

CMS Response to Public Comments Received for CMS-10697

The Centers for Medicare and Medicaid Services (CMS) received comments from two submitters, one of which is an individual and the other is an advocacy organization. This is the reconciliation of their comments.

Comment:

The commenter expressed support for CMS' continued use of Coverage with Evidence Development (CED). They mentioned that CED provides a balance between expanding access to innovative healthcare services and ensuring that Medicare beneficiaries receive items and services supported by scientific evidence. The commenter notes that the additional information collected under CED helps to understand the long-term benefits and risks of treatments.

Response:

We appreciate the commenter's support for CED.

Comment:

The commenter requested that CMS reconsider the national coverage determination (NCD) to remove the CED requirements for amyloid-targeting therapies. The commenter asserted that sufficient evidence exists to address the CED questions CMS identified in the NCD.

Response:

We appreciate this comment. However, a request for an NCD reconsideration for the Monoclonal Antibodies Directed Against Amyloid for the treatment of Alzheimer's Disease NCD is beyond the scope of this information collection. The process for NCD reconsiderations is outlined in the August 7, 2013, Federal Register notice (78 FR 48164).