March 21, 2022

Dear ICER Staff:

Thank you for tackling a topic of growing importance and complexity with your upcoming Obesity Management review. The draft background and scope documents published on March 3, 2022 highlight many important issues in the treatment of obesity and outline a well-structured plan for the analysis. On behalf of Anthem/IngenioRx, we would like to offer the following comments for ICER's consideration as the team continues work on this important review.

Outlined below are three primary suggestions we hope ICER can address in the full report:

- **Describing Coverage of Weight Loss Treatments:** The current draft background section states that "insurance coverage and pre-authorization" may pose a barrier to use of anti-obesity agents; however, this statement is broad and warrants further explanation. Unlike drugs used to treat most other chronic diseases, drugs approved for weight loss may be included on a PBM/health plan formulary but remain inaccessible for members due to an exclusion at the benefit level (GAO 2019, Waidmann 2022). Individual employers/states have the authority to deem this category of drugs a "benefit exclusion," thus making any agent in this category non-covered and not reviewable on an appeal. In the final report, we suggest that ICER expand upon the difference between weight loss agents that are "not on formulary" and cases where the entire category of weight loss treatments is a "benefit exclusion." This distinction is important because in many cases changes must be made at the benefit level, rather than the formulary level, in order to expand patient access to treatment.

- **State Mandated Coverage of Weight Loss Treatments:** A new trend in this space is the growing number of states mandating coverage of anti-obesity treatments (screening, nutritional counseling, bariatric surgery and/or pharmacologic therapy) (Waidmann 2022). The impact of these new regulations is still to be determined, but may impact product pricing, coverage and access going forward. ICER may wish to further investigate possible impact of these new regulations and consider how these changes may impact their model as applicable.

- **Use of Canadian Guidelines:** Although more recent than US guidelines, Canadian guidelines may not accurately represent the US population affected by obesity or accurately reflect medication access in the US. We suggest that ICER consider including guidelines from US based organizations, such as the American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity (Garvey 2016), into the background section of their final draft to ensure guideline recommendations carried forward in the report remain relevant to US patients, providers, and payers.

The following table includes additional feedback ICER may wish to consider:

Applicable Statement	Anthem/IngenioRx Comment
Page 1 (end of paragraph 2): "Given the prevalence of obesity and its impact on health, the costs of obesity are staggering, estimated to be $260 billion in the US.[11]"	The cited study includes only a small subset of the US population, specifically adults between age 18 to 65 with biological children in the home and may not provide the most accurate estimate of total spend on obesity in the US. Anthem/IngenioRx suggests that ICER consider additional studies that include broader populations. Biener 2020, Tremmel 2017, Lopez 2020 are just a few we identified but there may be others ICER would like to include to help address the limitations of this spend estimate.
Page 2 (end of paragraph 3): "Since bupropion, naltrexone, and topiramate are available as single agents, clinicians may also use them "off label" alone and in combination for weight loss."	Phentermine may also be frequently used "off-label" as long-term therapy either alone or in combination with topiramate when cost and/or insurance coverage is of concern (Mauer 2021). Anthem/IngenioRx agree with focusing the cost-effectiveness evaluation on agents approved for long-term use but suggest ICER acknowledge that phentermine may also be used off-label along with bupropion, naltrexone and topiramate.
Page 4 (middle of paragraph 1): "…and the weight loss achieved is still less than that seen for bariatric surgery."	Another growing area of research worth mentioning is the use of anti-obesity medications after bariatric surgery for insufficient initial weight loss or weight regain (Stanford 2017). Anthem/IngenioRx suggest ICER explore this growing area and determine if there is sufficient data to evaluate use of anti-obesity agents after surgery as an additional subgroup in their final analysis. If the data in this area is inconclusive, it may be an area for future research worth mentioning in the report.
Page 5 (outcomes of interest): Adverse Events	In addition to the listed adverse events experienced by individuals taking these medications, ICER may want to consider looking for information related to birth defects associated with use of anti-obesity agents. Certain anti-obesity agents, such as Qsymia, have REMS programs related to the risk of use in pregnancy while other agents, such as Contrave, are not recommended in pregnancy. Given that many of these anti-obesity agents are likely to be used in women of childbearing potential and that weight loss may increase fertility in women previously unable to conceive, Anthem/IngenioRx suggests ICER consider acknowledging the risk of birth defects alongside other identified adverse events of interest.

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March 23, 2022
Submitted electronically to: publiccomments@icer.org
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Novo Nordisk (henceforth referred to as "NN") is a global healthcare company committed to helping improve the lives of people with obesity by changing how the world sees, prevents, and treats obesity including development of effective medications for chronic weight management. As the manufacturer of Wegovy® (semaglutide) injection 2.4 mg and Saxenda® (liraglutide) injection 3 mg, NN appreciates the opportunity to provide comments to ICER regarding the *Medications for Obesity Management Draft Background and Scope* document released on March 3, 2022. We strive for an evidence-driven approach for this evaluation.

As acknowledged by ICER, obesity is a serious, chronic, and progressive disease. The economic burden of obesity is substantial. It was estimated to be $1.72 trillion for the United States in 2016, consisting of $480.7 billion in direct healthcare costs and $1.24 trillion in indirect costs.[1] Much of this cost is related to chronic diseases driven by obesity and overweight.[1] Obesity-related comorbidities are projected to add $48–$66 billion a year to aggregate U.S. healthcare spending through 2030.[2] Hence, when evaluating medications for chronic weight management, these downstream costs are of relevance.

NN shares ICER's commitment to improving the quality and effectiveness of care for all patients. NN's commitment to obesity research is demonstrated by a robust clinical development program. STEP (Semaglutide Treatment Effect in People with obesity) trials have found that semaglutide 2.4 mg has achieved and maintained clinically meaningful weight loss (WL) when compared with placebo, and has demonstrated improvements in cardiometabolic parameters.[3–8]

After careful review of the draft scope, NN is seeking clarity on the following: (1) interventions and comparators; (2) base population and sub-populations; (3) weight loss outcomes; (4) long-term health outcomes included in the model.

1. Interventions and comparators. NN supports ICER's decision to not include devices and surgical interventions in this evaluation. We further agree with ICER that defining the scope to include comparisons only between medications for chronic weight management (long term) is appropriate because they have most similar setting of care (clinic), populations (BMI ≥30 kg/m^2 or 27 kg/m^2 with at least one comorbidity) and primary trial outcomes.

For chronic diseases such as diabetes, hypertension, hyperlipidemia, medications are prescribed along with lifestyle modifications because it is understood that lifestyle changes are an adjunct to pharmaceutical intervention. Similarly, medications for chronic weight management are expected to be prescribed "as an adjunct to a reduced calorie diet and increased physical activity." Therefore, lifestyle modification is included in both treatment and comparator arms in all clinical trials for regulatory approval of medications for chronic weight management. In

addition, there are many and varied lifestyle management programs available, which may make inclusion in the comparative effectiveness research challenging. ***We are interested in gaining clarity on how the ICER team will plan to define lifestyle modification and whether/how commercial WL programs will be considered or included as comparators in the model.***

2. Base population and sub-populations. NN agrees that the base case proposed by ICER is well-aligned with the indicated populations for the stated interventions, including semaglutide 2.4mg. While analyses of subgroups stratified by BMI also are valuable to examine, the lowest BMI subgroup (25 to 29.9 kg/m^2) proposed by ICER extends below the BMI inclusion criteria for the interventions' trials (≥27 kg/m^2), and therefore is not represented in any trial data, thus representing off label use of these products.[9–12] ***We recommend modifying the lowest subgroup to be patients with BMI 27 to 29.9 kg/m^2 who also have at least one weight-related comorbidity.***

While NN shares ICER's assessment that type 2 diabetes or pre-diabetes subgroups are clinically relevant to include in the evaluation, we advise caution about comparisons made between treatments as variations in the clinical trial designs and reporting could result in differences in the available data. In addition to percent WL, data on changes in glycated hemoglobin levels and changes in glycemic category (normo-glycemia, pre-diabetes, type 2 diabetes), and subgroup data for participants who had prediabetes at baseline, are available from the STEP trials. ***We are interested in gaining additional understanding of how the ICER team will approach potential pre-diabetes and diabetes subgroups in the modeling.***

3. Weight loss outcomes:

- **Duration of clinical trials**. As per the 2007 FDA Draft Guidance on Developing Products for Weight Management, evidence on medication effectiveness should only be derived from studies with at least 52 weeks duration. ***We recommend ICER takes this into consideration when developing the comparative effectiveness review and the economic model.***

- **Including categorical WL in addition to percent WL:** As per FDA guidelines for chronic weight management trials, in addition to percent WL, categorical WL should be assessed when evaluating efficacy of anti-obesity medications. Mean and categorical WL (or the proportion of patients who achieved 5%, 10%, 15%, or 20% body weight reduction) were captured in all STEP trials.[3–8] In addition, prior research has found that WL of 5-15% can lower the risk of certain obesity-related comorbidities and complications, including type 2 diabetes, hypertension, and osteoarthritis as well as other conditions associated with excess weight.[13–19] Categorical WL may also provide a better understanding of the distribution of expected WL as compared with just the mean percent WL. Therefore, including categorical WL in ICER's Clinical Evidence Review and, if possible, the Comparative Value Analyses would more fully capture the value of each intervention under evaluation.

- **Weight re-gain:** NN agrees that capturing the metric of weight re-gain is of importance since most people living with obesity struggle to achieve and maintain their WL[20] due to metabolic adaptation, impacting quality of life and long-term health outcomes. Hence, weight re-gain is considered to be an important metric for evaluating long-term benefits of treatment.[21,22]

NN looks forward to ICER's consideration of including categorical WL, alongside percent WL and weight re-gain in its analyses.

4. Long-term health outcomes: Obesity is a serious and chronic disease that is associated with increased risk of a vast number of comorbidities[23–25] that contribute to poor health outcomes as noted by the CDC and Obesity Medicine Association. We agree with the long-term health outcomes outlined in the scoping document. ***However, with knowledge of the evidence gaps as regards the association between WL and the risk of comorbidities and complications, we look forward to gaining clarity on how ICER will integrate these downstream outcomes and costs into their analyses.***

We appreciate the opportunity to provide input on the scoping document and look forward to engaging with ICER throughout this review.

Sincerely,

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Appendix

Table 1: Clinical Trials of the Wegovy® (Semaglutide 2.4mg) Clinical Development Program

Trial	N	Population	Primary End Point(s)	Secondary End Points
STEP 1 Weight Management[7]	1,961 Randomized 2:1 to 68 weeks of treatment with once-weekly subcutaneous semaglutide 2.4 mg or placebo, plus lifestyle intervention. 333 patients who completed the 68 weeks were enrolled in an off-treatment observational follow-up trial of 52 weeks' duration (to week 120).	-BMI equal to or above 30 kg/m2 or -BMI equal to or above 27 kg/m2 and ≥1 weight-related comorbidity (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease History of at least one self-reported unsuccessful dietary effort to lose body weight	Mean percentage change in body weight from baseline to week 68. Achievement of a reduction in body weight of 5% or more from baseline to week 68.	Confirmatory secondary end points were achievement of a reduction in body weight of 10% or more and 15% or more by week 68 and the change from baseline to week 68 in waist circumference, systolic blood pressure (SBP), physical functioning score on the 36-item Short Form Health Survey (SF-36), and physical function score on the Impact of Weight on Quality of Life–Lite Clinical Trials (IWQOL-Lite-CT) questionnaire.
STEP 2 Weight Management in T2D[3]	1,210 randomized 1:1:1 to 68 weeks of treatment with once-weekly subcutaneous semaglutide 2·4 mg, semaglutide 1·0 mg, or placebo, plus lifestyle intervention.	-BMI equal to or above 27 kg/m2 -History of at least one self-reported unsuccessful dietary effort to lose body weight	Mean percentage change in body weight from baseline to week 68. Achievement of a reduction in body weight of 5% or	Confirmatory secondary end points (semaglutide 2·4 mg vs placebo, unless stated otherwise) were: proportions of patients achieving bodyweight reductions of at least 10% or 15% at week 68, change from baseline to week 68 in waist circumference, percentage

		-Diagnosed with type 2 diabetes 180 days or longer prior to the day of screening -hemoglobin A1c 7-10% (53-86 mmol/mol) (both inclusive))	more from baseline to week 68 (semaglutide 2.4 mg vs. placebo).	change in bodyweight (semaglutide 2·4 vs 1·0 mg) at week 68, change from baseline to week 68 in HbA1c, SBP, SF-36 physical functioning score, and IWQOL-Lite-CT physical function score.
STEP 3 Weight Management with Intensive Behavioral Therapy[6]	611 Randomized 2:1 to semaglutide, 2.4 mg or placebo, both combined with a low-calorie diet for the first 8 weeks and intensive behavioral therapy during 68 weeks. Intensive behavioral therapy was defined as 8 weeks low-calorie diet followed by a reduced calorie diet for the remainder of the 68 weeks + physical activity (100 min/week which was increased by 25 min every 4 weeks to reach 200 min/week) + 30 intensive behavioral therapy visits	-BMI equal to or above 30 kg/m2 or -BMI equal to or above 27 kg/m2 or more with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease -History of at least one self-reported unsuccessful dietary effort to lose body weight	Mean percentage change in body weight from baseline to week 68. Achievement of a reduction in body weight of 5% or more from baseline to week 68.	Confirmatory secondary end points (in hierarchical testing order) included: achievement of a reduction in body weight of 10% or more and 15% or more by week 68 and the change from baseline to week 68 in waist circumference, SBP, and physical functioning score on the SF-36 (v2.0 Acute).

STEP 4 Sustained Weight Management[4]	902 participants received once-weekly subcutaneous semaglutide during run-in. After 20 weeks 803 participants who reached the 2.4-mg/wk semaglutide maintenance dose were randomized 2:1 to 48 weeks of continued semaglutide or switched to placebo, plus lifestyle intervention in both groups.	-BMI equal to or above 30 kg/m2 or -BMI equal to or above 27 kg/m2 or more with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease -History of at least one self-reported unsuccessful dietary effort to lose body weight	Percentage change in body weight from randomization (week 20) to week 68.	Confirmatory secondary end points included the change from randomization (week 20) to week 68 in waist circumference, SBP, and physical functioning score on the SF-36 (v2.0 Acute).
STEP 5 Long-Term Weight Management[8]	304 Randomized 1:1 to 104 weeks' treatment with semaglutide 2.4 mg or Placebo, plus lifestyle intervention in both groups.	-BMI equal to or above 30 kg/m2 or -BMI equal to or above 27 kg/m2 or more with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease	Mean percentage change in body weight from baseline to week 104. Achievement of a reduction in body weight of 5% or more from baseline to week 104.	Confirmatory secondary end points (in hierarchical testing order) included: achievement of a reduction in body weight of 10% or more and 15% or more by week 104; and change from baseline to week 104 in waist circumference and SBP.

		-History of at least one self-reported unsuccessful dietary effort to lose body weight		
STEP 8 Head-to-Head Comparison vs. Liraglutide[5]	338 Randomized 3:1:3:1 to once-weekly semaglutide, 2.4 mg or matching placebo, or once-daily liraglutide, 3.0 mg or matching placebo, plus diet and physical activity.	-BMI equal to or above 30 kg/m2 or -BMI equal to or above 27 kg/m2 or more with the presence of at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease -History of at least one self-reported unsuccessful dietary effort to lose body weight	Mean percentage change in body weight from baseline to week 68.	Confirmatory secondary end points (in hierarchical testing order) included: achievement of a reduction in body weight of 10% or more, 15% or more, and 20% or more by week 68.

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March 21, 2022

Institute for Clinical and Economic Review (ICER)
Via Email - publiccomments@icer.org

On behalf of the Obesity Action Coalition (OAC), I am pleased to submit the following comments on the Treatments for Obesity Management Scoping Document. Special thanks to the ICER team for including the voice of people impacted by obesity in developing, designing, and responding to this review.

OAC in general was pleased with the review. Our comments are as follows:

1. Consider referring to obesity as a disease instead of a condition. While it is true that obesity is a condition, not all conditions are diseases and AMA and many others recognize obesity as a chronic disease (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4988332/). Disease language is important as it helps create better understanding of the complexity of obesity but also its seriousness. The Office of Personnel Management (OPM) of the US Federal Government's language around obesity and obesity treatment is a good example (Page 9 and 10: https://www.opm.gov/healthcare-insurance/healthcare/carriers/2022/2022-03.pdf)
2. We very much appreciate the inclusion of weight bias and stigma in the scoping document. It is likely worth adding an acknowledgement that stigma itself has health consequences (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092785/pdf/12916_2018_Article_1116.pdf) to your appropriate list of social, educational, personal and employment consequences.
3. There is a single reference to dietary supplements in the document and we encourage deleting this reference. The evidence around the effectiveness and safety of dietary supplements is lacking and they shouldn't be lumped together with FDA-approved medications even when referring to earlier generations of medications.
4. Lifestyle interventions are mentioned as being "helpful for some" with the implication that this type of treatment is the first line for most people with obesity. However, it should be noted that clinical research has only documented a clinical benefit for intensive lifestyle therapy such as the Diabetes Prevention Program. In clinical practice, though, the delivery of such intensive programs is in fact relatively rare. For example, the DPP has only reached about 425,000 individuals according to CDC (https://www.cdc.gov/diabetes/library/reports/reportcard/national-dpp.html) and CMS only delivers intensive lifestyle therapy to less than 1% of beneficiaries with a clinical need for it (https://doi.org/10.1002/oby.21578 and https://www.politico.com/news/2019/10/22/medicare-diabetes-hhs-055006). As you build models to compare effectiveness, we ask that you take this into consideration.

We look forward to continuing to participate in the ICER review of this important topic.

Sincerely,

Joseph Nadglowski, Jr., President/CEO

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March 22, 2022

Greetings Institute for Clinical and Economic Review (ICER) Colleagues,

Below (as well as on the attached PDF) are the ICER Consolidated Comments on Behalf of the Obesity Medicine Association (OMA). Future correspondence should be directed to OMA's Executive Director per the contact information at the conclusion of this narrative.

General Comments:
It seems slightly out of order that OMA has been asked to provide general comments on the Medications for Obesity Management Draft and Scope document versus being involved in the development process of the document. In general, our society questions as to why we were not asked to comment earlier in the process. To that end, were other organizations (such as pharmaceutical companies) asked to comment on the Draft and Scope document earlier in the process?

OMA Board of Trustee Member, Dr. Suzanne Cuda's Comments:
Although this draft is aimed at the adult population and I have a different perspective based on my treatment of children and adults, I had a couple of comments. First the generalized definition of prevalence of obesity in children is not defined. In the reference cited, it is defined as > than the 95th percentile. Since there are so many ways to classify obesity in children, I think this should be added.

Secondly, I am struck by the focus on a decrease in BMI instead of metabolic improvement (listed as a secondary outcome) and no mention of mental health at all. Also, the draft discusses difficulty with insurance coverage for medications, but it doesn't address coverage for metabolic and bariatric surgery, which is also an important issue.

Finally, the lack of trials in youth for medications is a big issue and should be addressed. Although we use as much as we can off label, our children deserve much more.

OMA Board of Trustee President, Dr. Ethan Lazarus' Comments:
On page #2 of the Draft Background and Scope document, 2nd paragraph, delete "engendered interest among patients and providers." This sounds like an opinion and does nothing to strengthen this paper. Also, it sounds like the funding is coming from Novo Nordisk.

In the next paragraph, delete "a combination of phentermine and fenfluramine..." Clinically, why are we still talking about this?

On page #4 at the top, delete "comparable to bariatric surgery", as this is not true. Instead, say, "significantly more robust weight loss than the older agents." Again, this sounds like a promotion for Novo Nordisk.

In the same paragraph, delete "less than that seen for bariatric surgery", and restate instead, "medication-assisted weight loss yields far greater and sustained weight loss than behavioral treatment alone, while surgical weight loss generally exceeds medication-assisted weight loss."

In the next sentence, delete "often", "that medications will require chronic use..."

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On page #6 under “outcomes”, shouldn't one of the outcomes be safety, given the concerns raised in previous paragraphs?

On page #7 in the 2nd paragraph under the header, "of adults who HAVE obesity or overweight" (change to person-first language to read “have” versus “are”)

OMA Board of Trustee Immediate Past-President, Dr. Craig Primack’s Comments:
I am not in favor of generically grouping dietary manipulation in with behavioral or lifestyle change. There are excellent proven diets like the Mediterranean diet and meal replacement strategies that are enhanced when combined with medical strategies. I would love to see these mentioned in this document.

I am not sure how to add this, but metabolic and bariatric surgery is great as a tool for about two years, then it tends to be variable for the majority of patients. With Semaglutide and Liraglutide, there are many studies that now show when you cease these medications, the patient’s weight increases.

OMA Board of Trustee Secretary/Treasurer, Dr. Harold Bays’ Comments:
See the attached PDF with Dr. Bays’ comments

On behalf of OMA, we thank you for the opportunity to comment on this document!

Sincerely,

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