a. Policy

The Center for Medicare & Medicaid Services (CMS) has a mechanism, known as coverage with evidence development (CED), through which CMS’ provides conditional payment for items and services while generating clinical data to demonstrate their impact on health outcomes.

Under the Coverage with Evidence Development (CED) program, Medicare reimburses for promising new technologies that do not currently meet the standard for full coverage.

b. Purpose

The purpose of this process is to educate the research staff on this policy and how it affects the process of review by CRAO.

c. Begin Steps / Process

a. For those device studies that are under the CED, Medicare Administrative Contractor (MAC) A/B approval letters are not required.

b. For studies that are a part of a CED, the study sponsor would need to provide the appropriate documentation to our study site. This documentation should be uploaded into Section 14.1-3 (just as you would if MAC A/B approval letters were needed).

c. CRAO ancillary committee review would occur in the normal manner. At a Leadership Review Meeting, Dr. Silver and the CRAO Director would review the document to ensure the device is indeed part of the CED policy.

d. While the study is in ‘Leadership Review’, (and CRAO review has been completed), the CRAO analyst can release ‘Conditional Approval’ until a determination is made by Dr. Silver. In some cases, this process could occur in parallel and final approval could be released.

e. The outcome of this meeting will be documented in eResearch and would also be emailed to the study coordinator or project manager in the designated department. If Dr. Silver confirms the device is under the CED policy, the analyst will request the IRB committee to send the study back to CRAO for ‘Final Approval’.

Approved by: Gina Vuocolo-Branch, Director
Date: 01/09/2013

Revised: CRAO

Calendar Review Analysis Office
CED Policy
UNIVERSITY OF MICHIGAN CLINICAL RESEARCH

CALENDAR REVIEW ANALYSIS OFFICE

Centers for Medicare & Medicaid Services’ Coverage Evidence Development Policy & CRAO Process

f. At time of initial submission or CRAO review, if the study sponsor does not provide documentation that the device falls under the CED policy, then current process of obtaining MAC A/B approval letters would be followed.