Medicare Evidence Development & Coverage Advisory Meeting (MedCAC)
Clinical Trial Policy: Summary of Voting Results

(Alan M. Garber, MD, PhD - Chair; Alex Krist, MD - Vice-chair [served as Chair during voting for # 7-8])

	Krist	Davenport-Ennis	Aubry	Berger	Grant	Hlatky	Janjan	Lo	Schwartz	Sugarman	Bergthold	Ryan	Alving	Goodman	Gross	Wartman	Zarin	Voting Members Tally	Overall Votes
1. In this reconsideration, we are asking the MedCAC to consider two options for the general standards: 1) a broad standard, or 2) an endorsement of standards of good clinical research as defined in existing guidance documents or texts. If the MedCAC recommends a general definition, we would like a recommendation on whether or not the definition should include specific characteristics. • Option 1.a. Use a general definition. • Option 1.b. Use the existing "highly desirable characteristics" to define a good clinical study. • Option 1.c. Endorse external sources that describe characteristics of a good clinical study.	1b	1b	1b	1b	1b	1c	1b	1b	1b	1b	1b	1a	1b	Did not register a vote.	1b	1c	1b	**a=0 b=9 c=1**	**a=1 b=13 c=2**
In addition to the vote on study characteristics, the panel recommended revisions to a broad definition to include: 1) diagnostics tests; 2) prevention studies; and 3) a requirement that studies include written protocols. Also, the panel recommended that the definition include acceptable study designs and types of studies.																			
2a. CMS will continue Medicare-specific requirements in the revised Clinical Trial Policy. There are currently three Medicare-specific criteria. The first is a statutory issue and not a clinical study standard and will be removed from consideration. The remaining two current standards are: • The study must not be designed primarily to test toxicity or disease pathophysiology. Phase I trials may meet the standard only if the disease is chronic, life threatening, or debilitating. ("Yes" votes were for first standard only, as revised.) • Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group. (The panel recommended that this bullet be deleted from the policy.)																			
Should these two current standards remain in the revised policy? (Yes/No)	yes	yes	yes	no	yes	no	no	no	no	no	yes	no	no	Did not register a vote.	no	no	yes	**yes=4 no=6**	**yes=6 no=10**
2.b. CMS is proposing several new Medicare-specific standards. *Should CMS add the following standards? (Yes/No)*																			
1. The study must be registered on the ClinicalTrials.gov website prior to patient enrollment.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	**yes=10 no=0**	**yes=16 no=1**
2. The study protocol must specify method and timing o public release of pre-specified outcomes, regardless of results or completion of trial.	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no	yes	yes	yes	no	yes	**yes=9 no=1**	**yes=14 no=3**
3. The study must have explicitly discussed consideration of relevant subpopulations (as defined by age, gender, race/ethnicity, or other factors) in the study protocol.	yes	yes	yes	no	yes	no	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	**yes=8 no=2**	**yes=14 no=3**
4. If the study results are to be used to inform Medicare coverage policy, the study must contain an explicit discussion of how the enrollment process will ensure that sufficient Medicare populations are included to clinically and statistically determine that Medicare populations benefit from the intervention.	yes	no	no	no	no	no	yes	yes	no	no	yes	no	yes	no	no	no	no	**yes=3 no=7**	**yes=5 no=12**

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5. Any standard required through a national coverage determination using coverage with evidence development (CED). ("Yes" votes were conditioned on the premise that CMS add clarifying language to the revised policy.)	yes	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	Did not register a vote.	yes	yes	yes	**yes=9 no=1**	**yes=14 no=2**
3. Should studies continue to be "deemed" to have met the definition of a good clinical study if *(Yes/No)*																			
1. The study is reviewed and approved as scientifically sound and funded by a Federal agency.	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	yes	yes	**yes=9 no=1**	**yes=16 no=1**
2. The study has been reviewed and approved as scientifically sound by centers or cooperative groups tha are funded by a Federal agency.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=10 no=0**	**yes=17 no=0**
3. The study is conducted under an investigational new drug application (IND) reviewed by the FDA and authorized to proceed with the study if no deficiencies are identified by the FDA.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=10 no=0**	**yes=17 no=0**
4. The study has been required and reviewed by the FDA as a post-approval study.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=10 no=0**	**yes=17 no=0**
4. Since the self-certification process did not occur and CMS does not intend to include this in the revised policy, CMS is proposing to require IND Exempt studies to follow the other processes allowed under the revised policy.																			
Does the panel agree? (Yes/No)	yes	no	yes	yes	no	yes	yes	yes	yes	yes	yes	no	Abstained from voting.	no	no	no	yes	**yes=8 no=2**	**yes=10 no=6**
5. Should CMS consider studies that have been approved by but not funded by a Federal agency as "deemed?" (Yes/No)	no	no	no	no	no	no	no	no	no	no	no	yes	no	no	no	no	no	**yes=0 no=10**	**yes=1 no=16**
6. Should CMS adopt additional methods to approve studies for Medicare coverage such as: *5 Most Desirable 4 Somewhat Desirable 3 Unsure 2 Less Desirable 1 Least Desirable*																			
1. Any study required through a national coverage determination using coverage with evidence development (CED).	5	3	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	**4.88**	**4.88**
2. Establish a Federal inter-agency panel to review study protocols.	2	1	3	1	2	2	2	3	3	2	1	1	1	1	1	5	1	**1.88**	**1.88**
3. Establish a multi-stakeholder panel to review study protocols. (Discuss funding issue).	2	4	2	3	4	4	4	2	2	3	3	3	2	2	2	2	1	**2.65**	**2.65**
4. Work with other Federal agencies to incorporate into their current study panel scoring process an item that asks "Does this study meet the requirements of the Medicare Clinical Trial Policy?"	3	3	4	4	3	3	4	1	1	1	3	3	3	1	1	1	1	**2.35**	**2.35**
7. Do you believe the proposed change to the term "routine clinical services" clarifies the definition? *(Yes/No)*	**Served as Panel Chair during voting of these questions-- did not register a vote.**	no	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=7 no=1**	**yes=14 no=1**
8.a. Should CMS adopt the following definition? *(Yes/No)*																			

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Administrative services are all non-clinical services such as investigator salaries; protocol development; recruiting participants; data quality assurance activities, statistical analyses; dissemination of findings; and study management. Administrative services are not covered.		yes	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=8 no=0**	**yes=15 no=0**
8.b. Should CMS adopt the following definition?*(Yes/No)*																			
Investigational clinical services are those items and services that are being investigated as an objective within the study for its effect on health outcomes including items and services involved in the control arm of the study. Investigational clinical services meeting one of the following conditions are covered.		yes	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=8 no=0**	**yes=15 no=0**
1. The item or service is currently available (covered) to the Medicare beneficiary outside the study.		yes	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=8 no=0**	**yes=15 no=0**
2. The item or service is required through the NCD process for CED and is being evaluated for its effect on health outcomes.		yes	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=8 no=0**	**yes=15 no=0**
3a. When Medicare has issued a national non-coverage policy, the item has been designated by the FDA as an HUD, has received HDE status and is the investigational item or service in a study that meets the requirements of the policy.		yes	yes	Abstained from voting.	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	**yes=7 no=0**	**yes= 13 no=1**
3b. When no national Medicare policy exists, the item has been designated by the FDA as an HUD, has received HDE status and is the investigational item or service in a study that meets the requirements of the policy.		yes	yes	yes	yes	Did not register a vote.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	**yes=8 no=0**	**yes=15 no=0**