CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 698	**Date: January 20, 2017**
	Change Request 9940

SUBJECT: The Process of Prior Authorization

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to inform the Medicare Administrative Contractors (MACs) about the prior authorization process. Also, this CR will direct the MACs to individualized Operational instruction(s) that will highlight the specifications for each new prior authorization program that the Centers for Medicare & Medicaid Services (CMS) will implement as applicable. This CR also provides an overview of 42 C.F.R. 414.234 for the Durable Medical Equipment (DME) MACs.

EFFECTIVE DATE: No later than – February 21, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: No later than - February 21, 2017

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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/Table of Contents
N	3/3.10/Prior Authorization
N	3/3.10/3.10.1/Prior Authorization Program for Certain DMEPOS

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

Pub. 100-08	Transmittal: 698	Date: January 20, 2017	Change Request: 9940

SUBJECT: The Process of Prior Authorization

EFFECTIVE DATE: February 21, 2017
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I. GENERAL INFORMATION

A. Background: Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item or service is furnished to the beneficiary and before the claim is submitted for processing. It is a process that permits the submitter (e.g., provider, supplier, beneficiary, etc.) to send in medical documentation in advance of providing and billing for an item or service, to verify its eligibility for Medicare claim payment. Contractors shall, at the direction of CMS or other authorizing entity, conduct prior authorizations and alert the submitter of any potential issues with the information, as submitted.

A prior authorization request decision can be either a provisional affirmative or a non-affirmative decision. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the item or service likely meets Medicare's coverage, coding, and payment requirements. A non-affirmative decision is a finding that the submitted information/documentation does not meet Medicare's coverage, coding, and payment requirements, and if a claim associated with the prior authorization is submitted for payment, it would not be paid. Contractors shall provide notification of the reason for the non-affirmation, if a request is non-affirmative, to the submitter. If a prior authorization request receives a non-affirmative decision, the prior authorization request can be resubmitted an unlimited number of times.

For any item or service to be covered by Medicare it must--

- Be eligible for a defined Medicare benefit category;
- Be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and
- Meet all other applicable Medicare coverage, coding and payment requirements.

With each new prior authorization program, the MACs will be required to educate the stakeholders regarding the new item(s) or service(s) being prior authorized, the requisite information and timeframes for prior authorization submissions, and the vehicle(s) for submitting such information to the contractor for assessment.

Each prior authorization program will have an associated Operational Guide and will be available on the CMS website.

Prior Authorization may also be a condition of payment. This means that claims submitted without an indication that the submitter made a prior authorization request (i.e., unique tracking number (UTN)) the claim will be denied for payment.

This next section only applies to the DME MACs.

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 C.F.R. 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, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis.

- The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 C.F.R. 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.

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.

B. Policy: 42 C.F.R 414.234.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9940.1	Contractors shall educate stakeholders each time a new prior authorization program is launched for a particular item or service, the requisite information and timeframes for prior authorization submissions, and the vehicle(s) for submitting such information to the contractor for assessment.	X	X	X	X					SMRC
9940.1.1	Contractors shall make sure submitters are aware of the timeframes for contractors to render prior authorization decisions, for each individual prior authorization program.	X	X	X	X					SMRC
9940.1.2	Contractors shall hold group or individualized training sessions, as appropriate, to notify the stakeholders of upcoming prior authorization programs, which have been publicly announced, and to	X	X	X	X					SMRC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	make sure ongoing understanding of the specific requirements.									
9940.2	Contractors shall, at a minimum, provide public access to agency-developed prior authorization operational guides, by posting the link(s) on their website.	X	X	X	X					SMRC
9940.3	Contractors shall assess information/documentation included in the prior authorization submission for completeness according to the appropriate operational instruction. Information may include, but is not limited to: • Beneficiary Information (i.e., name, Medicare number, date of birth) • Physician/Practitioner Information (i.e., name, provider identification number, address) • Supplier Information (i.e., name, national supplier clearinghouse (NSC) number, identification number, address) • Documentation from the medical record to support the medical necessity of the item or service • Any other relevant documents as deemed necessary by the contractor to process the prior authorization	X	X	X	X					SMRC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9940.4	Contractors shall notify the submitter (and beneficiary upon request) if the prior authorization submission results in a provisional affirmative or non-affirmative decision.	X	X	X	X					SMRC
9940.4.1	If the decision is non-affirmative, contractors shall notify the submitter of the reason(s) for the non-affirmation.	X	X	X	X					SMRC
9940.4.2	If the decision is non-affirmative, contractors shall accept an unlimited number of resubmissions of a prior authorization request, unless otherwise specified in the operational instruction.	X	X	X	X					SMRC
9940.5	Contractors shall communicate to the submitter their prior authorization decisions and the assigned UTN, within the timeframes defined in the applicable operational instruction.	X	X	X	X					SMRC
9940.6	Contractors shall send detailed decision letters to submitters.	X	X	X	X					SMRC
9940.6.1	Contractors shall only send decision letters, as appropriate, based on existing laws and regulations.	X	X	X	X					SMRC
9940.6.2	If appropriate for the given prior authorization program, contractors shall send detailed decision(s) to the beneficiary address on file with the Social Security Administration.	X	X	X	X					SMRC
9940.6.3	If appropriate for the given prior authorization program, contractors shall send detailed decision(s) to the supplier address on file with the NSC.	X	X	X	X					SMRC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9940.6.4	If appropriate for the given prior authorization program, contractors shall send detailed decision(s) to the provider address on file.	X	X	X	X					SMRC
9940.6.5	Contractors shall, as appropriate based on the corresponding operational instruction, notify the submitter by other expedited means- such as telephone communication.	X	X	X	X					SMRC
9940.7	If a claim is submitted for payment without an affirmative prior authorization decision on file, contractors shall use their existing processes to either suspend claims for additional review or to process claims as denials, based on each individualized prior authorization program, as detailed in the operational instruction/guide.	X	X	X	X					SMRC
9940.8	If for certain items or services, delays in receipt of a prior authorization decision could jeopardize the life or health of the beneficiary, contractors shall expedite their decisions based on the operational instruction/guide.	X	X	X	X					SMRC
9940.8.1	If the claim processing systems would unavoidably delay the delivery of the UTN in an expedited fashion, contractors shall nonetheless render an affirmative or non-affirmative decision to the submitter within the mandated, expedited timeframe.	X	X	X	X					SMRC
9940.8.2	Contractors shall alert the submitter that an expedited decision is being provided, so that the item or service may be	X	X	X	X					SMRC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	provided, but that the submitter should hold their claim and not submit it until such time as the UTN is received (in order to avoid a claims payment denial).									
9940.9	Contractors shall refer to the operational instruction when conducting prior authorization requests for the prior authorization program(s) outlined in 42 C.F.R. 414.234.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9940.10	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X	

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Jennifer Phillips, 410-786-1023 or Jennifer.Phillips@cms.hhs.gov , Doris Jackson, 410-786-4459 or Doris.Jackson@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.698, Issued: 01-20-17)

Transmittals for Chapter 3

3.10 – Prior Authorization

3.10.1- Prior Authorization of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS)

3.10 – Prior Authorization

(Rev.698; Issued; 01-20-17 Effective; 02-21-17 Implementation: 02-21-17)

A. Overview

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item or service is furnished to the beneficiary and before the claim is submitted for processing. It is a process that permits the submitter (e.g., provider, supplier, beneficiary, etc.) to send in medical documentation in advance of providing and billing for an item or service, to verify its eligibility for Medicare claim payment. Contractors shall, at the direction of CMS or other authorizing entity, conduct prior authorizations and alert the submitter of any potential issues with the information, as submitted.

For any item or service to be covered by Medicare it must:

- *Be eligible for a defined Medicare benefit category,*
- *Be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and*
- *Meet all other applicable Medicare coverage, coding and payment requirements.*

Contractors shall communicate to the submitter (and beneficiary upon request) their prior authorization decision and the assigned unique tracking number (UTN), which indicates that the submitter requested a prior authorization, for corresponding claim submissions.

For certain prior authorization programs, the requirement to prior authorize is a condition of payment, as further described in the sections below.

Absent any explicit CMS instruction to the contrary, submitters may correct identified issues with their prior authorization request(s) and resubmit their request(s) for prior authorization without restriction.

Contractors shall conduct prior authorization reviews within the timeframes defined by CMS in the corresponding prior authorization program operational instruction(s).

The prior authorization process is further described in following sections.

B. Condition of Payment

Contractors shall determine if the requirement to prior authorize a particular item or service is a condition of payment, as specified in the individual operational instruction(s). If prior authorization is a condition of payment, claims submitted without an indication that the submitter made a prior authorization request (i.e., UTN) shall be denied upon receipt.

C. Outreach and Education

Contractors shall educate stakeholders each time a new prior authorization program is launched for a particular item or service, the requisite information and timeframes for prior authorization submissions, and the vehicle(s) for submitting such information to the contractor for assessment. Contractors shall make sure submitters are aware of the timeframes for contractors to render prior authorization decisions, for each individual prior authorization program.

Each prior authorization program will have an associated Operational Guide and will be available on the CMS website. Contractors shall, at a minimum, provide public access to agency-developed prior authorization operational guides, by posting the link(s) on their website.

Contractors shall hold group or individualized training sessions, as appropriate, to notify the stakeholders of upcoming prior authorization programs and to make sure there is ongoing understanding of the specific requirements for those applicable prior authorization programs.

D. Prior Authorization Submission

Contractors shall assess the information/documentation included in the prior authorization submission for completeness. Requisite information for individualized prior authorization programs will be included in the operational guides, and shall be available on the CMS website.

Requisite information may include, but is not limited to:

- *Beneficiary Information (i.e., name, Medicare number, date of birth)*
- *Physician/Practitioner Information (i.e., name, provider identification number, address)*
- *Supplier Information (i.e., name, national supplier clearinghouse (NSC) number, identification number, address)*
- *Documentation from the medical record to support the medical necessity of the item or service, and*
- *Any other relevant documents as deemed necessary by the contractor to process the prior authorization.*

E. Prior Authorization Decisions

Contractors shall notify the submitter if their prior authorization submission results in a provisional affirmative, or non-affirmative decision.

- *A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the item or service likely meets Medicare's coverage, coding, and payment requirements.*
- *A non-affirmative decision is a finding that the submitted information/documentation does not meet Medicare's coverage, coding, and payment requirements, and if a claim associated with the prior authorization is submitted for payment, it would not be paid. Contractors shall provide notification of the reason(s) for the non-affirmation, if a request is non-affirmative, to the submitter. If a prior authorization request receives a non-affirmative decision, the prior authorization request can be resubmitted an unlimited number of times, unless otherwise specified.*

Contractors shall send detailed decision letters to submitters. As appropriate for the given prior authorization program, contractors shall send detailed decision letters to other stakeholders (e.g., beneficiaries) using their official address on file. In addition, there may be certain prior authorization programs that require the Contractors to notify the appropriate entity by other means, such as telephone. If a claim is submitted for payment without an affirmative prior authorization decision on file, contractors shall use their existing processes to either suspend claims for additional review or to process claims as denials, based on each individualized prior authorization program, as detailed in the operational instruction.

F. Expedited Request

For certain items or services, delays in receipt of a prior authorization decision could jeopardize the life or health of the beneficiary. Contractors shall, for such items or services, expedite their decisions based on the operational instruction.
If the claim processing systems would unavoidably delay the delivery of the UTN in an expedited fashion, contractors shall nonetheless render an affirmative or non-affirmative decision to the submitter within the mandated, expedited timeframe. Contractors shall alert the submitter that the decision is being provided as expediently as possible, so that the item or service may be provided, but that the submitter should hold their claim and not submit it until such time as the UTN is received (in order to avoid a claims payment denial).

3.10.1 - Prior Authorization Program for Certain DMEPOS
(Rev.698; Issued; 01-20-17 Effective; 02-21-17 Implementation: 02-21-17)

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 C.F.R. 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,

administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis.

- *The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 C.F.R. 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.*

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.