



March 20, 2014

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850.

**Topic Refinement: Therapeutic Options for Obesity in the Medicare Population Project
ID: OBET0913**

Submission Period: From 9AM March 6 to 5PM March 20, 2014

The Obesity Care Continuum (OCC) is pleased to submit comments regarding the March 6, 2014 Agency for Healthcare Research and Quality's (AHRQ) Technology Assessment Program Topic Refinement draft key question document entitled, Therapeutic Options for Obesity in the Medicare Population.

The Obesity Care Continuum was established in 2011 and currently includes the Obesity Action Coalition, The Obesity Society, the Academy of Nutrition and Dietetics, the American Society for Metabolic and Bariatric Surgery, and the American Society of Bariatric Physicians. With a combined membership of over 125,000 healthcare professionals, researchers, educators and patient advocates, the OCC is dedicated to promoting access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity.

Evidence-based literature clearly demonstrate that people affected by obesity can substantially improve their health and quality of life when they have access to a continuum of medically necessary treatment – including behavioral, nutritional, pharmaceutical, psychosocial and surgical treatment. Even a 5 to 10 percent weight-loss produces clinically significant reductions in risk factors for chronic diseases such as diabetes, hypertension, arthritis, heart disease, mental illness, lipid disorders, pulmonary disease (obstructive sleep apnea and restrictive lung disease), and certain cancers.

Therefore, the OCC is pleased that AHRQ will be examining the comparative effectiveness of the full range of obesity treatments, including obesity surgery, pharmacologic options, lifestyle interventions, and combination of interventions on the Medicare population with BMI \geq 30. We believe that the proposed questions outlined in the topic refinement document target many of the key areas that should be addressed.

However, we do believe that some additional outcomes of interest should be considered for Key Question 1.

- (a) The OCC suggests adding measures of body composition based on validated methodologies.
- (b) Intermediate outcomes of interest should include weight cycling, weight regain, and weight maintenance among Medicare beneficiaries as well as percentage of fat, and peak exercise capacity.

- (c) The OCC notes that although “cancer” appears in Figure 1 Analytic Framework, it does not appear in the Key Questions. Studies show obesity related cancers include ovarian, esophageal, post-menopausal breast, endometrial, colon and rectal, kidney, pancreatic, thyroid, gallbladder, and other cancers. In addition, AHRQ should include asthma, hip replacement, degenerative bone disease, rheumatoid arthritis, reflux disorders, eating disorders, obstructive sleep apnea, nonalcoholic steatohepatitis (NASH), measurement of HgA1c/insulin/c-peptide, Diabetes mellitus, and hypertension as obesity-related complications.
- (d) The OCC encourages AHRQ to also consider the patient-recorded outcome of nutrition quality of life.
- (e) AHRQ should include in the adverse effects outcome of interest the extent to which patients with obesity may be ineligible for certain transplants, such as kidney transplants. In addition, AHRQ should look at both hospital admission and hospital readmission.

In addition, the OCC believes that AHRQ should conduct a secondary analysis to determine, for intensive behavioral therapy, (1) the settings in which interventions occur (e.g., primary care provider’s office, obesity medicine clinic, ambulatory care facility, registered dietitian nutritionist’s office, etc.) and (2) if a particular setting leads to better outcomes for intensive behavioral therapy. It is critical that this evidence review provide this information to interested agencies such as the United States Preventive Services Task Force and the Centers for Medicare and Medicaid Services as they are tasked with recommending and determining provider coverage, respectively, for successful evidence-based obesity interventions.

Lastly, the OCC recommends that AHRQ categorize its research and findings by class, or level of obesity, to align with and help to evaluate clinical practice guidelines that often structure recommendations based on such categorizations. This will help determine whether that categorization is relevant to quantitative outcome measures and an assessment of the effectiveness of particular interventions.

Key Question 2:

As noted above in Key Question 1 (c), the Key Questions do not specifically address cancer. Studies show obesity related cancers include ovarian, esophageal, post-menopausal breast, endometrial, colon and rectal, kidney, pancreatic, thyroid, gallbladder, and other cancers. In addition, AHRQ should include asthma, hip replacement, degenerative bone disease, rheumatoid arthritis, reflux disorders, eating disorders, sleep apnea, and nonalcoholic steatohepatitis (NASH) as an obesity-related complication.

Lack of Medicare Coverage Will Greatly Complicate Evidence Review

The OCC also believes that compiling the needed data in these areas will be extremely difficult given Medicare coverage policy surrounding critical treatment avenues such as FDA-approved obesity drugs and intensive behavioral therapy. In the case of the former, this task should be very problematic given that Medicare Part D continues to prohibit coverage of any FDA approved drugs for weight loss or weight gain.

While Medicare began covering intensive behavioral therapy in 2011 for beneficiaries affected by obesity, the rules issued by the Centers for Medicare & Medicaid Services (CMS) utilize an overly-restrictive coverage policy regarding eligible providers – limiting coverage to primary care physicians in a

primary care setting. Under this approach, obesity medicine specialists, registered dietitians, bariatric surgeons, and mental health professionals are prohibited from independently providing these services. Medicare's coverage policy on IBT is also contradictory to the recommendations and evidence review issued by the United States Preventive Services Task Force, which state that "intensive interventions may be impractical within many primary care settings."

Again, we appreciate AHRQ undertaking this critical technology assessment and look forward to commenting on the draft document when it is released.

For more information about the Obesity Care Continuum, please contact me at 571-235-6475 or via email at chris@potomaccurrents.com. Thank you.

Sincerely,

A handwritten signature in blue ink that reads "Christopher Gallagher". The signature is written in a cursive, slightly slanted style.

Christopher Gallagher
Washington Coordinator
Obesity Care Continuum