SUBJECT: Updates to the Prior Authorization (PA) Guidance Within Publication (Pub.) 100-08

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 3 of Pub. 100-08 to account for recent updates to policies related to the PA process.

EFFECTIVE DATE: March 3, 2020
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: March 3, 2020

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>R</td>
<td>3/Table of Contents</td>
</tr>
<tr>
<td>R</td>
<td>3/3.10/3.10.1/Prior Authorization Program for Certain DMEPOS</td>
</tr>
<tr>
<td>N</td>
<td>3/3.10/3.10.2/Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services</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:
Business Requirements
Manual Instruction
Attachment - Business Requirements

SUBJECT: Updates to the Prior Authorization (PA) Guidance Within Publication (Pub.) 100-08

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I. GENERAL INFORMATION

A. Background: The CMS has recently published new regulation (CMS-1717-FC) in which a new PA process was established for certain hospital outpatient department services. Additionally, updates were made and recently published in regulation regarding PA for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-1713-FC). This instruction updates medical review guidance provided in Chapter 3 of Pub. 100-08 to account for recent updates to policies related to the PA process. This update will align Pub.100-08, Ch.3 with language within those regulations.

The policies are outlined in 84 Code of Federal Regulations (CFR) 61446-61465 for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services and 84 CFR 60742-60777 for the Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.

B. Policy: 84 CFR 61446-61465 and 84 CFR 60742-60777

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>
<th>A/B MAC</th>
<th>DME MAC</th>
<th>Shared-System</th>
<th>Maintainers</th>
<th>Other</th>
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<tbody>
<tr>
<td>11633.1</td>
<td>The contractor shall use this section as overall guidance regarding the PA process.</td>
<td>X</td>
<td>X</td>
<td></td>
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<td></td>
</tr>
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III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
<th>A/B MAC</th>
<th>DME MAC</th>
<th>CEDI</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>A/B MAC</td>
<td>A B HHH</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
IV. SUPPORTING INFORMATION

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

"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): Justin Carlisle, 410-786-4265 or justin.carlisle@cms.hhs.gov, Yuliya Cook, 410-786-0157 or yuliya.cook@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
Medicare Program Integrity Manual
Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

Table of Contents
(Rev. 937; 01-31-20)

Transmittals for Chapter 3

3.10.1 - Prior Authorization Program for Certain DMEPOS
3.10.2 - Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services
3.10.1 - Prior Authorization Program for Certain DMEPOS
(Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 CFR §405 and §414.234. Among other things, these sections establish a Master List of certain DMEPOS items meeting inclusion criteria and potentially subject to prior authorization. CMS will select Healthcare Common Procedure Coding System (HCPCS) codes from the Prior Authorization Master List that shall require prior authorization, at its discretion. In selecting HCPCS codes, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis, and may implement prior authorization nationally or locally.

The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 CFR 414.234. The Master List can be found on the CMS website.

The Required Prior Authorization List is the items selected from the Prior Authorization Master List to be implemented in the Prior Authorization Program. The Required Prior Authorization List can be found on the CMS website, and will be updated as additional codes are selected for prior authorization.

CMS may elect to exempt suppliers from prior authorization program upon demonstration of compliance with Medicare coverage, coding, and payment rules.

The CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking. CMS provides notification of the suspension of the prior authorization requirements via—(i) Federal Register notice; and (ii) Posting on the CMS prior authorization Web site.

3.10.2 - Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services
(Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)

A prior authorization process for certain hospital OPD services is described in 42 CFR §§419.80 through 419.89 as a method for controlling unnecessary increases in the volume of covered services. These sections establish requirements for the submission of a prior authorization request (PAR), the timeframes for the review of a PAR, and the process for CMS to exempt providers from prior authorization requirements.

The list of hospital OPD services requiring prior authorization will be updated through formal notice-and-comment rulemaking. Technical updates to the list of services, such as changes to the name of the service or the HCPCS code, will be published on the CMS website.

The CMS may elect to exempt a provider from this prior authorization process upon a provider’s demonstration of compliance with Medicare coverage, coding, and payment rules after semiannual assessments. Providers must reach a prior authorization provisional affirmation threshold of 90 percent or greater to be eligible for exemption.

The CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.