



Related MLN Matters Article #: MM5870

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Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

Key Words

MM5870, CR5870, R81BP, Compendia, Indications, Drugs, Biologicals, Anti-Cancer, Chemotherapeutic

Provider Types Affected

Providers who bill Medicare Carriers and Part A/B Medicare Administrative Contractors (A/B MACs) for drugs and biologicals used in anti-cancer chemotherapeutic regimens

Key Points

- The effective date of the instruction is January 1, 2008.
- The implementation date is March 7, 2008.
- A compendium (a comprehensive listing of either Food and Drug Administration-approved drugs and biologicals, or of a specific subset of drugs and biologicals -- for example, a compendium of anti-cancer treatment):
 - Is indexed by the drug or biological, rather than by disease; and
 - Includes a summary of the pharmacologic characteristics of each drug or biological's pharmacologic characteristics and may include information on dosage, as well as recommended or endorsed uses in specific diseases.
- Section 1861(t)(2)(B)(ii)(I) of the Social Security Act lists the following three drug compendia that may be used to determine the medically accepted indications for drugs and biologicals used in an anti-cancer chemotherapeutic regimen :
 - American Hospital Formulary Service-Drug Information (AHFS-DI),
 - American Medical Association Drug Evaluations (AMA-DE), and
 - United States Pharmacopoeia-Drug Information (USP-DI).

- Changes in the pharmaceutical reference industry limit the availability of some of these statutorily named compendia for the Centers for Medicare & Medicaid Services (CMS) reference.
- Therefore, Section 1861(t)(2) of the Act provides the Secretary of the Department of Health and Human Services the authority to revise the list of compendia for determining medically-accepted indications for drugs.
- Change request (CR) 5870 announces that the 2008 Physician Fee Schedule contains a new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

Process for Changing List of Compendia

- Starting January 15, 2008, and each following January 15th, CMS will provide an annual 30-day open request period for the public to submit requests for additions or deletions to the compendia list that is on the CMS website.
- By March 15th, CMS will post **complete** requests to its website for public notice and comment. Requests considered complete (and therefore, accepted for review) must include the following information:
 - The requestor's full name and contact information (including the mailing address, e-mail address, and telephone number);

Note: If the requestor is not an individual person, the information will identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- Full identification of the requested compendium, including name, publisher, edition (if applicable), date of publication, and any other information needed for its accurate and precise identification;
- A complete copy (written, electronic, or available online at no cost to the Government) of the requested compendium;
- The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium; and
- Detailed, specific documentation that the requested compendium does or does not comply with the conditions of this rule.

Note: Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed. Therefore, they will not be accepted.

- CMS will accept these public comments for a 30-day period beginning on the day the request is posted on the website.
- In addition to this annual process, CMS may also generate a request for changes to the list at any time an urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

Request Submission Instructions

- Providers should note that a request can have only a single compendium as its subject (to provide greater clarity on the scope of the agency's review of a given request). A requestor may submit multiple requests, each requesting a different action.

- Requests must be in writing and submitted in either one (but not both) of the following two ways:
 - In order to facilitate administrative efficiency, electronic requests are preferred. Each solicitation will include the electronic address for submissions.
 - Hard copy requests can be sent to:

**Centers for Medicare & Medicaid Services
Coverage and Analysis Group
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD, 21244.**

Note: Providers should make sure that they allow sufficient time for hard copies to be received prior to the close of the open request period.

Request Review

- Compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy should have these desirable characteristics:
- Extensive breadth of listings;
 - Quick processing from application for inclusion to listing;
 - Detailed description of the evidence reviewed for every individual listing;
 - Use of pre-specified published criteria for weighing evidence;
 - Use of prescribed published process for making recommendations;
 - Publicly transparent process for evaluating therapies;
 - Explicit “Not recommended” listing when validated evidence is appropriate;
 - Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies;
 - Explicit “Equivocal” listing when validated evidence is equivocal; and
 - A process for public identification and notification of potential conflicts of interest of the compendia’s parent and sibling organizations, reviewers, and committee members with an established procedure to manage recognized conflicts.
- When reviewing requests, CMS may consider:
 - A compendium’s attainment of these listed characteristics;
 - Additional reasonable factors (For example, factors that are likely to impact the compendium’s suitability for this use, such as a change in ownership or affiliation, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. That broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians, or both in choosing among treatment options.); and
 - The process by which the compendium grades the evidence used in making recommendations regarding off-label uses, as well as the grades themselves. Further, to facilitate administrative

efficiency in the review of requests, CMS (at its discretion) may combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions.

Publishing Review Results

- CMS will publish decisions on the CMS website within 90 days after the close of the public comment period.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5870.pdf> on the CMS website.

The list of compendia is located at

http://www.cms.hhs.gov/CoverageGenInfo/02_compensia.asp#TopOfPage on the CMS website.

Providers can find more information about the official instruction to their Medicare contractor about the new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen by going to CR5870 at

<http://www.cms.hhs.gov/Transmittals/downloads/R81BP.pdf> on the CMS website.

The amended *Medicare Benefit Policy Manual*, Chapter 15 (Covered Medical and Other Health Services, Section 50.4.8 (Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen) is an attachment to that CR.

If providers have questions, they may contact their Medicare DME MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.