		Dhruva	Fisch	Flannery	Ford	Kanter	Maddox	Mora	Ogunwobi	Stearns	Whitney	Riddle	Kremer	Patel	Canos	Umscheid	Hodes
	For each voting question, please use the following scale identifying the level of importance for each criterion – a score of 0 being <u>not</u> important, a score of 1 point being important, and a score of 2 points being essential. 0 Not Important 1 Important 2 Essentail																
1	**SPONSOR** e. The study is sponsored by an organization or individual capable of completing it successfully, •The study is conducted by sponsors/investigators with the resources and skills to complete it successfully	2	2	2	2	2	2	2	2	2	0	1	0	1	1	2	2
2	**COMMUNICATION** No existing Requirement, •A written plan describes the schedule for completion of key study milestones to ensure timely completion of the CED process.	1	2	2	2	2	2	2	2	2	2	2	0	2	2	2	2
3	**GOVERANCE** No existing Requirement, •The protocol describes the information governance and data security provisions that have been established.	2	2	2	2	2	2	2	2	2	1	1	0	2	2	2	2
4	**CONTEXT** b. The rationale for the study is well supported by available scientific and medical evidence. c. The study results are not anticipated to unjustifiably duplicate existing knowledge. •The rationale for the study is supported by scientific evidence and study results are expected to fill the specified knowledge gap and provide evidence of net benefit.	2	2	2	2	2	2	2	2	2	2	2	0	2	2	2	2
5	**CONTEXT** a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects. •Sponsors/investigators establish an evidentiary threshold for the primary outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.	2	2	2	2	2	2	2	2	2	2	2	0	2	2	2	2

		Dhruva	Fisch	Flannery	Ford	Kanter	Maddox	Mora	Ogunwobi	Stearns	Whitney	Riddle	Kremer	Patel	Canos	Umscheid	Hodes
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6	**Outcomes** No existing requirement •The primary outcome(s) for the study are clinically meaningful and important to patients. A surrogate outcome that reliably predicts these outcomes may be appropriate for some questions.	2	2	2	2	2	2	2	2	2	2	1	0	2	2	2	2
7	**Protocol** h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements. j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR). •The CED study is registered with ClinicalTrials.gov and a complete protocol is delivered to CMS.	2	2	2	2	2	1	1	2	2	2	1	0	2	2	2	2
8	**Population** No existing criterion •The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended users of the intervention. This includes attention to the intended users' racial and ethnic backgrounds, gender, and socio-economic status, at a minimum.	2	2	2	2	2	2	2	2	2	2	2	0	2	1	2	2
9	**Generalizable** m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility. •When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their usual sites of care, although randomization to receive the product may be in place.	2	1	2	1	1	1	1	2	1	0	1	0	1	1	1	1
10	**Data quality** No existing requirement •The data are generated or selected with attention to completeness, accuracy, sufficiency of duration of observation to demonstrate durability of results, and sufficiency of sample size as required by the question.	2	2	2	2	2	2	2	2	2	2	2	0	2	1	1	1

		Dhruva	Fisch	Flannery	Ford	Kanter	Maddox	Mora	Ogunwobi	Stearns	Whitney	Riddle	Kremer	Patel	Canos	Umscheid	Hodes
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11	**Data use** No existing requirement •Sponsors/investigators provide information about the validity of the primary exposure and outcome measures, including when using primary data that is collected for the study and when using existing (secondary) data.	**2**	**2**	**2**	**2**	**2**	**1**	**2**	**1**	**2**	**2**	**1**	**0**	**1**	**1**	**2**	**2**
12	**Design** d. The study design is methodologically appropriate, and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination. •The study design is selected to generate valid evidence safely and efficiently for decision making by CMS. If a contemporaneous comparison group is not included, this choice must be justified. g. All aspects of the study are conducted according to appropriate standards of scientific integrity. •The sponsors/investigators minimize the impact of confounding and biases on inferences with rigorous design and appropriate statistical techniques.	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**1**	**0**	**0**	**1**	**1**	**2**	**2**
13	**Design-subpopulations** Current CED Requirements (version 2014) (l) The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion Requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion Requirements are expected to have a negative affect on the recruitment or retention of underrepresented populations, the protocol must discuss why these Requirements are necessary. •In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations, defined by gender and age, as well as clinically- relevant subgroups as motivated by existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, is also appropriate to include, but not required.	**2**	**0**	**2**	**2**	**2**	**0**	**1**	**2**	**2**	**2**	**1**	**0**	**2**	**0**	**2**	**2**
14	**Reproducibility** No existing requirement •Sponsors/investigators using secondary data will demonstrate robustness of results by conducting alternative analyses and/or using supplementary data.	**2**	**1**	**2**	**1**	**1**	**0**	**2**	**2**	**1**	**2**	**1**	**0**	**1**	**1**	**1**	**1**

15	**Reporting** Current CED Requirements (version 2014) (k) The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results). •The study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication.	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**0**	**2**	**2**	**2**	**2**

		Dhruva	Fisch	Flannery	Ford	Kanter	Maddox	Mora	Ogunwobi	Stearns	Whitney	Riddle	Kremer	Patel	Canos	Umscheid	Hodes
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16	**Sharing** No existing Requirements, The sponsors/investigators commit to sharing analytical output, methods, and analytic code with CMS or with a trusted third party in accordance with the rules of additional funders, institutional review boards, and data vendors as applicable. The schedule for sharing is included among the study milestones. The study should comply with all applicable laws regarding subject privacy, including section 165.514 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)	**2**	**2**	**2**	**2**	**2**	**1**	**2**	**2**	**2**	**2**	**2**	**0**	**2**	**2**	**2**	**2**
17	**Legal** Current CED Requirements (version 2014) (i), The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options. The study is not designed to exclusively test toxicity, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely-debilitating diseases, refer to additional requirements set forth in 21 CFR §312.81(a).	**2**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**1**	**0**	**2**	**0**	**1**	**1**	**1**	**1**