SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2016

I. SUMMARY OF CHANGES: This transmittal announces the changes that will be included in the July 2016 quarterly release of the edit module for clinical diagnostic laboratory services. The national coverage determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12-190.34) were processed uniformly throughout the nation effective April 1, 2003.

EFFECTIVE DATE: July 1, 2016
*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 5, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Recurring Update Notification
SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2016

EFFECTIVE DATE: July 1, 2016
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IMPLEMENTATION DATE: July 5, 2016

I. GENERAL INFORMATION

A. Background: This transmittal announces the changes that will be included in the July 2016 quarterly release of the edit module for clinical diagnostic laboratory services. The NCDs for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12-190.34) were processed uniformly throughout the nation effective April 1, 2003.

B. Policy: In accordance with Chapter 16, §120.2, Publication 100-04, the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the ICD-10-CM codes. This instruction communicates requirements to shared system maintainers (SSMs) and contractors notifying them of changes to the laboratory edit module to update it for changes in laboratory NCD code lists for July 2016. Changes are being made to the NCD code lists as described below.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>9584.1</td>
<td>The module developer shall add ICD-10-CM codes E61.1, M79.641, M79.642, M79.644, and M79.645 to the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.</td>
<td>FU Associates</td>
</tr>
<tr>
<td>9584.2</td>
<td>The module developer shall provide the revised software as a mainframe (i.e., load module) to CMS to be distributed to the Shared System Maintainers (SSMs).</td>
<td>FU Associates</td>
</tr>
</tbody>
</table>
III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>9584.3</td>
<td>The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release.</td>
<td>A/B MAC</td>
</tr>
</tbody>
</table>

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

<table>
<thead>
<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
</tr>
</thead>
</table>

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, patricia.brocatosimons@cms.hhs.gov, Wanda Belle, wanda.belle@cms.hhs.gov, Kimberly Long, kimberly.long@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).
VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0