Local Coverage Determination (LCD): Molecular Pathology Procedures for Human Leukocyte Antigen (HLA) Typing (L34518)

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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<td>First Coast Service Options, Inc.</td>
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<td>J - N</td>
<td>Florida</td>
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<td>09302 - MAC B</td>
<td>J - N</td>
<td>Virgin Islands</td>
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LCD Information

Document Information

**LCD ID**
L34518

**Original Effective Date**
For services performed on or after 10/01/2015

**Revision Effective Date**
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Molecular Pathology Procedures for Human Leukocyte Antigen (HLA) Typing

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N/A

**Source Proposed LCD**
N/A

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

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.

Title XVIII of the Social Security Act, Section 1862(a)(1)(D) states that no Medicare payment may be made for any expenses incurred for items or services that are investigational or experimental.

42 Code of Federal Regulations (CFR) section 410.32(d)(3) indicates diagnostic tests are payable only when the physician who is treating the beneficiary for a specific medical problem and who uses the results in such treatment.

CMS Internet-Only Manual (IOM), Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 80.1, 80.1.1, 80.1.2, 80.1.3, laboratory services must meet applicable requirements of CLIA.

CMS IOM, Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, Section 110.8, Blood Platelet Transfusions.

CMS IOM, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.4.1.3, Diagnosis Code Requirement.

CMS IOM, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.3, Limitation of Liability Determinations.


Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

As outlined in the CPT Molecular Pathology procedures sections, Human Leukocyte Antigen (HLA) typing is performed to assess compatibility of recipients and potential donors as a part of solid organ and hematopoietic stem cell/ bone marrow pretransplant testing. HLA testing is also performed to identify HLA alleles and allele groups (antigen equivalents) associated with specific diseases and individualized responses to drug therapy (e.g., HLA-B*27 and ankylosing spondylitis and HLA-B57:01 and abacavir hypersensitivity), as well as other clinical uses. One or more HLA genes may be tested in specific clinical situations (e.g., HLA A, B, C,-DRB1, and
DQB1 for kidney transplantation). Each HLA gene typically has multiple variant alleles or allele groups that can be identified by typing.

HLA antigens are divided into types: Class I (A, B, C) and Class II (DR, DP, DQ). The primary use for HLA testing is to match organ and tissue transplant recipients with compatible donors. Different kinds of transplants necessitate different levels of matching between donor and intended recipient. This may determine which HLA tests are performed and which HLA genes are tested for. HLA typing identifies the unique constellation of HLA antigens for an individual.

HLA typing using newer DNA technologies provides tests that are more robust, accurate and reliable in resolving allele-level differences in HLA genes that cannot be detected by serology. DNA tests can be performed using a variety of source materials (lymphocytes, whole blood, buccal swabs, biopsy samples, frozen tissue) and are less affected by viability and sample age. Several approaches to HLA typing are used, offering a range of typing resolution levels from low (antigen-level) to high (allele-level). Examples include, tests used to identify HLA types that rely on amplification of limited stretches of genomic DNA within the HLA genes. The genetic polymorphisms associated with the different HLA alleles are identified through hybridization with specific amplification primers: sequence-specific primer (SSP) or sequence specific oligonucleotide probes (SSO) or by direct sequencing-based typing (SBT).

**PCR-SSO**

Reverse SSO hybridization is used to determine HLA-A, -B, -C, -DR, -DQ and -DP locus types at an intermediate level of resolution, somewhat higher than serological testing. Tests of this type are used when low or intermediate resolution typing is required or as a screening test to identify potential donors or individuals who may later require higher resolution testing.

This technology is used for high volume testing and allows for relatively low-cost typing for bone marrow donor drives or other applications involving large sample numbers.

**PCR-SSP**

PCR-SSP is also used to determine HLA-DP and to determine, at a resolution similar to serological testing, HLA-A, -B, -C, -DR and DQ locus types. PCR-SSP is a very rapid test that can be performed in 3-4 hours from the time a sample is received. PCR-SSP is used for typing deceased organ donors when speed is an important consideration. PCR-SSP can also be used to provide higher resolution testing and may be employed to resolve alleles. In this technique, PCR primers are designed to anneal only to a specific set of alleles or to a single allele.

**SBT**

SBT provides the highest resolution HLA typing for HLA-A, -B, -C, -DR, -DQ and -DP locus alleles. SBT is used when the highest resolution typing is important as in donors and recipients of stem cell transplants or in examining disease associations.

**INDICATIONS:**

The commercial availability does not ensure that a molecular diagnostic test is indicated for clinical application. Molecular diagnostic testing is a rapidly evolving science in which the significance of detecting specific mutations has yet to be clarified in many circumstances. Analytical and clinical validity as well as clinical utility are the responsibility of the provider, and all testing must meet standards of care.

For the purpose of this LCD the Molecular Pathology Procedures for HLA typing will be considered medically and reasonable necessary when the following apply:

1. Transplantation:
   - Standard of care determination of HLA matching for solid organ transplant (donor/recipient).
   - Solid organ transplant registries include both serological HLA testing (e.g. crossmatch) and genomic molecular DNA typing. Family members, or unrelated living donors or cadaveric donors who donate bone marrow or a solid organ are HLA tested pretransplant to determine compatibility with the potential recipients.
   - Standard of care identification of determination of HLA matching for hematopoietic stem cell/bone marrow transplantation -allele-level typing will provide clinical guidance for the HLA-A,B,C Class I and DRB1, DQB1,DPB1, and DQA1 Class II loci in the average transplant program because it is well established that
mismatches at certain HLA loci between donor-recipients are closely linked to the risk of graft versus host disease. Potential marrow donors may enroll with a national registry such as the United States National Marrow Donor Program or the Canadian Blood Services registry.

2. Disease Association:

- Standard of care testing to diagnose certain HLA related diseases/conditions when the testing is supported by the clinical literature and is informative for the direct management of a patient bearing a certain allele(s). It is not expected that more than one test would be required in a given beneficiary’s lifetime. Possible covered indications when standard laboratory testing (tissue typing) not adequate:
  - HLA-B*27 for the diagnosis of certain cases of symptomatic patients with presumed ankylosing spondylitis or related inflammatory disease. HLA-B*27 is covered for ankylosing spondylitis in cases where other methods of diagnosis would not be appropriate or have yielded inconclusive results (NCD 190.1).
  - In the work-up of certain patients with an unclear diagnosis of celiac disease and gluten hypersensitivity usually related to ambiguous standard laboratory results and/or inconsistent biopsy results (e.g., HLA-DQ2 by HLA-DQB1*02 and of DQ8 by HLA-DQB1*0302).

3. Pharmacogenetics:

- Standard of care testing to diagnose certain HLA related drug hypersensitivity reactions when the testing is supported by the clinical literature and is informative for the direct management of a patient bearing a certain allele(s) associated to fatal skin drug reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis). It is not expected that more than one test would be required in a given beneficiary’s lifetime. Possible covered indications:
  - HLA-B*5701 when testing performed prior to the initiation of an abacavir-containing regime in the treatment of HIV Infection.
  - HLA-B*1502 when genotyping may be useful for risk stratification when the testing is performed prior to the initiation of carbamazepine therapy in the treatment of patients at high risk of having this allele. HLA-B*1502 occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians.

4. Identification of HLA compatible platelets for transfusion when standard typing is not adequate.

**LIMITATIONS:**

The following will be considered noncovered as applicable due to statutory exclusion, or lack of benefit, or not reasonable and necessary, or not separately billable (a component of the service per NCCI regulations).

- Tests considered screening in the absence of clinical signs and symptoms of disease (e.g., HLA-DQB1*06:02P as a positive/negative predictor for narcolepsy)
- Tests that do not provide the clinician with actionable data (information that will improve patient outcomes and/or change physician care and treatment of the patient)
- Tests that confirm a known diagnosis or known information (and no new data for decision making)
- Tests to determine risk for developing a disease or condition
- Tests without diagnosis specific indications
- Tests performed to measure the quality of a process
- Tests for Quality Control/Quality Assurance (QC/QA), i.e., tests performed to ensure a tissue specimen matches the patient
- Tests assessing the risk of allopurinol hypersensitivity reactions (HLA-B*58:01P)

**Summary of Evidence**

N/A

**Analysis of Evidence**

(Rationale for Determination)

N/A
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.

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
018x Hospital - Swing Beds
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
072x Clinic - Hospital Based or Independent Renal Dialysis Center
073x Clinic - Freestanding
075x Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
077x Clinic - Federally Qualified Health Center (FQHC)
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.

030X Laboratory - General Classification
031X Laboratory Pathology - General Classification

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>81370</td>
<td>HLA CLASS I AND II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-A, -B, -C, -DRB1/3/4/5, AND -DQB1</td>
</tr>
<tr>
<td>81371</td>
<td>HLA CLASS I AND II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-A, -B, AND -DRB1 (EG, VERIFICATION TYPING)</td>
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<tr>
<td>81372</td>
<td>HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); COMPLETE (IE, HLA-A, -B, AND -C)</td>
</tr>
<tr>
<td>81373</td>
<td>HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE LOCUS (EG, HLA-A, -B, OR -C), EACH</td>
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<tr>
<td>81374</td>
<td>HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT (EG, B*27), EACH</td>
</tr>
<tr>
<td>81375</td>
<td>HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-DRB1/3/4/5 AND -DQB1</td>
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<tr>
<td>81376</td>
<td>HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE LOCUS (EG, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, OR -DPA1), EACH</td>
</tr>
<tr>
<td>81377</td>
<td>HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT, EACH</td>
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<tr>
<td>81378</td>
<td>HLA CLASS I AND II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS), HLA-A, -B, -C, AND -DRB1</td>
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<tr>
<td>81379</td>
<td>HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); COMPLETE (IE, HLA-A, -B, AND -C)</td>
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</table>
HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE LOCUS (EG, HLA-A, -B, OR -C), EACH

HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, B*57:01P), EACH

HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE LOCUS (EG, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, OR -DPA1), EACH

HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

Group 1 Codes

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<th>ICD-10 CODE</th>
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<tr>
<td>D69.49</td>
<td>Other primary thrombocytopenia</td>
</tr>
<tr>
<td>D69.59</td>
<td>Other secondary thrombocytopenia</td>
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<tr>
<td>T86.00 - T86.819</td>
<td>Unspecified complication of bone marrow transplant - Unspecified complication of lung transplant</td>
</tr>
<tr>
<td>T86.830 - T86.839</td>
<td>Bone graft rejection - Unspecified complication of bone graft</td>
</tr>
<tr>
<td>T86.850 - T86.99</td>
<td>Intestine transplant rejection - Other complications of unspecified transplanted organ and tissue</td>
</tr>
<tr>
<td>Z48.21 - Z48.298*</td>
<td>Encounter for aftercare following heart transplant - Encounter for aftercare following other organ transplant</td>
</tr>
<tr>
<td>Z94.0 - Z94.9*</td>
<td>Kidney transplant status - Transplanted organ and tissue status, unspecified</td>
</tr>
<tr>
<td>Z95.3*</td>
<td>Presence of xenogenic heart valve</td>
</tr>
<tr>
<td>Z95.4*</td>
<td>Presence of other heart-valve replacement</td>
</tr>
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Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation:

* Diagnosis codes Z48.21-Z48.298; Z94.0-Z94.9; & Z95.3-Z95.4 should not be billed as a primary diagnosis.

All the codes within the asterisked range from the first code to the last code applies.

Group 2 Paragraph: The following limited coverage for CPT code 81374 for services meeting coverage criteria for HLA-B*27 testing has been established.

Group 2 Codes:

<table>
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<th>ICD-10 CODE</th>
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<tr>
<td>M08.1</td>
<td>Juvenile ankylosing spondylitis</td>
</tr>
<tr>
<td>M45.0 - M45.9</td>
<td>Ankylosing spondylitis of multiple sites in spine - Ankylosing spondylitis of unspecified sites in spine</td>
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<tr>
<td>M48.8X1 - M48.8X9</td>
<td>Other specified spondylopathies, occipito-atlanto-axial region - Other specified spondylopathies, site unspecified</td>
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Group 3 Paragraph: The following coverage for CPT code 81381 for services meeting coverage criteria for HLA-B*1502 testing has been established.

Group 3 Codes:

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<thead>
<tr>
<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>R56.00 - R56.9</td>
<td>Simple febrile convulsions - Unspecified convulsions</td>
</tr>
<tr>
<td>Z79.3*</td>
<td>Long term (current) use of hormonal contraceptives</td>
</tr>
<tr>
<td>Z79.891*</td>
<td>Long term (current) use of opiate analgesics</td>
</tr>
<tr>
<td>Z79.899*</td>
<td>Other long term (current) drug therapy</td>
</tr>
</tbody>
</table>

Group 3 Medical Necessity ICD-10 Codes Asterisk Explanation:
* Diagnosis codes Z79.3, Z79.891 and/or Z79.899 must also be reported with each primary diagnosis code. This is a dual diagnosis requirement.

All the codes within the asterisked range from the first code to the last code applies.

Group 4 Paragraph: The following diagnosis codes when billed with CPT code 81381 meet coverage criteria as indications for HLA-B*5701 testing prior to initiating abacavir therapy in patients with either Human Immunodeficiency Virus (HIV) disease or Asymptomatic Human Immunodeficiency virus (HIV) infection.

Group 4 Codes:

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<tr>
<td>B20</td>
<td>Human immunodeficiency virus [HIV] disease</td>
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<tr>
<td>Z21</td>
<td>Asymptomatic human immunodeficiency virus [HIV] infection status</td>
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</table>

Group 5 Paragraph: The following coverage for 81376, 81377, 81382, and 81383 has been established:

Group 5 Codes:

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<th>DESCRIPTION</th>
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<td>K90.0</td>
<td>Celiac disease</td>
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ICD-10 Codes that DO NOT Support Medical Necessity

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

All documentation must be maintained in the patient’s medical record and available upon request. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service).

Documentation must be adequate to verify that coverage guidelines listed above have been met. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-10-CM code) that warrants the test(s).

Examples of documentation requirements of the ordering physician/nonphysician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing, imaging results).

Documentation requirements of the performing laboratory (when requested) include, but are not limited to, lab accreditation, test requisition, test record/procedures, reports (preliminary and final), and quality control record.

Documentation requirements for LDT(s)/protocols (when requested) include diagnostic test/assay, lab/manufacturer, names of comparable assays/services (if relevant), description of assay, analytical validity evidence, clinical validity evidence, and clinical utility.

For HLA-B*27 testing for the diagnosis of symptomatic patients with presumed ankylosing spondylitis the following will be made: *Request documentation supporting the medical necessity of the test from the physician in all cases where ankylosing spondylitis is indicated as the reason for the test (NCD 190.1).*

Providers are required to code to specificity however, if CPT 81479 (unlisted molecular pathology procedure) is
used the documentation must clearly identify the unique molecular pathology procedure performed. When multiple procedure codes are submitted on a claim (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review a billed code cannot be linked to the documentation, these services will be denied based on Title XVIII of the Social Security Act, §1833(e).

For these tests, the ordering provider must provide to the laboratory copies of the signed informed consent documentation.

An Advance Beneficiary Notice of Noncoverage (ABN) is required before furnishing a beneficiary a test which the physician or laboratory believes to be noncovered as not reasonable or necessary. The physician or laboratory must obtain a signed ABN from the beneficiary (or representative) that the physician or laboratory has informed him/her on the non-coverage of the test and that there will be a charge for the test.

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)(A) of the Social Security Act.

Utilization Guidelines
Screening services, such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a benefit and not covered. Similarly, reimbursement may not be made for the costs of tests/examinations that assess the risk for and/or of a condition unless the risk assessment clearly and directly effects the management of the patient.

Title XVIII of the Social Security Act (SSA) §1862(a) (1) (A) states that no Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of malformed body member.” Based on this statute, CMS states that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute."

Sources of Information
https://www.fda.gov
https://www.fda.gov/ForPatients/Illness/HIVAIDS/ucm126372.htm
http://www.hla.ucla.edu/labservices/labservicesHLA.htm
http://labtestsonline.org

Other MAC local coverage determinations (LCDs), articles (LCAs) and private insurers

**Bibliography**

N/A

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### Revision History Information

<table>
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<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tr>
<td>05/22/2018</td>
<td>R2</td>
<td>Revision Number: 2</td>
<td>Other (Revisions based on annual review completed on 04/25/2018.)</td>
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<tr>
<td></td>
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<td>Publication: June 2018</td>
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Explanation of Revision: Based on an annual review of the LCD, it was determined that some of the italicized language in the “Coverage Indications, Limitations, and/or Medical Necessity” and “Utilization Guidelines” sections of the LCD do not represent direct quotations from some of the CMS sources listed in the LCD; therefore, this LCD is being revised to assure consistency with the CMS sources. The effective date of this revision is based on date of service.

05/22/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.

| 01/09/2018            | R1                      | Revision Number: 1          | Other (Annual Review completed on 09/28/2017.) |
|                       |                         | Publication: January 2018   |                      |
|                       |                         | Connection LCR A/B2018-009  |                      |

Explanation of Revision: Based on an annual review of the LCD, it was determined that some of the italicized language in the “Documentation Requirements” section of the LCD does not represent direct quotation from the CMS sources listed in the LCD; therefore, this LCD is being revised to assure consistency with the CMS sources. The effective date of this revision is based on date of service.

01/09/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.
Associated Documents

Attachments
N/A

Related Local Coverage Documents
Article(s)
A55867 - Molecular pathology procedures for human leukocyte antigen (HLA) typing revision to the Part A and Part B LCD

Related National Coverage Documents
N/A

Keywords
N/A