OCC Advocacy News

April 2018 Newsletter of the Obesity Care Continuum

Prepared by Christopher Gallagher, OCC Washington Coordinator

OCAN Member Groups Comment regarding USPSTF Draft Recommendations on Behavioral Weight Loss Interventions

On March 19, 2018, fifteen members groups of the Obesity Care Advocacy Network (OCAN) submitted a joint comment letter to the United States Preventive Services Task Force (USPSTF) regarding the Task Force's February 20th draft recommendation statement on "Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults."

Citing the critical need for a multidisciplinary treatment approach to obesity following diagnosis, OCAN urged the USPSTF to amend its formal recommendation statement to: "The USPSTF recommends that clinicians offer or refer adults with obesity for evidence-based treatments including: intensive multi-component behavioral interventions, obesity pharmacotherapy, and surgery."

Additionally, OCAN raised concerns over the Task Force's assessment regarding obesity pharmacotherapy as well as the lack of consideration of bariatric surgery as a treatment option. Finally, OCAN groups urged the USPSTF to universally accept the use of people first language throughout its scientific documents and statements. See the end of this report to view the complete OCAN comments regarding the Task Force's draft recommendation statement.

OCAN Developing Comments on Short-Term, Limited-Duration Health Plans

At the time of this report, the Obesity Care Advocacy Network (OCAN) was developing comments in response to the February 21, 2018 proposed regulations that the Trump Administration released regarding short-term, limited-duration health insurance plans.

According to the proposed regulations, the rule would amend the definition of short-term, limited-duration insurance to include those offering a maximum

coverage period of less than 12 months and that "this action is being taken to lengthen the maximum period of short-term, limited-duration insurance, which will provide more affordable consumer choice for health coverage."

OCAN is likely to raise concern that expansion of these types of insurance products could have a chilling effect on patient access to care in the individual health insurance market as the target for these plans will be predominantly young and healthy individuals. Proliferation of these short-term health plans will lead to adverse selection and significantly raise the cost of coverage for people affected by obesity or other serious chronic health conditions. Additionally, short-term, limited-duration health plans are not subject to the key patient protections encompassed under the ACA, such as minimum coverage standards and rules that prohibit medical underwriting, rescissions, pre-existing condition exclusions, and lifetime and annual limits.

To learn more about short-term, limited duration health plans, please see the following link to the Kaiser Family Foundation's issue brief on the subject:

https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/

FDA Releases Benefit-Risk Assessment in Drug Regulatory Decision-Making

In late March, the Food and Drug Administration (FDA) released an updated implementation plan, "Benefit-Risk Assessment in Drug Regulatory Decision-Making." The plan provides an overview of the steps the agency has taken since 2013 to enhance benefit-risk assessment in human drug review, including implementation of the FDA's Benefit-Risk Framework (BRF) into its drug regulatory review processes and documentation, along with FDA's commitment to initiate a third-party evaluation of its BRF implementation.

The plan also outlined the agency's commitment to enhance and communicate benefit-risk assessment, including participating in a meeting to gather stakeholder input. FDA Commissioner Scott Gottlieb touted that the agency's implementation efforts have provided clarity and consistency in communicating the reasoning behind the FDA's drug regulatory decisions, while helping integrate the patient's perspective into drug development and regulatory decision-making. At the time of this report, the obesity community was drafting comments regarding the draft plan.

LINK TO FDA STATEMENT:

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm602999.htm

LINK TO FDA IMPLEMENTATION PLAN:

https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM602885.pdf

Bariatric Surgery Pilot for Georgia State Employees Fails to Pass

The Georgia State legislature adjourned on March 29, 2018 without passing House Bill 647 – legislation that would have resurrected a pilot program to provide coverage of bariatric surgery for state employees. The legislation was sponsored by Representative Katie Dempsey (R-GA-13) and was strongly supported by both the ASMBS and American College of Surgeons' State Chapters.

OCAN Comments regarding USPSTF Draft Recommendations on Behavioral Weight Loss Interventions:

March 19, 2018

USPSTF Coordinator
c/o USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Dear Task Force Members,

On behalf of the undersigned organizations of the Obesity Care Advocacy Network (OCAN), we are pleased to provide public comment regarding the United States Preventive Services Task Force (USPSTF) draft recommendations regarding "Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions."

We are pleased that the USPSTF recognizes the significant evidence surrounding multicomponent interventions as effective obesity treatment requires a multidisciplinary approach. Intensive behavioral counseling services are a critical component of fostering quality and successful weight loss outcomes and can be used as a stand-alone treatment, or in conjunction with pharmacotherapy or bariatric surgery.

That being said, we believe that the Task Force should amend its formal recommendation statement to: "The USPSTF recommends that clinicians offer or refer adults with obesity for evidence-based treatments including: intensive multi-component behavioral interventions, obesity pharmacotherapy, and surgery."

Additionally, we question the appropriateness of using BMI as opposed to obesity in the language of the recommendation. We believe this statement should reflect treatment of the disease of obesity – not a singular measurement of the disease. Current Guidelines, based on a systematic evidence review (AHA/ACC/TOS 2013) emphasize that BMI is only a screening step. The World Health Organization defines overweight and obesity as abnormal or excessive fat accumulation that may impair health. Thus obesity is a clinical diagnosis, based on the observation of increased body mass coupled with increased waist circumference and/or other evidence of health risk.

Intensive Multi-Component Behavioral Interventions

The February 2018 request for public comment from the USPSTF marks the third time that the Task Force has evaluated possible treatment avenues for individuals identified with overweight or obesity since 2003. The Task Force recommendations on high intensity behavioral treatment are similar to past recommendations from 2003 and 2012. We believe that the recommendations with regard to behavioral management of obesity are appropriate – particularly the evidence supporting a minimum of 12 high-intensity sessions a year.

That being said, we believe it would be extremely helpful – for patients, healthcare professionals and policymakers – if the Task Force would also emphasize its findings that "the evidence is insufficient to recommend for or against the use of moderate- or low-intensity counseling together with behavioral interventions to promote sustained weight loss in obese adults." Since the recommendations went into effect in 2013, we have observed that many health plans provide coverage for few if any sessions that would be considered high intensity.

Obesity Pharmacotherapy

While we are pleased that the USPSTF included obesity agents in its review, we are troubled by the assumptions and conclusions the Task Force has made regarding the effectiveness and durability of pharmacotherapy. Pharmacotherapy is only effective for sustained weight loss when used long-term. The argument that one should expect "maintenance of improvement after discontinuation of pharmacotherapy" is flawed as pharmacotherapy has been shown to double to triple the odds for chronic weight management when used long-term.

We note that while the Task Force does discuss the multifactorial causes of obesity, it fails to address the nature of obesity as a chronic and complex metabolic disease, in which patients who lose only 5-10 percent of their starting body weight have automatic increases in hunger as well as automatic reductions in basal metabolic rate that predispose them to weight regain.

Because obesity is a disease, we would not expect medications to continue to be effective once stopped any more than an anti-diabetic or anti-hypertensive would offer benefit once discontinued. Further, pharmacotherapy is indicated only as an adjunct to the behavioral interventions.

Because of weight-bias, it is estimated that only 2% of patients with an indication for pharmacotherapy receive it. Including pharmacotherapy in this statement would improve utilization of this important treatment, thus improving health outcomes and quality of life. The requirements of clinical trials mentioned in the USPSTF text (“selective inclusion criteria, show compliance with medication, meeting weight loss goals”) would mirror real-world use.

Bariatric Surgery

Current studies clearly show that for the right individuals, surgery can improve comorbidities, quality of life, and improve life expectancy. While we recognize that primary care providers don’t offer surgery, they are at the forefront of educating patients about the pros and cons of surgery. We feel the evidence is adequate to recommend surgery to the proper individuals, and that this should be communicated to primary care providers. It is estimated that 1% of those who may benefit from surgery receive it. While the primary care provider may not offer surgery, this would encourage proper referral to centers that do offer the procedure.

People-First Language

Finally, we are pleased that the USPSTF appears to be making a good faith effort to use people-first language when referring to individuals affected by overweight or obesity. While the Task Force followed this approach throughout the majority of the Draft Recommendation Summary, we did find two inappropriate mentions of the term “obese” in the summary document and numerous examples within the larger Draft Evidence Review.

Labeling individuals as obese creates negative feelings toward individuals with obesity, perpetuates weight bias, and must be avoided. Health care providers who use respectful communication with their patients, such as people-first language, create positive, productive discussions about weight and health. We urge the USPSTF and other authors and editors of scholarly research, scientific writing, and publications about obesity to use the same rules that are the norm

for referring to individuals with other disabilities, diseases, and health conditions: the use of people-first language.

Thank you again for your consideration of these comments, should you have any questions, please contact OCAN Washington Office Director Christopher Gallagher at 571-235-6475 or via email at chris@potomaccurrents.com.

Sincerely,

Academy of Nutrition and Dietetics
American Academy of PAs
American Association of Clinical Endocrinologists
American Gastroenterological Association
American Society for Metabolic and Bariatric Surgery
Black Women's Health Imperative
Eisai, Inc.
Endocrine Society
Healthcare Leadership Council
Novo Nordisk, Inc.
Obesity Action Coalition
Obesity Medicine Association
SECA
The Obesity Society
The Redstone Center