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May 16, 2022,

ATTN: Members of the Group Insurance Board

On behalf of the more than 75,000 members of the Obesity Action Coalition (OAC) including the more than 900 in Wisconsin, we would like to express our profound disappointment in the State of Wisconsin's Department of Employee Trust Funds (ETF) recommendation to the Group Insurance Board (GIB) that the Board NOT provide state employee coverage for anti-obesity medications (AOMs) for 2023.

Throughout the last five years, the OAC has been working closely with the State to educate both ETF staff and GIB members about the complex and chronic nature of obesity and how steps must be taken to both prevent *and* treat this disease. We applauded ETF for its sound approach in 2019 when staff recommended that the GIB provide coverage for bariatric surgery and accompanying intensive behavioral therapy services beginning in 2020.

Following this positive step toward providing comprehensive coverage, we are obviously troubled by the failure of ETF to support coverage for AOMs for the 2023 plan year. We are roughly a decade removed from the Food & Drug Administration (FDA) approving the first of many new AOMs, enabling patients and their providers the ability to take advantage of another critical treatment tool. Currently, 24 states have taken steps to expand care by providing coverage for anti-obesity medications for their state employees, with several additional states in the planning process.

Most troubling are the cost and utilization assumptions made by Segal that ETF are using for their recommendation – predicting a 3% utilization rate and annual cost of $20-30 million. AOM utilization and real-world data from neighboring state employee health benefits plans, including Minnesota and Michigan, in addition to data from Wisconsin Medicaid, demonstrate that when access to AOMs is available, utilization has historically tended to remain below 1% for patients with obesity. Although Wisconsin Medicaid has provided AOM access to patients through a prior authorization process for more than 4 years, prescribing of AOM therapy remains below the national average (<1%). Given this low utilization of AOMs, it is likely the cost of treatment associated with covering the AOM class would be far less than the anticipated $20 - $30 million annual cost identified by Segal in their analysis – especially since Segal is basing these cost figures on one single branded drug as opposed to the entire class of United States Pharmacopeia recognized anti-obesity agents, many of which are generics and significantly lower in cost. By comparison, the following data shows approximate one year of AOM cost for the identified entity:

- Minnesota State Employees - $2M (50,000 lives)
- Michigan State Employees - $2.7M (67,000 lives)
- Wisconsin Medicaid - $7.9M (1.1 million lives)

OAC also takes exception with the belief that "neither Segal nor ETF was able to determine any projected savings from these drugs at this time… and that … ETF will continue to review literature and cost-benefit analyses on weight-loss drugs as they become available to determine whether these drugs should be added in the future." As obesity is a leading contributor to rising health care costs in the United States[1], we respectfully challenge the comment regarding the inability to determine any projected savings from AOM therapy at this time and would encourage a review of the extensive evidence showing improvement in outcomes and comorbidities seen when patients improve their obesity status.

[1] Economic value of nonsurgical weight loss in adults with obesity J Manag Care Spec Pharm. 2021;27(1):37-50

Finally, OAC is concerned that comments made by the obesity community to ETF and GIB earlier this year appear not to be in the official record as letters dated January 14, 2022 and April 15, 2022 are nowhere to be found under the "Board Correspondence" section of the agenda for the upcoming May 18th meeting or previous February 16th meeting. Therefore, we ask that the following two comment letters also be entered into the record.

In closing, we urge the Board to reject the ETF staff recommendation and provide coverage for AOMs to ensure that state employees have access to comprehensive evidence-based treatment options to address this complex and chronic disease.

Sincerely,

Joe Nadglowski, OAC President and CEO

April 15, 2022

On behalf of the Wisconsin State Chapter of the American Society for Metabolic and Bariatric Surgery (ASMBS), Wisconsin Academy of Nutrition and Dietetics (WAND), Obesity Action Coalition (OAC), Obesity Medicine Association (OMA) and The Obesity Society (TOS), we urge the Employee Trust Funds (ETF) and the Group Insurance Board (GIB) to adopt state employee health plan coverage for pharmacotherapy and medical nutrition therapy (aka nutrition counseling) for the treatment of overweight or obesity.

Our groups truly appreciate the positive ETF staff recommendation surrounding bariatric surgery in 2019, which led the GIB to approve coverage of "bariatric surgery and required precursor weight management and nutrition services for members with BMI of 35 or greater" beginning in benefit year 2020. To date, numerous state employees have taken advantage of this new benefit and are now healthier and thriving because of the surgery and accompanying counseling services.

Since WAND, OAC and the ASMBS Wisconsin State Chapter submitted its January 14th comments to the GIB, a major coverage announcement regarding obesity treatment has been issued by the federal government. In a February 17, 2022, carrier letter and subsequent technical guidance, the federal Office of Personnel Management (OPM) released specific instructions for health insurance carriers that administer Federal Employee Health Benefit (FEHB) plans -- "clarifying that FEHB carriers are not allowed to exclude anti-obesity medications from coverage based on a benefit exclusion or a carve out…" and that "FEHB Carriers must have adequate coverage of FDA approved anti-obesity medications (AOMs) on the formulary to meet patient needs and must include their exception process within their proposal."

In issuing this new guidance, OPM is quite clear -- emphasizing that "obesity has long been recognized as a disease in the US that impacts children and adults…" and that "obesity is a complex, multifactorial, common, serious, relapsing, and costly chronic disease that serves as a major risk factor for developing conditions such as heart disease, stroke, type 2 diabetes, renal disease, non-alcoholic steatohepatitis, and certain types of cancer." This new guidance comes eight years after OPM first warned plans that it is not permissible to exclude weight loss drugs from FEHB coverage on the basis that obesity is a "lifestyle" condition and not a medical one or that obesity treatment is "cosmetic."

These definitive statements from OPM should ensure that all federal employees, and their family members, will now have access to comprehensive obesity care. We believe that state employees in Wisconsin deserve the same access and hope that the GIB will support this goal by adopting coverage for pharmacotherapy and medical nutrition therapy (aka nutrition counseling) for the treatment of overweight or obesity. Our growing knowledge regarding the complexity of obesity, the tremendous advances in treatment, and the growing recognition of, and support for treating obesity as the chronic disease that it is, clearly make health plans that continue to exclude coverage for evidence-based treatment avenues out of date and out of touch with the current scientific evidence surrounding obesity care.

Should you have any questions or need additional information, please feel free to contact us or Chris Gallagher via email at chris@potomaccurrents.com or telephone at 571-235-6475. Thank you.

January 14, 2022

On behalf of the Wisconsin State Chapter of the American Society for Metabolic and Bariatric Surgery, Wisconsin Academy of Nutrition and Dietetics and the Obesity Action Coalition, we urge the Employee Trust Funds (ETF) and the Group Insurance Board (GIB) to adopt state employee health plan coverage for pharmacotherapy and medical nutrition therapy (aka nutrition counseling) for the treatment of overweight or obesity.

Our groups truly appreciate the positive ETF staff recommendation surrounding bariatric surgery in 2019, which led the GIB to approve coverage of "bariatric surgery and required precursor weight management and nutrition services for members with BMI of 35 or greater" beginning in benefit year 2020. To date, numerous state employees have taken advantage of this new benefit and are now healthier and thriving because of the surgery and accompanying counseling services.

Obesity, COVID-19 and Communities of Color

While these benefit additions in 2020 have been critical for state employees who wish to address their obesity and severe obesity, thousands of other state workers with overweight or obesity, who do not have a BMI of 35 or above, remain without covered options to treat their obesity, such as pharmacotherapy or robust medical nutrition therapy (MNT) services. The inability for state employees to access comprehensive obesity treatment services is especially alarming given the COVID-19 pandemic and obesity being a significant risk factor for serious cases of the virus -- tripling the rate of hospitalization and increasing the risk for death for affected individuals.

In addition to being an epidemic, obesity is also a critical health equity issue! Nationwide and in Wisconsin, obesity disproportionately impacts Black and Latinx individuals. An analysis of UW Health patient data found that 50% of Black adults and 40% of Latinx adults are living with obesity, compared to 36% of White adults. The devastating effect of obesity was laid bare during the COVID-19 pandemic, as Black and Latinx adults in our state were twice as likely to be hospitalized compared with white adults. Rural areas in Wisconsin also have higher obesity rates than urban and suburban areas, increasing the risk of poor health outcomes for rural communities.

For these reasons, the ETF and GIB should take action to address coverage gaps in obesity care services in the state employee health plan surrounding Food and Drug Administration (FDA) - approved anti-obesity medications (AOMs) and MNT services.

Pharmacotherapy

In December of 2021, the Navitus Pharmacy & Therapeutics (P&T) Committee for ETF completed a clinical review of pharmacotherapy options available to treat obesity and the P&T Committee designated the anti-obesity medication class in general as a "may add." This means their customers, including ETF, should work with their PBM account manager to add coverage for this category if they so desire.

We are hopeful that the GIB will act on this recommendation to ensure that state employees have the same access to the broad scope of obesity drugs -- including both generic and branded products that are currently available to Wisconsin Medicaid recipients. It is also important to note that the neighboring states of Michigan and Minnesota provide state employee coverage for obesity drugs as well as the growing momentum in Iowa to secure drug coverage in that state employee plan.

Many of the aforementioned AOMs represent significant medical advances in this space that have taken place during the last ten years. These new drugs and many others that are progressing through the FDA's approval process show great promise for helping millions of Americans address their overweight or obesity. For example, the FDA recently approved Wegovy, where clinical trials for the drug demonstrated that nearly half of the patients on the drug lost 15 percent of their total body weight. Other obesity medications in the agency's approval pipeline will likely match, or even exceed the results of Wegovy.

Providing coverage for obesity drugs is also good policy and is supported by a number of organizations representing key state policy stakeholders. For example, in 2015, the National Council of Insurance Legislators that represents legislators who chair Insurance Committees in state legislatures across the country adopted its first ever disease-specific policy statement – urging Medicaid, state employee and state health exchange plans to update their benefit structures "to improve access to, and coverage of treatments for obesity such as pharmacotherapy and bariatric surgery."

In 2018, the National Lieutenant Governors Association went on record supporting efforts to reduce obesity stigma and support access to obesity treatment options for state employees and other publicly funded healthcare programs. And late last year, the National Hispanic Caucus of State Legislators and National Black Caucus of State Legislators adopted formal policy recognizing that "health inequities in communities of color have led to a disproportionate impact of COVID-19 and that states must address the high rates of obesity to improve the health of racial minorities and prepare for the next public health epidemic…..and ensure that their constituents, including those using Medicaid, have access to the full continuum of treatment options for obesity."

Our growing knowledge regarding the complexity of obesity, the tremendous advances in treatment, and the growing recognition of, and support for treating obesity as the chronic disease that it is, clearly make health plans that continue to exclude coverage for FDA-approved obesity drugs out of date and out of touch with the current scientific evidence surrounding these new pharmaceutical treatments.

ACA-Mandated Preventive Care Services: Screening for Obesity and Referral for Behavioral Interventions

Under Section 2713 of the Affordable Care Act (ACA), non-grandfathered health plans must cover evidence-based preventive care services for adults that have a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF), an independent panel of clinicians and scientists commissioned by the Agency for Healthcare Research and Quality. An "A" or "B" letter grade indicates that the panel finds there is high certainty that the services have a substantial or moderate net benefit. The services required to be covered without cost-sharing include screening for depression, diabetes, cholesterol, various cancers, HIV and sexually transmitted infections, as well as screening and counseling for obesity.

The Public Health Service (PHS) Act and federal regulations also allow plans to use "reasonable medical management" techniques to determine the frequency, method, treatment, or setting for a preventive item or service <u>to the extent it is not specified in a recommendation or guideline.</u> While there is no formal regulatory definition or parameters for reasonable medical management, medical management techniques are typically used by plans to control cost and utilization of care or comparable drug use. For example, plans can impose limits on number of visits or tests if unspecified by a recommendation, cover only generics or selected brands of pharmaceuticals, or require prior authorization to acquire a preferred brand drug.

On October 23, 2015, the Tri-Agencies (The Departments of Health and Human Services, Labor, and Treasury) issued "Frequently Asked Questions (FAQs)" guidance regarding weight management services, which highlighted how health plan use of "reasonable medical management" techniques has raised many questions about how plans should implement the preventive services policy specific to obesity. In its guidance, the Tri-Agencies highlighted how the 2012 USPSTF recommendation "specifies that intensive, multicomponent behavioral interventions include, for example, the following:

• Group and individual sessions of high intensity (12 to 26 sessions in a year),
• Behavioral management activities, such as weight-loss goals,
• Improving diet or nutrition and increasing physical activity,
• Addressing barriers to change,
• Self-monitoring, and
• Strategizing how to maintain lifestyle changes."

Despite the Tri-Agencies guidance and two subsequent updates to the Task Force's recommendations regarding obesity, we have found that many health plans provide coverage for few if any sessions that would be considered high intensity.

For example, the essential health benefits (EHB) benchmark plan for Wisconsin state health exchange (UnitedHealthcare Insurance Company, Choice Plus), includes the following language under the Exclusions & Limitations section under the subheading of "Physical Appearance" of the certificate of coverage: "Weight loss programs whether or not they are under medical supervision. Weight loss programs for medical reasons are also excluded." The plan also excludes "any product dispensed for the purpose of appetite suppression or weight loss" or "surgical and non-surgical treatment of obesity." While the preventive care services section of the plan document does state there is coverage for "evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force," we found no mention of the USPSTF recommended benefit for obesity screening and referral for counseling services. One could argue that the plan does cover MNT for obesity/overweight, in that it's exclusion for MNT/nutrition counseling notes it "does not apply to medical nutrition education services that are provided by appropriately licensed or registered health care professionals when both of the following are true:

- Nutritional education is required for a disease in which patient self-management is an important component of treatment
- There exists a knowledge deficit regarding the disease which requires the intervention of a trained health professional"

We also note that the state employee health plan's certificate of coverage outlining the Uniform Benefits (UB) offered under the Group Health Insurance Program (GHIP) covers nutrition counseling by a registered dietitian nutritionist (RDN), however it excludes "weight loss programs including dietary and nutritional treatment in connection with obesity unless prescribed for the purposes of meeting authorization requirements to undergo bariatric surgery, as determined by the Health Plan…or any diet control program, treatment, or supply for weight reduction unless prescribed for the purposes of meeting authorization requirements to undergo bariatric surgery, as determined by the Health Plan." While the UB certificate for the GHIP does mention coverage for USPSTF preventive care services, the plan document is silent regarding obesity screening and referral for behavioral interventions as a covered preventive care service.

Benefits and Savings Associated with Comprehensive Obesity Treatment

As the ETF and GIB review adding coverage for pharmacotherapy as well as ensuring that state employees affected by obesity have equal access to mandated preventive care services, we urge them to follow the same forward-thinking approach that was used for evaluating coverage for bariatric surgery in 2019. For example, the April 14, 2019, ETF memo to the GIB regarding 2020 benefit changes, which made the following points:

1. "Obesity is the most prevalent health condition in the ETF population"
2. "Calculating return on investment for bariatric surgery is challenging, due to the complexity of obesity as a medical condition. Several studies indicate that bariatric surgery is cost effective. One study estimated that the cost of a bariatric surgery could be recovered in full in approximately 30 months"
3. "The GHIP's relatively stable membership lends particularly well to being able to recoup these costs."

We were pleased that ETF and the GIB recognized the benefits of providing bariatric surgery coverage when they stressed both the stable membership of the GHIP and the two to three-year return on investment (ROI) associated with surgical intervention. The decision to also require coverage for the "precursor weight management and nutrition services" demonstrates that the ETF and GIB are truly committed to ensuring that bariatric surgery patients have appropriate tools to achieve the best outcomes for addressing their obesity.

Adding coverage for AOMs and ensuring robust MNT services as envisioned by the USPSTF for state employees affected by obesity will afford patients with a broad range of evidence-based treatment tools to address this complex and chronic disease at an earlier stage – possibly avoiding bariatric surgery. The latest round of FDA-approved and pending obesity drugs can also be an alternative for those who may not be ready or comfortable with surgical intervention. However, for those with severe obesity and ideal candidates for bariatric surgery, accompanying drug coverage would ensure even better outcomes for those individuals who may begin to suffer weight regain.

Expanding coverage for MNT services by removing the exclusion for obesity/overweight and designing coverage that aligns with the Tri-Agencies' guidance provides patients the opportunity to engage with RDNs who offers cost-effective, quality care that fosters patient and provider satisfaction while improving patient outcomes. Research has shown that for every $1 invested in an RDN-led lifestyle modification program for obesity/overweight, there has been a nearly $15 return.[1] Several studies have shown that medical nutrition therapy (MNT) provided by RDNs improves clinical outcomes, reduces costs, decreases medication usage, and reduces hospital admissions by 9.5% for individuals with obesity and other weight-related chronic diseases.[2]

The US Preventive Services Task Force (USPSTF), American Heart Association, American College of Cardiology, and The Obesity Society all agree that intensive nutrition counseling provided by clinicians, including RDNs, should be recommended for adults with overweight or obesity (BMI<35) with chronic disease.[3] For weight loss in adults with overweight or obesity, at least 14 MNT encounters (either individual or group) over a period of at least 6 months are recommended. These "high-frequency, comprehensive" weight loss interventions result in weight loss of 5-7% of initial weight which is significant in improving the biochemical landscape. At minimum monthly MNT encounters over a period of at least 1 year are also recommended to maintain weight lost.[4]

In conclusion, we are hopeful that the ETF and GIB will take action to address these gaps in critical treatment avenues for state employees affected by obesity. Should you have any questions or need additional information, please feel free to contact us or Chris Gallagher at chris@potomaccurrents.com.

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[1] Wolf AM, Crowther JQ, Nadler JL, Bovbjerg VE. The return on investment of a lifestyle intervention: The ICAN Program. Paper presented at: American Diabetes Association 69th Scientific Sessions (169-OR); June 7, 2009; New Orleans, LA.

[2] Medical nutrition therapy (MNT) systematic review (2009). Academy of Nutrition and Dietetics Evidence Analysis Library. http://www.andeal.org/topic.cfm?menu=3949.
Johnson R; The Lewin Group. What does it tell us, and why does it matter? J Am Diet Assoc. 1999;99:426-427.

[3] Registered dietitians: your nutrition experts [brochure]. Academy of Nutrition and Dietetics; 2013. http://www.eatrightpro.org/~/media/eatrightpro%20files/practice/patient%20care/registered_dietitians_your_nutrition_experts.ashx.

[4] Adult Weight Management Guideline (2014). Academy of Nutrition and Dietetics Evidence Analysis Library. https://www.andeal.org/template.cfm?template=guide_summary&key=4326.