

# Medicare Posts Final National Coverage Determination for the Use of Erythropoiesis Stimulating Agents

## In Cancer and Related Neoplastic Conditions

Additional information from the FDA can be found at:  
[www.fda.gov/cder/drug/infopage/RHE/default.htm](http://www.fda.gov/cder/drug/infopage/RHE/default.htm)

The CMS decision was effective on July 30, 2007. Details of the full coverage policy are available at the CMS coverage website at:  
[www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203](http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=203).

The Centers for Medicare & Medicaid Services (CMS) announced its final national coverage determination (NCD) for the use of Erythropoiesis Stimulating Agents (ESA) in cancer and related neoplastic conditions. This NCD was opened in response to Food and Drug Administration's (FDA) boxed warning regarding the use of ESAs.

**The final NCD no longer distinguishes between those cancers that have erythropoietin receptors and cancers without such receptors. In addition, CMS has made no determination regarding ESA use for myelodysplastic syndrome (MDS).** MDS is a pre-malignant syndrome that transforms into acute myeloid leukemia in many patients. In cases where no determination is made, Medicare local contractors have the discretion to make reasonable and necessary determinations regarding ESA use.

The final NCD provides coverage with

restrictions for the treatment of anemia secondary to myelosuppressive anticancer chemotherapy in certain cancer conditions, such as solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia. The NCD details these restrictions, which include limiting initiation of ESA therapy to when the hemoglobin level is less than 10g/dL, limiting the ESA treatment duration to a maximum of 8 weeks after a chemotherapy session ends, limiting the starting dose to the FDA recommended starting dose, and limiting dose escalation levels.

Visit [www.oagpo.com](http://www.oagpo.com) for a FAQ document from ASCO describing the requirements facing physicians when prescribing Erythropoiesis Stimulating Agents (ESA) such as Procrit and Aranesp. This provides much needed clarification of the new NCD-National Coverage Determination. The document can be found on the homepage under News and Events and also in Reimbursement Resources. **OA**