, where repeated cytogenetic studies may be appropriate. At the present time, it should be noted that, even in cases of genetic disorders, the general policy limitation is for once per lifetime testing. When clinically-relevant technological advances (such as with FISH testing), are available, and repeat testing is believed to be medically reasonable and necessary, such claims must be billed using an additional ICD-9-CM code. (See the section titled ICD-9-CM Codes that Support Medical Necessity and attached Coding Guidelines for additional information.)

Since "Urovysion", a proprietary test for recurrent bladder cancer identification and monitoring, utilizes multiple probes, which are applied simultaneously, it is not, strictly speaking, correctly identified by any of the CPT codes included in this LCD. Therefore, it is not considered a part of this policy.

There is little evidence in the literature that consistent chromosomal abnormalities in the conditions of polycythemia vera, agnogenic myeloid metaplasia, idiopathic thrombocytopenia and multiple myeloma are known, or that their identification is likely to affect patient care; consequently, these are considered to be payable diagnoses only when the medical record contains clear, unequivocal documentation that this testing is medically reasonable and necessary for the individual case under consideration.

Concerning the testing of HER-2/neu antibodies, the following is a quote from the CMS Program Memorandum, Transmittal AB-99-84, Nov. 1, 1999. ... "HER-2/neu tests on histological sections of breast cancers may provide useful prognostic information and therapeutic indications for treating metastatic disease with anti-HER-2/neu antibodies. When a test for HER-2/neu over expression on a histological section is performed using the fluorescent in situ hybridization (FISH) technique and a DNA probe, the test should be billed as 88365, tissue in situ hybridization, a code paid under the physician fee schedule. This code includes both a professional component and a technical component. When a test for HER-2/neu protein over expression is performed using an immunocytochemistry technique, the test should be billed as 88342, immunocytochemistry..." Thus, the CPT codes listed under CPT/HCPCS Codes in this policy should not be used when billing for HER-2/neu antibodies.

Since there is no current provider category for PhD Geneticists, notwithstanding the certainty that such providers are capable of demonstrating superb training and expertise, Medicare Contractors do not have the authority to create a provider category to allow payment for their services. We encourage these providers to continue discussion with CMS in this regard.

We recognize that Cytogenetic Testing is an emerging technology with rapidly expanding indications and will accept recommendations to reconsider the list of covered diagnoses. However, these requests for reconsideration must be submitted as a formal and must be accompanied by complete copies of relevant peer-reviewed literature that support the recommendation.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

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.

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.

CPT/HCPCS Codes

88230	TISSUE CULTURE FOR NON-NEOPLASTIC DISORDERS; LYMPHOCYTE
88233	TISSUE CULTURE FOR NON-NEOPLASTIC DISORDERS; SKIN OR OTHER SOLID TISSUE BIOPSY
88235	TISSUE CULTURE FOR NON-NEOPLASTIC DISORDERS; AMNIOTIC FLUID OR CHORIONIC VILLUS CELLS
88237	TISSUE CULTURE FOR NEOPLASTIC DISORDERS; BONE MARROW, BLOOD CELLS
88239	TISSUE CULTURE FOR NEOPLASTIC DISORDERS; SOLID TUMOR
88240	CRYOPRESERVATION, FREEZING AND STORAGE OF CELLS, EACH CELL LINE
88241	THAWING AND EXPANSION OF FROZEN CELLS, EACH ALIQUOT
88245	CHROMOSOME ANALYSIS FOR BREAKAGE SYNDROMES; BASELINE SISTER CHROMATID EXCHANGE (SCE), 20-25 CELLS
88248	CHROMOSOME ANALYSIS FOR BREAKAGE SYNDROMES; BASELINE BREAKAGE, SCORE 50-100 CELLS, COUNT 20 CELLS, 2 KARYOTYPES (EG, FOR ATAXIA TELANGIECTASIA, FANCONI ANEMIA, FRAGILE X)
88249	CHROMOSOME ANALYSIS FOR BREAKAGE SYNDROMES; SCORE 100 CELLS, CLASTOGEN STRESS (EG, DIEPOXYBUTANE, MITOMYCIN C, IONIZING RADIATION, UV RADIATION)
88261	

	CHROMOSOME ANALYSIS; COUNT 5 CELLS, 1 KARYOTYPE, WITH BANDING
88262	CHROMOSOME ANALYSIS; COUNT 15-20 CELLS, 2 KARYOTYPES, WITH BANDING
88263	CHROMOSOME ANALYSIS; COUNT 45 CELLS FOR MOSAICISM, 2 KARYOTYPES, WITH BANDING
88264	CHROMOSOME ANALYSIS; ANALYZE 20-25 CELLS
88267	CHROMOSOME ANALYSIS, AMNIOTIC FLUID OR CHORIONIC VILLUS, COUNT 15 CELLS, 1 KARYOTYPE, WITH BANDING
88269	CHROMOSOME ANALYSIS, IN SITU FOR AMNIOTIC FLUID CELLS, COUNT CELLS FROM 6-12 COLONIES, 1 KARYOTYPE, WITH BANDING
88271	MOLECULAR CYTOGENETICS; DNA PROBE, EACH (EG, FISH)
88272	MOLECULAR CYTOGENETICS; CHROMOSOMAL IN SITU HYBRIDIZATION, ANALYZE 3-5 CELLS (EG, FOR DERIVATIVES AND MARKERS)
88273	MOLECULAR CYTOGENETICS; CHROMOSOMAL IN SITU HYBRIDIZATION, ANALYZE 10-30 CELLS (EG, FOR MICRODELETIONS)
88274	MOLECULAR CYTOGENETICS; INTERPHASE IN SITU HYBRIDIZATION, ANALYZE 25-99 CELLS
88275	MOLECULAR CYTOGENETICS; INTERPHASE IN SITU HYBRIDIZATION, ANALYZE 100-300 CELLS
88280	CHROMOSOME ANALYSIS; ADDITIONAL KARYOTYPES, EACH STUDY
88283	CHROMOSOME ANALYSIS; ADDITIONAL SPECIALIZED BANDING TECHNIQUE (EG, NOR, C-BANDING)
88285	CHROMOSOME ANALYSIS; ADDITIONAL CELLS COUNTED, EACH STUDY
88289	CHROMOSOME ANALYSIS; ADDITIONAL HIGH RESOLUTION STUDY
88291	CYTOGENETICS AND MOLECULAR CYTOGENETICS, INTERPRETATION AND REPORT
88299	UNLISTED CYTOGENETIC STUDY

ICD-9 Codes that Support Medical Necessity

Note:

171.9 Medical record must contain documentation of either: alveolar soft part sarcoma, alveolar rhabdomyosarcoma, clear cell sarcoma, desmoplastic small round cell tumor, Ewing sarcoma, myxoid liposarcoma, low grade fibromyxoid sarcoma, extra skeletal myxoid chondrosarcoma, inflammatory myofibroblastic tumor or synovial sarcoma in order to use these diagnosis codes

288.01 Limited to infantile genetic agranulocytosis only

V49.89 To be used only when repeat testing is believed to be medically reasonable and necessary

171.9	MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE SITE UNSPECIFIED
189.0	MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS
200.00 - 200.88	RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.00 - 201.98	HODGKIN'S PARAGRANULOMA UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.98	NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES
203.00 - 203.82	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE
204.00 - 208.92	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LEUKEMIA, IN RELAPSE
225.2	BENIGN NEOPLASM OF CEREBRAL MENINGES
238.4	POLYCYTHEMIA VERA
238.74	MYELOYDYSPLASTIC SYNDROME WITH 5Q DELETION
259.0	DELAY IN SEXUAL DEVELOPMENT AND PUBERTY NOT ELSEWHERE CLASSIFIED
273.3	MACROGLOBULINEMIA
284.01	CONSTITUTIONAL RED BLOOD CELL APLASIA
284.09	OTHER CONSTITUTIONAL APLASTIC ANEMIA
284.1	PANCYTOPENIA
284.2	MYELOPHTHISIS
284.9	APLASTIC ANEMIA UNSPECIFIED
285.0	SIDEROBLASTIC ANEMIA
285.1	ACUTE POSTHEMORRHAGIC ANEMIA
285.21	ANEMIA IN CHRONIC KIDNEY DISEASE
285.22	ANEMIA IN NEOPLASTIC DISEASE

285.29	ANEMIA OF OTHER CHRONIC DISEASE
285.8	OTHER SPECIFIED ANEMIAS
285.9	ANEMIA UNSPECIFIED
287.30 - 287.39	PRIMARY THROMBOCYTOPENIA, UNSPECIFIED - OTHER PRIMARY THROMBOCYTOPENIA
287.4	SECONDARY THROMBOCYTOPENIA
288.01 - 288.8	CONGENITAL NEUTROPENIA - OTHER SPECIFIED DISEASE OF WHITE BLOOD CELLS
289.6	FAMILIAL POLYCYTHEMIA
289.7	METHEMOGLOBINEMIA
289.81	PRIMARY HYPERCOAGULABLE STATE
289.82	SECONDARY HYPERCOAGULABLE STATE
289.83	MYELOFIBROSIS
289.89	OTHER SPECIFIED DISEASES OF BLOOD AND BLOOD- FORMING ORGANS
334.8	OTHER SPINOCEREBELLAR DISEASES
388.5	DISORDERS OF ACOUSTIC NERVE
389.10	SENSORINEURAL HEARING LOSS UNSPECIFIED
629.9	UNSPECIFIED DISORDER OF FEMALE GENITAL ORGANS
630	HYDATIDIFORM MOLE
631	OTHER ABNORMAL PRODUCT OF CONCEPTION
632	MISSED ABORTION
646.33	HABITUAL ABORTER ANTEPARTUM CONDITION OR COMPLICATION
655.00 - 655.23	CENTRAL NERVOUS SYSTEM MALFORMATION IN FETUS UNSPECIFIED AS TO EPISODE OF CARE IN PREGNANCY - HEREDITARY DISEASE IN FAMILY POSSIBLY AFFECTING FETUS AFFECTING MANAGEMENT OF MOTHER ANTEPARTUM CONDITION OR COMPLICATION
656.40	INTRAUTERINE DEATH AFFECTING MANAGEMENT OF MOTHER UNSPECIFIED AS TO EPISODE OF CARE
656.41	INTRAUTERINE DEATH AFFECTING MANAGEMENT OF MOTHER DELIVERED
656.43	INTRAUTERINE DEATH AFFECTING MANAGEMENT OF MOTHER ANTEPARTUM
656.50	POOR FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER UNSPECIFIED AS TO EPISODE OF CARE
656.51	POOR FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER DELIVERED
656.53	POOR FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER ANTEPARTUM CONDITION OR COMPLICATION

656.60	EXCESSIVE FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER UNSPECIFIED AS TO EPISODE OF CARE
656.61	EXCESSIVE FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER DELIVERED
656.63	EXCESSIVE FETAL GROWTH AFFECTING MANAGEMENT OF MOTHER ANTEPARTUM
657.00	POLYHYDRAMNIOS UNSPECIFIED AS TO EPISODE OF CARE
657.01	POLYHYDRAMNIOS WITH DELIVERY
657.03	POLYHYDRAMNIOS ANTEPARTUM COMPLICATION
658.00	OLIGOHYDRAMNIOS UNSPECIFIED AS TO EPISODE OF CARE
658.01	OLIGOHYDRAMNIOS DELIVERED
658.03	OLIGOHYDRAMNIOS ANTEPARTUM
659.50	ELDERLY PRIMIGRAVIDA UNSPECIFIED AS TO EPISODE OF CARE
659.51	ELDERLY PRIMIGRAVIDA DELIVERED
659.53	ELDERLY PRIMIGRAVIDA ANTEPARTUM
659.60	OTHER ADVANCED MATERNAL AGE UNSPECIFIED AS TO EPISODE OF CARE OR NOT APPLICABLE
659.61	OTHER ADVANCED MATERNAL AGE DELIVERED WITH OR WITHOUT ANTEPARTUM CONDITION
659.63	OTHER ADVANCED MATERNAL AGE ANTEPARTUM CONDITION OR COMPLICATION
740.0 - 759.83	ANENCEPHALUS - FRAGILE X SYNDROME
783.22	UNDERWEIGHT
783.40	UNSPECIFIED LACK OF NORMAL PHYSIOLOGICAL DEVELOPMENT
783.41	FAILURE TO THRIVE
783.42	DELAYED MILESTONES
783.43	SHORT STATURE
796.5	ABNORMAL FINDING ON ANTENATAL SCREENING
796.6	NONSPECIFIC ABNORMAL FINDINGS ON NEONATAL SCREENING
V13.61	PERSONAL HISTORY OF HYPOSPADIAS
V13.69	PERSONAL HISTORY OF OTHER CONGENITAL MALFORMATIONS
V18.4	FAMILY HISTORY OF MENTAL RETARDATION
V19.5	FAMILY HISTORY OF CONGENITAL ANOMALIES
V49.89	OTHER SPECIFIED CONDITIONS INFLUENCING HEALTH STATUS

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

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

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must indicate the medical necessity for performing the test. Additionally, a copy of the results should be maintained in the medical records. For billing for testing which is limited to "once per lifetime" under the terms of this LCD, see #4 in attached Coding Guidelines. Documentation that these tests meet standards of medical reasonableness and necessity must be maintained in the patient's medical record and must be made available to Medicare upon request.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy or electronic documentation of the test results and interpretation, along with copies of the ordering/referring physician's order for the studies. The ordering physician must state the clinical indication/medical necessity for the study in their order for the test.

Copies of the medical records must be made available upon Medicare request.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Appendices

Utilization Guidelines

CPT codes will be limited to once per lifetime. When clinically-relevant technological advances (such as with FISH testing), are available, and repeat testing is believed to be medically reasonable and necessary, such claims must be billed using the instructions included in #4 of attached Coding Guidelines.

Sources of Information and Basis for Decision

WPS has consolidated the existing LCDs for MAC Jurisdiction 5 according to the instructions provided by CMS so that they are the same throughout the jurisdiction. In the vast majority of cases, one least restrictive LCD was selected as the jurisdictional LCD. In some cases, appropriate revisions, such as combining sections of LCDs that only addressed a portion of a general topic into a single, more complete document, were made to improve the clinical appropriateness of the LCD while keeping with the least restrictive requirement.

In situations where one or more of the states in the jurisdiction does not have an LCD on a topic, then the existing LCDs were reviewed and, based on the merits of the LCD, a decision was made to make the LCD jurisdictional or to have no LCD on that topic with the approval of CMS.

Some revisions of the existing LCDs were necessary to remove references to the former contractor and to update the Sources of Information and Basis for Decision. CPT, HCPCS and ICD-9 codes will be updated as necessary.

According to the J5 MAC contract, the J5 consolidated LCDs are posted on the web site for the 45 day final notification period prior to the policy implementation date. The MAC contractor is not required to utilize the formal notice and comment revision process specified in Chapter 13 of the Program Integrity Manual (PIM) until the consolidation process is final. However, WPS welcomes provider input regarding the J5 consolidated LCDs. Based on the comments received, LCDs will be revised as necessary during the transition from the existing to new contractor.

This policy does not reflect the sole opinion of the contractor or contractor medical director. Although the final decision rests with the contractor, this policy was developed in consideration of the active LCDs maintained by the preceding Medicare contractors for Jurisdiction 5.

Eugene Braunwald, et al, eds, *Harrisons Principle of Internal Medicine*, (16th ed). New York: McGraw-Hill, 2005

Jacobs, D., Demott, W., Grady, H., Horvat, R., Huestis, D., and Kasten, B. (2002). *Laboratory Test Handbook*. Hudson: Lexi-Comp, Inc.

CPT Assistant, Volume 9, Issue 10, October 1999, pgs. 2, 3.

DeVita VT, et al, eds, *Cancer Principles and Practice of Oncology*, 5th ed, Philadelphia, Lippincott-Raven, 1997

Medical consultants

Advisory Committee Meeting Notes

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

10/01/2008

Revision History Number

3

Revision History Explanation

07/30/2009: Restored accidental removal of contract number 05392 (WPS Part B MAC Eastern Missouri), effective 10/01/08. Correctly removed contract number 05392 effective 8/1/2009, as it is being combined with contractor number 05302 (WPS Part B MAC Missouri - Entire State.)

6/30/09 Removed contractor number 05392 because as of 8/1/09 E MO will join with the current number for W MO

ICD-9 update

Reason for Change**Last Reviewed On Date**

09/15/2008

Related Documents

This LCD has no Related Documents.

LCD Attachments

[Billing and Coding Guidelines \(PDF - 7,432 bytes\)](#)

All Versions

Updated on 07/30/2009 with effective dates 08/01/2009 - N/A

Updated on 07/30/2009 with effective dates 10/01/2008 - 07/31/2009

Updated on 07/17/2009 with effective dates 10/01/2008 - N/A

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Updated on 12/07/2007 with effective dates 02/01/2008 - N/A