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CMS Seeks to Restrict Coverage Through New National Coverage Determinations

Issues List of Possible Target Therapies and Invites Comments

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On July 30, 2008, the Centers for Medicare & Medicaid Services (CMS) released a list of potential topics for future National Coverage Determinations (NCDs). This is the first time CMS has publicly identified a list of potential NCD topics. CMS committed to posting potential NCDs publicly in the guidance document entitled "Factors CMS Considers in Opening a National Coverage Determination" released on April 11, 2006.

CMS's list of potential NCDs include a range of drug, biologic and medical device products, some of which have been the subject of Medicare guidance in the past year. Within the potential NCD list, CMS highlights its concerns about the sufficiency of medical evidence supporting the use of certain products in patient therapy. Potential NCD topics on the CMS list include:

- Thrombopoiesis stimulating agents (*e.g.*, romiplostim)
- ESAs (Erythropoiesis Stimulating Agents), including use in treating chronic kidney disease (CKD)
- Levocarnitine
- Parenteral iron supplementation
- Bisphosphonates
- Gene expression profiling tests used in cancer therapy
- Treatment of wet AMD (Age-related Macular Degeneration)
- Proton beam therapy for prostate cancer
- Artificial cervical discs



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- Minimally invasive methods for bariatric surgery
- Biological therapies for treatment of chronic wounds
- Bone morphogenetic protein
- Hip resurfacing
- Ablation for atrial fibrillation
- Off-label use of drug eluting coronary stents
- Vertebroplasty and kyphoplasty
- Lumbar fusion for degenerative disc disease
- Peripheral arterial stenting and vascular intervention
- Pharmacogenomic testing

Stakeholders with an interest in any of these important topics should consider taking advantage of this opportunity to comment on CMS's concerns. CMS uses public comments to develop Medicare coverage and payment policy on drugs, biologics and medical devices used to treat the Medicare population.

CMS requests public comments by September 28, 2008 on the proposed NCD topics, which are available at http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=19.

Please contact us if you have questions or we can assist you in preparation of public comments.

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