

March 30, 2006 MCAC Votes on Questions as Amended by the MCAC
**Compendia for coverage of off-label uses of drugs and biologicals in an anti-cancer
chemotherapeutic regimen**

I. A good compendium should be evidence-based. What additional characteristics are desirable and of high priority in a robust, evidencebased compendium? Rate each characteristic below on its desirability and on the priority of that desirability rating. This list is provided as a reference. The MCAC may amend this list.

D scores	Desired 2	Equivocal 1	Undesired -1
P scores	High Priority 3	Intermediate 2	Low Priority 1

	Characteristic	Vote (3 Leftmost numbers are non-voting members' votes)	Weight Overall	Weight Voting
A	Extensive breadth of listings	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 2 2 3 2 2 3 2 3 3 3 3 3 3 3 3	80	66
B	Quick throughput from application for inclusion to listing	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 3 3 3 3 3	86	70
C	Detailed description of the evidence reviewed for every individual listing	3 3 3 3 3 2 3 3 3 3 3 3 3 3 3 3 3 2 3 3 3 2 3 3 3 3 3 3 2 2 2 2	76	60
D	Use of prespecified published criteria for weighing evidence	2 3 3 2 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 2 3 3 3 3 3 3 3 3 3 3 3 3	80	67
E	Use of prespecified published process for making recommendations	2 3 2 3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 2 3 3 3 3 3 3 3 3 3 3 3 3 3	82	72
F	Publicly transparent process for evaluating therapies	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 3 3 3 3 3 3 3 3 3 3 3	88	72
G	Explicit "Not Recommended" listings when validated evidence is appropriate	3 2 3 1 3 1 3 3 3 3 3 3 2 1 2 3 3 2 3 3 3 3 3 3 3 2 2 2 2 2 2	47	34
H	Bias toward "Recommended" when validated evidence is equivocal	1 1 1 3 1 3 2 1 2 1 1 2 2 1 1 3 3 2 3 3 3 2 2 2 3 3 2 2 2 2 2	-3	5
I	Bias toward "Not Recommended" when validated evidence is equivocal	1 1 2 1 3 1 2 1 1 3 1 1 1 1 1 3 3 2 3 2 3 2 3 3 3 3 2 2 2 2 2	-15	-11
J	Explicit listing of appropriate combinations of therapies	2 3 3 3 3 1 3 2 3 2 2 3 3 2 2 1 3 3 3 3 2 3 2 3 2 2 2 2 2 2 2	53	40
K	Explicit recommendations on the sequential use of a therapy or combination in relation to other therapies	3 3 3 1 3 1 1 1 3 1 2 3 1 1 2 2 3 3 1 2 2 1 2 3 3 2 2 2 1 2	20	4

L	Silence, i.e. no listing, when validated evidence is equivocal	2 1 1 3 2 3 2 1 1 1 1 2 2 2 2 1 3 1 3 2 3 2 2 3 2 3 2 2 2 2	11	14
M	Explicit "Equivocal" listing when validated evidence is equivocal	3 3 2 1 3 2 3 3 3 3 3 3 3 3 3 3 3 2 1 3 2 3 3 3 3 2 2 2 3 2	67	53
N	Public identification of the members of the advisory/scientific review committee	2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 3 3 2 2 2 2 3 3	76	64
O	Public notification of reviewers' and committee members' conflict(s) of interest, including institutional funding sources	3 3 3 1 3 3 3 3 3 3 2 3 3 3 3 3 3 3 1 3 3 3 2 3 3 2 2 3 3 3	75	57
P	Public notification of all funding sources of the compendium and its parent and sibling organization(s), including unrestricted grants and gifts	3 3 3 1 3 3 3 2 3 3 3 3 3 3 3 3 3 3 1 3 3 3 2 3 3 2 2 3 3 3	75	57
Q	Net benefit analysis based on potential harm and potential benefit	3 3 3 3 3 2 1 3 1 3 2 3 3 2 3 2 3 2 3 2 2 1 2 3 3 2 2 2 2 3	50	36
R	Explicit stratification of the risks of available therapies	2 3 3 2 2 2 1 3 2 3 2 3 2 2 3 2 3 3 2 2 2 1 2 2 3 2 2 2 2 2	45	31

2. How confident are you that the AHFS and USPDI compendia have adequately stated evidence-based criteria and processes?

AHFS	Very confident 5	Somewhat confident 4 (13 votes)	Unsure 3 (2 votes)	Somewhat unconfident 2	Very unconfident 1	Voting Members Avg 3.83	Overall Avg 3.87
USPDI	Very confident 5 (1 vote)	Somewhat confident 4 (11 votes)	Unsure 3 (2 votes)	Somewhat unconfident 2 (1 vote)	Very unconfident 1	Voting Members Avg 3.92	Overall Avg 3.80

3. How confident are you that the AHFS and USPDI compendia adhere to evidence-based criteria and processes in making recommendations?

AHFS	Very confident 5 (1 vote)	Somewhat confident 4 (5 votes)	Unsure 3 (6 votes)	Somewhat unconfident 2 (3 votes)	Very unconfident 1	Voting Members Avg 3.42	Overall Avg 3.27
USPDI	Very confident 5 (1 vote)	Somewhat confident 4 (7 votes)	Unsure 3 (5 votes)	Somewhat unconfident 2 (2 votes)	Very unconfident 1	Voting Members Avg 3.58	Overall Avg 3.47

4. Considering each separately, how confident are you that compendia other than the AHFS and USPDI have adequately stated evidencebased criteria?

DRUGDEX	Very confident 5 (2 votes)	Somewhat confident 4 (7 votes)	Unsure 3 (3 votes)	Somewhat unconfident 2 (3 votes)	Very unconfident 1	Voting Members Avg 3.75	Overall Avg 3.53
F&C	Very confident 5 (1 vote)	Somewhat confident 4 (4 votes)	Unsure 3 (2 votes)	Somewhat unconfident 2 (8 votes)	Very unconfident 1	Voting Members Avg 3.00	Overall Avg 2.87
NCCN	Very confident 5 (6 votes)	Somewhat confident 4 (9 votes)	Unsure 3	Somewhat unconfident 2	Very unconfident 1	Voting Members Avg 4.50	Overall Avg 4.40
ClinPharm	Very confident 5	Somewhat confident 4 (4 votes)	Unsure 3 (6 votes)	Somewhat unconfident 2 (5 votes)	Very unconfident 1	Voting Members Avg 3.08	Overall Avg 2.93

5. Considering each separately, how confident are you that compendia other than the AHFS and USPDI adhere to evidence-based criteria and processes in making recommendations?

DRUGDEX	Very confident 5	Somewhat confident 4 (7 votes)	Unsure 3 (7 votes)	Somewhat unconfident 2 (1 vote)	Very unconfident 1	Voting Members Avg 3.42	Overall Avg 3.40
F&C	Very confident 5 (1 vote)	Somewhat confident 4 (2 votes)	Unsure 3 (7 votes)	Somewhat unconfident 2 (5 votes)	Very unconfident 1	Voting Members Avg 3.00	Overall Avg 2.93
NCCN	Very confident 5 (6 votes)	Somewhat confident 4 (8 votes)	Unsure 3 (1 vote)	Somewhat unconfident 2	Very unconfident 1	Voting Members Avg 4.50	Overall Avg 4.33
ClinPharm	Very confident 5 (1 vote)	Somewhat confident 4 (1 vote)	Unsure 3 (9 votes)	Somewhat unconfident 2 (4 votes)	Very unconfident 1	Voting Members Avg 2.92	Overall Avg 2.93

6. Considering each compendium separately, please rate it on each of the desired characteristics.

VMA: Voting Member Average

OA: Overall Average

R scores		Well done 3	Uncertain 2	Not well done 1
----------	--	----------------	----------------	--------------------

	Characteristic	Compendium	R score Vote (3 Leftmost numbers are non-voting members' Votes)	VMA	OA
A	Extensive breadth of listings	AHFS	2 2 2 3 2 2 1 2 2 2 2 2 3 3 2	2.17	2.13
		USP-DI	3 2 3 3 3 3 2 3 3 2 3 3 3 3 2	2.75	2.73
		DRUGDEX	3 2 3 3 3 2 2 3 3 3 3 3 3 3 2	2.75	2.73
		F&C	2 2 2 2 3 2 2 2 3 2 2 3 3 2 2	2.33	2.27
		NCCN	3 1 2 3 3 2 3 3 3 3 3 3 3 3 2	2.83	2.67
		CLIN PHARM	2 2 2 3 2 2 2 2 2 2 2 2 2 2 2	2.08	2.07
B	Quick throughput from application for inclusion to listing	AHFS	1 1 2 1 2 2 1 2 2 2 3 2 3 3 2	2.08	1.93
		USP-DI	2 1 3 1 3 2 2 3 2 2 3 3 3 2 2	2.33	2.27
		DRUGDEX	2 1 3 1 2 2 2 3 2 3 3 3 3 2 2	2.33	2.27
		F&C	2 1 2 2 2 3 2 2 1 2 3 2 3 2 2	2.17	2.07
		NCCN	3 1 3 3 3 2 3 3 2 3 2 3 3 3 2	2.67	2.60
		CLIN PHARM	2 1 2 2 2 2 2 2 1 3 2 2 3 2 2	2.08	2.00
C	Detailed description of the evidence reviewed for every individual listing	AHFS	2 1 2 3 2 2 1 2 2 2 3 2 3 2 2	2.17	2.07
		USP-DI	2 2 3 3 3 2 2 3 2 2 3 3 3 3 3	2.67	2.60
		DRUGDEX	2 1 3 1 3 2 2 3 2 3 2 3 3 2 2	2.33	2.27
		F&C	2 1 2 2 3 2 2 1 2 2 1 1 3 1 1	1.75	1.73
		NCCN	3 2 2 3 3 2 3 3 2 3 2 3 3 3 3	2.75	2.67
		CLIN PHARM	2 1 2 2 3 2 2 2 2 2 1 2 2 1 1	1.83	1.80
D	Use of prespecified published criteria for weighing evidence	AHFS	2 1 1 2 3 3 2 2 2 3 2 2 2 3 3	2.42	2.20
		USP-DI	3 2 1 3 3 2 2 2 2 2 3 2 2 3 3	2.42	2.33
		DRUGDEX	3 2 1 2 3 3 2 2 2 3 2 2 2 3 3	2.42	2.33
		F&C	2 1 1 2 3 2 2 2 2 2 1 2 2 2 1	1.92	1.80
		NCCN	2 1 1 3 3 3 3 3 2 3 3 2 2 3 3	2.75	2.47
		CLIN PHARM	2 1 1 3 3 3 2 2 2 3 1 2 2 1 1	2.08	1.93
E	Use of prespecified published process for making recommendations	AHFS	1 3 2 2 3 3 2 3 2 2 2 2 2 2 3	2.33	2.27
		USP-DI	1 3 3 3 3 1 2 3 2 2 3 2 2 2 3	2.33	2.33
		DRUGDEX	1 3 3 2 3 3 2 3 2 3 2 2 3 2 3	2.50	2.47
		F&C	1 2 2 2 2 1 2 3 2 2 2 2 3 1 1	1.92	1.87
		NCCN	2 3 2 3 3 3 3 3 2 3 3 3 3 3 3	2.92	2.80
		CLIN PHARM	1 3 2 3 2 3 2 3 2 2 2 2 1 1 1	2.00	2.00

F	Publicly transparent process for evaluating therapies	AHFS	1 1 2 1 3 2 2 2 1 1 3 3 3 3 2	2.17	2.00
		USP-DI	1 1 3 1 3 2 2 2 1 2 3 3 3 2 2	2.17	2.07
		DRUGDEX	1 1 3 1 3 2 2 2 1 3 2 2 3 1 2	2.00	1.93
		F&C	1 1 2 2 2 2 2 2 1 2 2 2 3 1 1	1.83	1.73
		NCCN	1 3 2 3 3 2 3 3 1 3 3 3 3 3 3	2.75	2.60
		CLIN PHARM	1 1 2 2 3 2 2 2 1 2 2 2 2 1 1	1.83	1.73
G	Explicit "Not Recommended" listings when validated evidence is appropriate	AHFS	1 3 3 2 3 2 2 2 1 3 2 2 2 2 1	2.00	2.07
		USP-DI	1 1 3 3 3 2 2 3 1 2 2 3 2 2 1	2.17	2.07
		DRUGDEX	1 1 3 2 3 2 2 3 1 2 2 2 2 2 1	2.00	1.93
		F&C	1 1 2 2 2 2 2 2 1 3 2 2 2 2 1	1.92	1.80
		NCCN	1 1 2 3 3 2 3 3 1 3 2 2 2 2 1	2.25	2.07
		CLIN PHARM	1 1 2 3 2 2 2 2 1 2 2 2 2 2 1	1.92	1.80
H	Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies	AHFS	2 1 2 3 2 2 2 2 2 2 2 2 2 2 2	2.08	2.00
		USP-DI	1 1 3 3 2 3 2 2 2 2 2 2 2 2 2	2.17	2.07
		DRUGDEX	2 1 3 2 2 3 2 2 3 2 2 2 2 2 2	2.17	2.13
		F&C	2 1 2 3 2 2 2 2 2 2 2 2 2 2 2	2.08	2.00
		NCCN	1 1 3 3 2 3 3 2 3 2 3 3 2 2 2	2.50	2.33
		CLIN PHARM	2 1 2 2 2 3 2 2 3 2 2 2 2 2 2	2.17	2.07
I	Explicit "Equivocal" listing when validated evidence is equivocal	AHFS	1 1 2 2 3 2 2 3 2 2 2 2 1 2 1	2.00	1.87
		USP-DI	1 1 3 2 3 2 2 2 2 2 3 2 1 2 2	2.08	2.00
		DRUGDEX	2 1 3 2 2 2 2 2 2 3 2 3 1 2 2	2.08	2.07
		F&C	2 1 2 2 2 2 2 2 2 2 2 2 1 1 1	1.75	1.73
		NCCN	1 1 2 2 3 2 3 3 2 3 3 3 3 3 3	2.75	2.47
		CLIN PHARM	2 1 2 2 2 2 2 2 2 2 2 2 1 1 1	1.75	1.73
J	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.	AHFS	1 3 3 1 2 2 2 1 1 2 3 3 3 3 3	2.17	2.20
		USP-DI	1 3 3 1 2 3 2 1 1 2 3 3 3 2 3	2.17	2.20
		DRUGDEX	1 3 3 1 2 3 2 1 1 3 2 2 3 2 3	2.08	2.13
		F&C	1 2 2 2 2 3 2 1 1 2 2 2 3 2 2	2.00	1.93
		NCCN	1 2 2 3 2 3 3 2 1 3 3 3 3 3 3	2.67	2.47
		CLIN PHARM	1 1 2 2 2 3 2 1 1 2 2 2 2 2 2	1.92	1.80
K	Net clinical benefit analysis based on potential harm and potential benefit.	AHFS	3 3 2 2 2 3 2 1 2 1 2 2 2 2 1	1.83	2.00
		USP-DI	3 1 2 3 2 2 2 1 2 1 2 2 2 1 1	1.75	1.80
		DRUGDEX	2 1 2 3 2 2 2 1 3 1 1 2 1 1 1	1.67	1.67
		F&C	2 1 2 2 2 2 2 1 2 1 1 2 1 1 1	1.50	1.53
		NCCN	3 3 2 3 2 2 2 1 3 1 3 3 2 3 1	2.17	2.27
		CLIN PHARM	2 1 2 2 2 1 2 1 3 1 2 2 1 1 1	1.58	1.60

7. Do you believe that the interests of the Medicare program and its beneficiaries are best served by having a particular number or type of available published compendia on the off-label use of anti-cancer drugs and biologicals for cancer treatment?

The individual MCAC members noted in their responses that their preferences for this item would depend on a number of factors, including the quality and breadth of available

compendia. It may be that several narrow compendia would be needed, or one comprehensive one. Some mentioned a concern that having only one would create difficulty for CMS, oncologists, and/or patients, given the ongoing changes in the publishing marketplace. Several members supported competition among compendia, saying that this would only be possible if there were 3 or more competing. Some members noted that the larger the number of compendia, the greater the likelihood of errors of inclusion or omission regarding specific anti cancer therapies.

8. If the answer to question 7 is yes, what is the minimum and/or maximum number or type of compendia that should be available?

Answers varied from a minimum of one to an undefined maximum. The MCAC considered this question and Question 7 above together.

9. How confident are you that prescribers can rely on currently available published compendia to determine appropriate off-label uses of drugs and biologicals for anti-cancer chemotherapy?

Very confident	Somewhat confident	Unsure	Somewhat unconfident	Very unconfident	Voting Members	Overall Avg
5	4 (8 votes)	3 (4 votes)	2 (1 vote)	1 (1 vote)	Avg 3.5	3.33