
CMS Manual System

Pub. 100-08 Medicare Program Integrity

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 70

Date: APRIL 9, 2004

CHANGE REQUEST 3136

I. SUMMARY OF CHANGES: With the revisions being made to the Medicare Coverage Database (MCD) in February of 2004, ACs (carriers, FIs, and PSCs with SAD article responsibility) are required to complete several conversion tasks with the Self-Administered Drug (SAD) Exclusion List Articles in the MCD.

NEW/REVISED MATERIAL - EFFECTIVE DATE: May 10, 2004

***IMPLEMENTATION DATE: May 10, 2004**

**II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/3.2/Articles

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

<input checked="" type="checkbox"/>	Business Requirements
<input checked="" type="checkbox"/>	Manual Instruction
<input type="checkbox"/>	Confidential Requirements
<input type="checkbox"/>	One-Time Notification
<input type="checkbox"/>	Recurring Update Notification

***Medicare contractors only**

3.2 - Articles

(Rev. 70, 04-09-04)

Contractors have an obligation to assist providers in complying with Medicare's coverage, coding and medical review related billing and claim rules.

For the purposes of this manual, the term "article" will be used to describe any bulletin article, Web site article, educational handout or any other non-LMRP document intended for public release that contains coverage/coding statements or medical review related billing or claims considerations. For the purposes of this manual, the term "publish" will be used to describe any form of dissemination including posting on a Web site, distributing at a seminar, including an e-mailing, and printing in a hardcopy bulletin.

Contractors may publish articles communicating certain information to providers.

- When National Coverage Determinations (NCD) or other coverage instructions issued by CMS include specific conditions or parameters for which services may be covered, contractors may develop and publish a list of covered codes related to the coverage provision. Contractors may automate denials for codes not included on the list without the development of an LMRP if the NCD indicates or states that no other condition or parameters will be covered.
- Contractors may publish definitions of procedure codes, lists of items that may be billed under a particular code, or minimum requirements that providers must meet in order to bill using a certain code.
- The contractor may publish a product classification list that instructs providers about which specific products meet the definitional requirements of a particular HCPCS code. Developing or revising an LMRP for this article is unnecessary.
- The contractor may explain which off-labeled uses of FDA approved drugs are considered reasonable and necessary with the ICD-9-CM codes that reflect such uses.
- The contractor may explain benefit category decisions and publish a list of drugs/biologicals that are considered usually self-administered.

On a flow basis, contractors shall report those injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient. Contractors must enter their self-administered drug exclusion list into the Medicare Coverage Database. This database can be accessed at www.cms.hhs.gov/mcd.

In order to ensure that the Self-Administered Drug (SAD) Exclusion List report in the Medicare Coverage Database functions correctly, contractors must:

- *Ensure that all CPT code information in a SAD exclusion article is listed in field 22.*
- *Ensure that all SAD exclusion articles are entered with the “SAD article” type. Contractors must not use the “General Detailed,” “General Basic,” or “FAQ” article types for their SAD exclusion articles.*
- *Ensure that the “End Date” for each drug listed in field 22 is correct. The end date should reflect the date that the drug is no longer excluded as self-administered.*
- *Review their SAD articles annually to ensure that the following requirements are met:*

<i>Drugs that have never been SAD-excluded</i>	<i>Not on the list</i>
<i>Drugs that were once SAD-excluded, but now are not SAD-excluded</i>	<i>Either: On the list with an accurate “End Date,” or Were deleted from the list with an accurate article “Effective Date”</i>
<i>Drugs that are currently SAD-excluded</i>	<i>On the list</i>

- The contractor may explain which HCPCS code or group of codes properly describes a particular service.
- The contractor may publish State non-physician licensure information that governs services billed by the physician under the "incident to" provision.

Articles may not conflict with NCDs or coverage provisions in interpretive manuals. Although a comment and notice process is not required, contractors are encouraged to consult with stakeholders in the provider community when developing articles.

Contractors must monitor comments about articles from clinician providers and respond to their concerns, as needed, by issuing revised or clarifying articles.

NOTE: Nothing in this section precludes the contractors from making individual claim determinations, even in the absence of an article or LMRP.

Beginning in 2003, contractors will be required to enter into the Medicare coverage database those articles that address local coverage, coding or medical review related billing and claims considerations. Instructions for this requirement are in PM AB-02-098. Articles may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. Contractors are encouraged to send articles to specialty societies for inclusions in their

publications and Web sites. All newly created articles must be posted on the contractor's Web site where duplicate copies may be obtained by physician/suppliers.

Attachment - Business Requirements

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SUBJECT: New Requirements for Self-Administered Drug (SAD) Exclusion List Articles in the Medicare Coverage Database (MCD)

I. GENERAL INFORMATION

- A. Background:** On May 2, 2004, the Medicare Coverage Database will be revised to remove fields and put in place other changes necessary to ensure the proper functioning of the SAD report.

- B. Policy:** This CR sets forth the actions that contractors must take prior to May 2, 2004.

- C. Provider Education:** None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Req. #	Requirements	Responsibility
3136.1	Carriers, FIs and PSCs with SAD article responsibility shall report on a flow basis, those injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient. Contractors must enter their self-administered drug exclusion list into the MCD.	All carriers, FIs and PSCs with SAD article responsibility
3136.2	Carriers, FIs and PSCs with SAD article responsibility shall ensure that all CPT code information in a SAD exclusion article is listed in field 22, not in field 21 of the article data entry tool. Field 21 will be removed from the SAD article data entry form on May 2, 2004. Any contractor with data in field 21 of their SAD exclusion list must cut and paste it into field 22 before May 2, 2004. Field 21 is the "simple" CPT/ HCPCS Coding Information field. Field 22 is the more detailed CPT/ HCPCS Table Formatted Coding field.	All carriers, FIs and PSCs with SAD article responsibility
3136.3	Carriers, FIs and PSCs with SAD article responsibility shall ensure that all SAD exclusion articles are entered with the "SAD article" type. Contractor shall not use the "General Detailed," "General Basic," or "FAQ" article types for their SAD exclusion article. Contractors who entered SAD exclusion articles using an article type other than "SAD article" shall reenter the article using the "SAD article" type. Contractors shall complete this conversion by May 2, 2004.	All carriers, FIs and PSCs with SAD article responsibility

3136.4	Carriers, FIs and PSCs with SAD article responsibility shall ensure that the “End Date” for each drug listed in field 22 is correct. The end date should reflect the date that the drug is no longer excluded as self-administered.	All carriers, FIs and PSCs with SAD article responsibility						
3136.5	<p>Carriers, FIs and PSCs with SAD article responsibility shall review SAD articles by May 2, 2004 and annually thereafter to ensure that the following requirements are met:</p> <table border="1" data-bbox="370 489 1190 764"> <tr> <td data-bbox="370 489 743 552">Drugs that have never been SAD-excluded</td> <td data-bbox="743 489 1190 552">Not on the list</td> </tr> <tr> <td data-bbox="370 552 743 699">Drugs that were once SAD-excluded, but now are not SAD-excluded</td> <td data-bbox="743 552 1190 699"> Either: - On the list with an accurate “End Date,” or - Were deleted from the list with an accurate article “Effective Date” </td> </tr> <tr> <td data-bbox="370 699 743 764">Drugs that are currently SAD-excluded</td> <td data-bbox="743 699 1190 764">On the list</td> </tr> </table>	Drugs that have never been SAD-excluded	Not on the list	Drugs that were once SAD-excluded, but now are not SAD-excluded	Either: - On the list with an accurate “End Date,” or - Were deleted from the list with an accurate article “Effective Date”	Drugs that are currently SAD-excluded	On the list	All carriers, FIs and PSCs with SAD article responsibility
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Drugs that are currently SAD-excluded	On the list							

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: May 10, 2004</p> <p>Implementation Date: May 10, 2004</p> <p>Pre-Implementation Contact(s): Melanie Combs, (410) 786-7683, mcombs@cms.hhs.gov</p> <p>Post-Implementation Contact(s): Melanie Combs, (410) 786-7683, mcombs@cms.hhs.gov</p>	<p>These instructions shall be implemented within your current operating budget.</p>
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