ENDOCRINE SOCIETY
Hormone Science to Health

June 13, 2023

USPSTF Coordinator
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Dear Members of the USPSTF:

On behalf of the Endocrine Society, thank you for the opportunity to provide comments on the Draft Research Plan: Weight Loss to Prevent Obesity-Related Morbidity and Morbidity in Adults: Interventions. Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the management and research of endocrine disorders, including obesity. Our members evaluate and treat obesity as well as other weight-related diseases, such as type 2 diabetes. The Society has authored clinical practice guidelines on the Pharmacological Management of Obesity and Pediatric Obesity. Given our work on this important issue, we would like to offer comments on the key discussion questions below:

Do primary care–relevant behavioral or pharmacotherapy weight loss and weight loss maintenance interventions for adults with higher body mass index (BMI) affect health outcomes?

The management of obesity includes a range of options such as lifestyle intervention, pharmacotherapy, and bariatric surgery. Research shows that all have resulted in improved outcomes for people living with obesity. In 2018 the USPSTF recommended several interventions for weight loss including behavioral- and pharmacotherapy. These interventions were designed to help individuals with obesity achieve or maintain a ≥5% weight loss through a combination of dietary changes and increased physical activity. This resulted in a USPSTF Grade B recommendation. Primary care providers were tasked to screen all adult patients for obesity and offer intensive counseling and behavioral interventions. However, we believe that these recommendations place too much responsibility on primary care providers (PCP) to deliver obesity care. These recommendations are derived from several clinical trials which demonstrated the benefit that lifestyle interventions

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have in achieving modest weight loss.[1234] However, none of these studies used PCPs to deliver these interventions. In each of these trials, a trained interventionist was used to deliver the sessions.

The Endocrine Society believes that the current recommendation places too much burden on PCPs. We urge the USPSTF to recommend that PCPs refer to evidence-based, specialized, community or commercial programs that can deliver effective lifestyle interventions. PCPs are not adequately equipped to deliver these lifestyle interventions and they are drastically underutilized. For example, the Intensive Behavioral Therapy (IBT for Obesity) benefit available to Medicare beneficiaries is underutilized due to restrictions in the referral process. As of 2019, only 2.16% of the more than 7.6 million Medicare FFS beneficiaries with obesity received IBT for obesity.[5] The Endocrine Society has urged the Centers for Medicare and Medicaid Services (CMS) to remove both the provider and location restrictions that prevent eligible Medicare beneficiaries from accessing the IBT for Obesity benefit. We also support the Treat and Reduce Obesity Act (TROA) legislation introduced in Congress which would remove these restrictions.

The Society appreciates that USPSTF is considering updates to the 2018 statement on anti-obesity medications (AOMs). The research shows that adding pharmacotherapy for weight management results in increased weight loss and overall improved health. The chart below describes the proportion of weight loss in

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[1] Wing RR; Look AHEAD Research Group. Does Lifestyle Intervention Improve Health of Adults with Overweight/Obesity and Type 2 Diabetes? Findings from the Look AHEAD Randomized Trial. Obesity (Silver Spring). 2021 Aug;29(8):1246-1258. doi: 10.1002/oby.23158. Epub 2021 May 14. PMID: 33988896. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/33988896/

[2] Ryan DH, Yockey SR. Weight Loss and Improvement in Comorbidity: Differences at 5%, 10%, 15%, and Over. Curr Obes Rep. 2017 Jun;6(2):187-194. doi: 10.1007/s13679-017-0262-y. PMID: 28455679; PMCID: PMC5497590. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/28455679/

[3] Heymsfield SB, Bourgeois B, Ng BK, Sommer MJ, Li X, Shepherd JA. Digital anthropometry: a critical review. Eur J Clin Nutr. 2018 May;72(5):680-687. doi: 10.1038/s41430-018-0145-7. Epub 2018 May 10. PMID: 29748657; PMCID: PMC6411053. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/29748657/

[4] Katzmarzyk PT, Martin CK, Newton RL Jr, Apolzan JW, Arnold CL, Davis TC, Denstel KD, Mire EF, Thethi TK, Brantley PJ, Johnson WD, Fonseca V, Gugel J, Kennedy KB, Lavie CJ, Price-Haywood EG, Sarpong DF, Springgate B. Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL): Rationale, design and baseline characteristics. Contemp Clin Trials. 2018 Apr;67:1-10. doi: 10.1016/j.cct.2018.02.002. Epub 2018 Feb 8. PMID: 29408562; PMCID: PMC5965693. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5965693/

[5] Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2019. Data.cms.gov. https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-otherpractitioners-by-geography-and-service/data.

individuals taking one of four AOMs compared to lifestyle modification alone. For many individuals with obesity, taking an AOM results in changes in hormonal signals affecting hunger and satiety and facilitates greater adherence to lifestyle approaches. The importance of a balanced approach that includes both lifestyle intervention and medication cannot be overstated and when applied together can improve an individual's health and quality-of-life. The Endocrine Society supports efforts to expand access to AOMs for Medicare beneficiaries. Currently, Medicare is not permitted to cover these medications. We have urged Congress to pass the Treat and Reduce Obesity Act (TROA) which would end the Medicare prohibition on coverage of AOMs.

Obesity Treatment Outcomes

Weight Loss %	Lifestyle Modification	Surgery	Medications			
	Patients in behavior programs (WW, IBT)	Patients with surgery at 10 years[1]	Patients on liraglutide 3 mg[3] Plus IBT[4]	Patients on semaglutide 2.4 mg weekly[5] Plus IBT[6]	Patients on phentermine/ topiramate 15/92 mg[7]	Patients on bupropion/ naltrexone[8] Plus IBT[9]
≥5%	48%[2]	96.6%	63% **(74%)**	86% **(87%)**	67%	42% **(66%)**
≥10%	25%[2]		33% **(52%)**	69% **(75%)**	47%	21% **(41%)**
≥15%	12%[5]		14% **(36%)**	51% **(56%)**	32%	10% **(29%)**
≥20%	10%[1]	72%		32% **(36%)**	15%	
≥30%	4%[1]	40%				

WW=weight watchers; IBT=intensive behavioral therapy.

1. Maciejewski ML et al. *JAMA Surgery*. 2016;151(11):1046-1055. 2. Jebb SA et al. *Lancet*. 2011;378(9801):1485-1492. 3. Pi-Sunyer X et al. *N Engl J Med*. 2015;373(1):11-22. 4. Wadden TA et al. *Obesity* (Silver Spring). 2019;27(1):75-86. 5. Wilding JPH et al. *N Engl J Med*. 2021;384(11):989-1002. 6. Wadden, TA et al. *JAMA*. 325.14 (2021):1403-1413. 7. Allison DB, et al. *Obesity* (Silver Spring). 2012; 20(2):330-342. 8. Greenway FL et al. *Lancet*. 2010;376(9741):595-605. 9. Wadden TA et al. *Obesity* (Silver Spring). 2011;19(1):110-120.

There are many studies on AOMs that are expected to be released in the coming months. For example, the Semaglutide Effects on Heart Disease and Stroke in Patients With Overweight or Obesity (SELECT) is due out later this year. There are others that should be reviewed. We recommend that you consider these important studies before making specific recommendations. PCPs need tools to help them deliver the care needed to achieve the health benefits mediated by better weight

management. Many of the studies expected to be released in the coming months will provide important insights towards achieving this goal.

What are the harms associated with weight loss interventions for adults?

There are a range of harmful side-effects that can occur because of any weight loss intervention. Harm depends on the specific intervention but some of the common potential harms with medications include side effects, teratogenicity, limited effectiveness resulting in less than expected weight loss and weight regain, and mental health risks. There is also the potential for the patient to experience high out-of-pocket costs because of coverage restrictions. Some harms can be seen across all weight management interventions. Medicare is prohibited from covering anti-obesity medications and there are restrictions on the referral process for Intensive Behavioral Therapy (IBT for Obesity). This is an issue that could easily be addressed if Congress passed legislation removing these restrictions.

Finally, we would encourage you to think about what further studies should be conducted to ensure that these medications and others that are coming to market are available and accessed by individuals seeking obesity care. These medications are changing the way obesity is treated. More research may be needed to define optimal approaches to weight loss. The Endocrine Society has over 11,000 clinicians across the country with expertise in delivering obesity care. Our expert members would be well suited to assist USPSTF in thinking about what questions need to be answered.

Thank you again for the opportunity to comment on this Draft Research Plan. We appreciate your attention and consideration of our comments. If you have any questions, please reach out to Rob Goldsmith at rgoldsmith@endocrine.org.

Sincerely,

Ursula Kaiser

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