Coverage with Evidence Development

Medicare Administrative Contractors that process Medicare claims develop the vast majority of coverage policy for items and services at the local/regional level. However, in certain cases, the Centers for Medicare and Medicaid Services (CMS) develop National Coverage Determinations (NCD) for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage.

NCDs are made through an evidence-based process, with opportunities for public participation. The NCD process is usually reserved for those items or services that have the potential to affect a large number of beneficiaries and that have the greatest impact on Medicare.

As summarized by Dr. Louis Jacques, director of the CMS office that oversees coverage determinations: "Under coverage with evidence development (CED), Medicare reimburses for promising new technologies that do not currently meet standards for full coverage. The CED program requires more evidence to be collected to determine the full potential of new technologies."[1] The decision to consider a CED option is entirely within CMS's discretion. CMS has used CED in 19 cases that vary in their data collection requirements, with some featuring randomized controlled trials and others relying on patient registries or other data collection strategies.[2] (See attached Neumann, Chambers table).

There are two types of CED:

- Coverage With Appropriateness Determination (CAD)
    - Additional clinical data is required that is not routinely available on claims forms to ensure that the item or service is being provided to appropriate beneficiaries according to the clinical criteria described in the NCD.
        - For example, an NCD with CAD could be issued if the technology should be restricted to specific patients or providers, or if there is a concern of inappropriate utilization.
- Coverage With Study Participation (CSP)
    - Existing evidence is inadequate to determine whether the "reasonable and necessary" standard is met, but beneficiaries may be enrolled in a clinical

[1] Dr. Louis Jacques, Director, Coverage and Analysis Group, Transcript of CMS Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on May 16, 2012 to "review desirable characteristics of evidence appropriate for Coverage with Evidence Development (CED)."

[2] Peter J. Neumann and James Chambers, "Medicare's Reset On 'Coverage With Evidence Development", *Health Affairs Blog, h*ttp://healthaffairs.org/blog/2013/04/01/medicares-reset-on-coverage-with-evidence-development/, April 1, 2013.

trial that is expected to generate sufficient data in a clinical trial registry to allow CMS to make a final coverage determination.

- For example, an NCD with CSP could be issued if evidence is available but it is not relevant to Medicare beneficiaries.

Advantages: The advantages of CED to companies are:

1. Permits coverage of a drug, biological, device, or drug device combination during the clinical trials (ordinarily only the related Medicare costs are covered – not the product!)
2. Provides a pathway to Medicare coverage for companies that do not have sufficient evidence to obtain an NCD.

Disadvantages: The disadvantages of CED are:

1. Prolongs a process and the related costs that may not, in the end, lead to an NCD.
2. Forecloses the possibility of a positive LCD (coverage by a Medicare Administrative Contractor) that is easier to obtain.