CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 81	**Date: FEBRUARY 7, 2008**
	Change Request 5870

Subject: 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

I. SUMMARY OF CHANGES: The 2008 Physician Fee Schedule contains a new rule for revising the compendia list for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. This change request manualizes that rule.

New / Revised Material
Effective Date: January 1, 2008
Implementation Date: March 7, 2008

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Table of Contents
N	15/50.4.5.1/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

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: 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

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-02	Transmittal: 81	Date: February 7, 2008	Change Request: 5870

SUBJECT: 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

Effective Date: January 1, 2008
Implementation Date: March 7, 2008

I. GENERAL INFORMATION

A. Background: Section 1861(t)(2)(B)(ii)(I) of the Act lists three drug compendia that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. The three drug compendia listed are:

- American Hospital Formulary Service-Drug Information (AHFS–DI)
- American Medical Association Drug Evaluations (AMA–DE)
- United States Pharmacopoeia-Drug Information (USP–DI)

Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for our reference. Section 1861(t)(2) of the Act provides the Secretary the authority to revise the list of compendia for determining medically-accepted indications for drugs.

B. Policy: The 2008 Physician Fee Schedule contains a new rule for revising the compendia list for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. This change request manualizes that rule.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5870.1	Contractors shall be aware of the new instructions specified in Pub. 100-02, chapter 15, section 50.4.5.1.	X			X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5870.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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 site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your 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							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: Kate Tillman, katherine.tillman@cms.hhs.gov or 410-786-9252
Coverage: Brijet Burton, brijet.burton@cms.hhs.gov or 410-786-7364

Post-Implementation Contact(s): Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MAC)*:

The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

Medicare Benefit Policy Manual

Chapter 15 - Covered Medical and Other Health Services

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(Rev. 81, 02-07-08)

50.4.5.1 - 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

(Rev. 81; Issued: 02-07-08; Effective: 01-01-08; Implementation: 03-07-08)

A. Background

A compendium is defined as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment. It includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; is indexed by drug or biological; and differs from a disease treatment guideline, which is indexed by disease. The list of compendia is located on the CMS Web site at ***http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp****.*

B. Desirable Characteristics of Compendia

Following are desirable characteristics of compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy:

- *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.*
- *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.*

C. Process for Changing List of Compendia

CMS will provide an annual 30-day open request period starting January 15th for the public to submit requests for additions or deletions to the compendia list contained on the CMS Web site at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp. Complete requests as defined in section 50.4.5.1.D will be posted to the Web site by March 15th for public notice and comment. The request will identify the requestor and

the requested action to the list. Public comments will be accepted for a 30-day period beginning on the day the request is posted on the Web site.

In addition to the annual process, CMS may 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.

D. Content of Requests

For a request to be considered complete and therefore accepted for review, it must include the following information:

- *The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall 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 compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.*

- *A complete written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide CMS with electronic access by furnishing at no cost to the Federal government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.*

- *The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.*

- *Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.*

A request may have only a single compendium as its subject. This will 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.

E. Submission of Requests

Requests must be in writing and submitted in one of the following two ways (no duplicates please):

- *Electronic requests are encouraged to facilitate administrative efficiency. 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

Allow sufficient time for hard copies to be received prior to the close of the open request period.

F. Review of Requests

CMS will consider a compendium's attainment of the desirable characteristics of compendia specified in 50.4.5.1.B when reviewing requests. CMS may consider additional reasonable factors in making a determination. (For example, CMS may consider 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. CMS may consider 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.) CMS will also consider a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence. CMS may, at its discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in the review of requests.

G. Publishing Review Results

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