

basis for determining eligibility for SSBCI.

(3) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.

(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

(ii) An MA organization must include in its bibliography a comprehensive list of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered, including any available negative evidence and literature.

(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.

(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.

(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422 subpart F nor does it limit CMS's authority to review plan benefits and