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NCA Tracking Sheet for Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis (CAG-00413N)

Issue

CMS received a formal request for a national coverage determination (NCD) for recombinant human erythropoietin (ESAs) for treatment of chronic kidney disease (CKD) and dialysis-related anemia.

Medicare has historically made payment for ESAs for particular indications with specific conditions. Erythropoiesis Stimulating Agents (ESAs) are drugs or biologic agents which interact with the erythropoietin receptor or its pathway. The most common of these are recombinant (genetically man-made) forms of the native protein, human erythropoietin, or analogues (modified forms) of the native protein. Because ESAs stimulate the bone marrow to make erythrocytes (red blood cells), ESAs have been used to treat anemia.

Anemia, which has multiple causes, is not uncommon in some patient populations, such as those with chronic renal disease. Emerging data have suggested that ESA use may be associated with decreased survival and increased morbidity in both renal and non-renal patient populations.

ESAs have FDA approved labeling that includes boxed warnings citing greater risks for death, serious cardiovascular events, and stroke in some chronic renal failure populations. The requestor points to recent clinical studies that have shown significant ESA-related adverse safety signals and asks CMS to establish coverage limitations for ESA use in both pre-dialysis and dialysis renal disease patient populations.

Some parties have suggested that prior ESA use may predict the long term success of subsequent kidney transplantation in patients with chronic kidney disease. We are commissioning a technology assessment from an outside entity.

Benefit Category

Drugs and Biologicals

Requestor Name(s)

Dennis Cotter, President; Medical Technology & Practice Patterns Institute (MTPPI)

Requestor Letter(s)

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Formal Request Accepted and Review Initiated

6/16/2010

Expected NCA Completion Date

6/16/2011

Proposed Decision Memo Due Date

3/16/2011

Lead Analyst(s)

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Actions Taken

June 16, 2010

CMS opens this NCA for Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with Chronic Kidney Disease (CKD) Including Patients on Dialysis and Patients not on Dialysis. CMS is also requesting a technology assessment from an outside entity. CMS is requesting public comments on the evidence regarding the effects of ESAs on health outcomes in adult CKD patients (pre-dialysis and dialysis). The initial 30-day public comment period begins with this posting date, and ends after 30 calendar days. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to the subject under review.

Instructions on submitting public comments can be found at http://www.cms.gov/InfoExchange/02_publiccomments.asp. You can also submit a public comment by clicking on the highlighted word **comment** in the title bar at the top of this page. **We strongly urge that all public comments be submitted through this website. Please do not submit personal health information in public comments. Comments with personal health information may not be posted to the website.**

October 26, 2010

CMS plans to convene a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on January 19, 2011.

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