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### **Obesity Action Coalition Comments on Gastric Sleeve NCD**

The Obesity Action Coalition (OAC) appreciates the opportunity to respond to the Center for Medicare & Medicaid Services (CMS) March 29, 2012 Proposed National Coverage Decision (NCD) Memo regarding Bariatric Surgery for the Treatment of Severe Obesity (CAG-00250R2) -- specific to laparoscopic sleeve gastrectomy (LSG). We are concerned that CMS' conclusions in the proposed decision memo were based on an incomplete review of available evidence with no prior precedence for the level of review and scope of remedy.

The OAC supports the comments of the surgical and medical organizations (American Society for Metabolic and Bariatric Surgery, American College of Surgeons, Society of American Gastrointestinal and Endoscopic Surgeons, The Obesity Society, and the American Society of Bariatric Physicians), which believe the proposed remedy for coverage involving a randomized control trial for LSG is redundant, cost-ineffective and in conflict with CMS published standards of scientific integrity and relevance.

We are also deeply troubled regarding the agency's suggested path regarding coverage with evidence development (CED) given CMS' failure to evaluate the majority of Medicare beneficiaries who could benefit from full coverage of LSG. Should CMS opt to finalize a CED approach, it will result in diminished access to care for the most vulnerable patients in the Medicare program – those beneficiaries under age 65 who are disabled, have End-Stage Renal Disease (ESRD) or who are dual eligible for both Medicare and Medicaid.

Numerous private health insurance plans adopted coverage of LSG throughout the last two years – affording this treatment option to more than 100 million Americans. A Medicare decision to adopt a CED approach to LSG will disadvantage Medicare beneficiaries and have a chilling effect on future, or even current private health plan coverage of this critical treatment option.

Given that the proposed decision memo did not include both recent and existing evidence, we are asking that CMS review these data and reevaluate the evidence in the same fashion it would examine and determine coverage policy for treatment avenues for other chronic disease states. Healthcare professionals need an arsenal of treatments to address the millions of Americans affected by obesity. In the case of severe obesity, proven surgical interventions, combined with multi-disciplinary pre-op and post-op care, are critical treatment tools that all Medicare beneficiaries should be able to access. LSG is part of this arsenal and Medicare should provide full coverage for this proven safe and effective surgical intervention.

Sincerely,

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