

## Bariatric Surgery

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### Draft Key Questions: Public Comment and Response

*November 15, 2023*

**Health Technology Assessment Program (HTA)**

Washington State Health Care Authority

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# Bariatric Surgery

Draft Key Questions:  
Public Comment and Response

Provided by:

Center for Evidence-based Policy  
Oregon Health & Science University



*November 15, 2023*

## Responses to Public Comment on Draft Key Questions

*The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.*

Draft key question document comments received:

- Ashley Hodes, MD, MBA, FACS, Senior Director Medical Safety, Surgical Operating Unit, Medtronic (submitted by Susan Hupp)
- Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association
- Marina Kurian, MD, FACS, FASMBS (submitted by Chris Gallagher)
- Joseph Nadglowski, Jr., OAC President and CEO (submitted by Chris Gallagher)

Specific responses pertaining to submitted comments are shown in Table 1.

**Table 1. Responses to Comments on Draft Key Questions for Bariatric Surgery**

Categories for specific comments: *Background and Context; Intervention; References; Guidelines and Standards; Language.*

| Comments   |  | Response   |
|--|--|--|
| <p><b>Commenter:</b> Ashley Hodes, MD, MBA, FACS, Senior Director, Medical Safety Surgical Operating Unit, Medtronic</p>   |  |  |
| <p><b>General comments:</b></p>  |  |  |
| <p>HCA Health Technology Assessment Program-<br/>                     Medtronic appreciates the opportunity to comment on bariatric surgery, which was selected for the Health Technology Assessment Program rereview. The attached comment letter includes Medtronic’s comments in support of coverage for single anastomosis duodeno ileal bypass with sleeve gastrectomy (SADI-S) and one anastomosis gastric bypass (OAGB).<br/>                     RE: Bariatric Surgery<br/>                     On behalf of Medtronic, I greatly appreciate the opportunity to submit comments regarding Bariatric Surgery, which was selected for the Health Technology Assessment Program rereview.<br/>                     Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high-quality products and innovative therapies that improve health outcomes for all patients.<br/>                     Medtronic supports coverage for single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI- S) and one anastomosis gastric bypass (OAGB). We would like to offer the following comments for the rereview of bariatric surgery.<br/>                     Thank you again for the opportunity to comment on the HCA Health Technology Assessment Program rereview for bariatric surgery.</p> |  | <p>Thank you for your comments.<br/>                     Please see detailed responses to specific points below.</p>   |
| <p><b>Specific comments:</b></p>   |  |  |
| <p><b>Intervention</b></p>   | <p><b>Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)</b><br/>                     The SADI-S surgery is a simpler version of the BPD/DS.<sup>i</sup> It causes weight loss by restricting food intake, reducing absorption of nutrients and calories, and reducing the hunger hormone similar to RYGB and BPD/DS.<sup>ii</sup> Both RYGB and BPD/DS rely on two new anastomoses being made to the small intestine. In contrast, the SADI-S procedure only needs a single new anastomosis that connects the small bowel directly distal to the stomach (duodenum) to a lower part of the small bowel (ileum).<sup>iii</sup> As anastomoses are technically challenging and can cause complications, SADI-S is both easier to perform and carries less risk than the procedures with two anastomoses.<sup>ii</sup><br/>                     This procedure was endorsed by an ASMBS expert panel<sup>iv</sup> and is supported by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).<sup>v</sup><br/>                     The loss of excess body weight with SADI-S was 80% after one year and 77% after three years; the total weight loss was 31% after one year and 30% after 3 years.<sup>vi</sup></p> | <p>Thank you for your comment.<br/>                     We will be reviewing the evidence for this procedure as part of the Health Technology Assessment report.</p> |

| Comments   |   | Response   |
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| <p><b>Commenter:</b> Ashley Hodes, MD, MBA, FACS, Senior Director, Medical Safety Surgical Operating Unit, Medtronic</p> |   |  |
| <b>Intervention</b>  | <p><b>One anastomosis gastric bypass (OAGB)</b></p> <p>The OAGB surgery is similar to SADI-S. OAGB creates a new single anastomosis between the stomach and the small bowel.<sup>iii</sup> In OAGB, the connection is between the lowest part of the stomach to a lower part of the small bowel instead of a connection between the duodenum with the lower small bowel, as is the case in SADI-S.<sup>iii</sup></p> <p>This procedure is supported by ASMBS<sup>vii</sup> and by IFSO.<sup>viii</sup></p> <p>OAGB is an effective surgery for weight loss. The excess weight loss was 64% at two years and 23% at five years.<sup>ix</sup> OAGB caused 10.8% more loss of excess body weight than RYGB one year after the surgery! The excess body weight loss after two years and five years was also found to be higher in OAGB than in RYGB.<sup>xi</sup></p>   | <p>Thank you for your comment.</p> <p>We will be reviewing the evidence for this procedure as part of the Health Technology Assessment report.</p>   |
| <b>References</b>  | <ul style="list-style-type: none"> <li>• Di Lorenzo N, Antoniou SA, Batterham RL et al. Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP. <i>Surg Endosc</i> 2020; 34(6):2332-58. <a href="https://doi.org/10.1007/s00464-020-07555-y">https://doi.org/10.1007/s00464-020-07555-y</a>.</li> <li>• Crossan K, Sheer AJ. StatPearls: Surgical Options in the Treatment of Severe Obesity. Treasure Island (FL); 2023.</li> <li>• Balamurugan G, Leo SJ, Sivagnanam ST et al. Comparison of Efficacy and Safety Between Roux-en-Y Gastric Bypass (RYGB) vs One Anastomosis Gastric Bypass (OAGB) vs Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S): a Systematic Review of Bariatric and Metabolic Surgery. <i>Obes Surg</i> 2023; 33(7):2194-209. <a href="https://doi.org/10.1007/s11695-023-06602-6">https://doi.org/10.1007/s11695-023-06602-6</a>.</li> <li>• Kailies K, Rogers AM. American Society for Metabolic and Bariatric Surgery updated statement on single-anastomosis duodenal switch. <i>Surg Obes Relat Dis</i> 2020; 16(7):825-30. <a href="https://doi.org/10.1016/j.soard.2020.03.020">https://doi.org/10.1016/j.soard.2020.03.020</a>.</li> <li>• Brown WA, Ooi G, Higa K, Himpens J, Torres A. Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement. <i>Obes Surg</i> 2018; 28(5):1207-16. <a href="https://doi.org/10.1007/s11695-018-3201-4">https://doi.org/10.1007/s11695-018-3201-4</a>.</li> <li>• Slagter N, Heide LJM de, Jutte EH et al. Outcomes of the One Anastomosis Gastric Bypass with Various Biliopancreatic Limb Lengths: a Retrospective Single-Center Cohort Study. <i>Obes Surg</i> 2021; 31(10):4236-42. <a href="https://doi.org/10.1007/s11695-021-05555-y">https://doi.org/10.1007/s11695-021-05555-y</a>.</li> <li>• American Society for Metabolic and Bariatric Surgery. ASMBS Endorsed Procedures and FDA Approved Devices   American Society for Metabolic and Bariatric Surgery; 2019 [cited 2023 Oct 20]. Available from: URL: <a href="https://asmbs.org/resources/endorsed-procedures-and-devices">https://asmbs.org/resources/endorsed-procedures-and-devices</a>.</li> <li>• Luca M de, Piatto G, Merola Get al. IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB). <i>Obes</i></li> </ul> | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of the report development.</p> |

| Comments   |   | Response |
|--|---|----------|
| <p><b>Commenter:</b> Ashley Hodes, MD, MBA, FACS, Senior Director, Medical Safety Surgical Operating Unit, Medtronic</p> |   |          |
|  | <p>Surg 2021; 31(7):3251-78. <a href="https://doi.org/10.1007/sl_1695-021-05413-x">https://doi.org/10.1007/sl_1695-021-05413-x</a>.</p> <ul style="list-style-type: none"> <li>Aleman R, Lo Menzo E, Szomstein S, Rosenthal RJ. Efficiency and risks of one-anastomosis gastric bypass. Ann Transl Med 2020; 8(Suppl 1):S7. <a href="https://doi.org/10.21037/atm.2020.02.03">https://doi.org/10.21037/atm.2020.02.03</a>.</li> <li>Uhe I, Douissard J, Podetta Met al. Roux-en-Y gastric bypass, sleeve gastrectomy, or one-anastomosis gastric bypass? A systematic review and meta-analysis of randomized-controlled trials. Obesity (Silver Spring) 2022; 30(3):614-27. <a href="https://doi.org/10.1002/oby.23338">https://doi.org/10.1002/oby.23338</a>.</li> <li>Magouliotis DE, Tasiopoulou VS, Tzovaras G. One Anastomosis Gastric Bypass Versus Roux-en-Y Gastric Bypass for Morbid Obesity: an Updated Meta-Analysis. Obes Surg 2019; 29(9):2721-30. <a href="https://doi.org/10.1007/s11695-019-04005-0">https://doi.org/10.1007/s11695-019-04005-0</a>.</li> </ul> |          |

| Comments  |   | Response  |
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| <p><b>Commenter:</b> Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association</p>   |   |   |
| <p><b>General comments:</b></p>   |   |   |
| <p>Hi<br/>Thank you for the opportunity to submit public comments on your current rereview of bariatric surgery. Please find the ADA letter of support for continued coverage of bariatric surgery.</p> |   | <p>Thank you for your comments.<br/><br/>Please see detailed responses to specific points below.</p>            |
| <p><b>Specific comments:</b></p>  |   |   |
| <p><b>Guidelines and Standards</b></p>  | <p>The ADA supports access to bariatric surgery and respectively requests continued coverage of this treatment option for obesity. Surgical procedures for obesity treatment can promote significant and durable weight loss and improve type 2 diabetes. <b>We encourage HTCC to review the ADA Standards of Care 2023 for the ADA’s guidelines for bariatric surgery.</b> We have also provided additional evidence and reports below to assist with the first contextual question.</p>   | <p>Thank you for your comment.<br/><br/>We will review this standard of care as part of report development.</p> |
| <p><b>Background and Context</b></p>  | <p>The American Diabetes Association (ADA) is a nationwide, nonprofit, voluntary health organization made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA’s mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.<br/><br/>Obesity is a growing chronic disease in Washington. As of 2021 almost 29% of adults had obesity and in 2020, youth aged 10 to 17 years old over 13% had obesity, a 50% increase since 2016. It also disproportionately impacts people of color, 33.4% of black</p> | <p>Thank you for your comment.</p>  |

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|---|--|
| <p><b>Commenter:</b> Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association</p> |  |
|   | <p>adults have obesity and 34.4% of the adult Hispanic population whereas only 29.3% of white adults have diagnosed obesity.</p> <p>Obesity is a serious, multifactorial, 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 13 types of cancer (which make up 40 percent of all cancers diagnosed). And as such, this disease requires treatment and management just like diabetes, cancer, or high blood pressure.</p> <p>Obesity is not a matter of personal choice or moral deficiency. Obesity is often the root cause and driver of other health complications. A recent report found that treating obesity can reduce diabetes (-8.9%), hypertension (-2.3%), heart disease (-2.6%), cancer (-1.3%), and disability (-4.7%) over 10 years in private insurance coverage and Medicare. The same assumption may be applied to Medicaid programs.</p> <p>Addressing obesity recognizes the barriers faced by many to achieve healthy living. These obstacles include lack of access to healthy foods and safe places to exercise among others. Medical intervention is effective in treating the chronic disease of obesity. The <i>ADA Standards of Care 2023</i> recommends person-centered intervention across the care continuum including:</p> <ol style="list-style-type: none"> <li><b>1. Screening and Prevention:</b> 1) screening for obesity (document height, weight, waist circumference), calculate BMI; 2) If needed, annual screening for obesity-related comorbidities.</li> <li><b>2. Intensive Behavioral Therapy (IBT):</b> 1) Offer intensive lifestyle modification program that includes personalized nutrition, physical activity and behavioral support with a trained professional.</li> <li><b>3. Pharmacotherapy:</b> Provide access to approved anti-obesity medications according to FDA guidelines.</li> <li><b>4. Bariatric Surgery:</b> Provide access to bariatric/ metabolic surgery as recommended by appropriate health care professional.</li> </ol> <p>We appreciate the opportunity to provide public comments on this important issue to address obesity in Washington particularly as it relates to the first contextual question along with expressing our support for continued coverage of bariatric surgery.</p> |
| <p><b>References</b></p>  | <p><u>Lifestyle Modification/Intensive Behavioral Therapy Studies</u></p> <ul style="list-style-type: none"> <li>• Putting the National Diabetes Prevention Program to Work: Predictors of Achieving Weight-Loss Goals in an Employee Population (cdc.gov)</li> <li>• Evidence - National DPP Coverage Toolkit</li> </ul> <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p>   |

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| <p><b>Commenter:</b> Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association</p> | <ul style="list-style-type: none"> <li>• <a href="https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp">https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp</a></li> <li>• Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin, .Diabetes Prevention Program Research Group, February 7, 2002 N Engl J Med 2002; 346:393-403. DOI: 10.1056/NEJMoa012512 <a href="https://www.nejm.org/doi/full/10.1056/nejmoa012512">https://www.nejm.org/doi/full/10.1056/nejmoa012512</a></li> <li>• Galaviz KI, Weber MB, Straus A, Haw JS, Narayan K MV, Ali MK. Global Diabetes Prevention Interventions: A Systematic Review and Network Meta-analysis of the Real-World Impact on Incidence, Weight, and Glucose. Diabetes Care. 2018 Jul;41(7):1526-1534. doi: 10.2337/dc17-2222. PMID: 29934481; PMCID: PMC6463613.</li> </ul>   |  |
| <p><b>References</b></p>  | <p><u>Obesity Medications</u></p> <ul style="list-style-type: none"> <li>• MacEwan J, Kan H, Chiu K, Poon JL, Shinde S, Ahmad NN. Anti-obesity Medication Use Among Overweight and Obese Adults in the United States: 2015–2018. Endocrine Practice [Internet] 2021 [cited 2023 Mar 16];27(11):1139–48. Available from: <a href="https://doi.org/10.1016/j.eprac.2021.07.004">https://doi.org/10.1016/j.eprac.2021.07.004</a></li> <li>• Pharmacologic Treatment of Overweight and Obesity in Adults - Endotext - NCBI Bookshelf (nih.gov)</li> <li>• ICER_Obesity_Evidence_Report_083122.pdf</li> </ul>  | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p> |
| <p><b>References</b></p>  | <p><u>Obesity Medications – Utilization Duration and Adherence</u></p> <ul style="list-style-type: none"> <li>• Joanna MacEwan, Hong Kan, Kevin Chiu, Jiat Ling Poon, Shraddha Shinde, Nadia N. Ahmad, “Antiobesity Medication Use Among Overweight and Obese Adults in the United States: 2015–2018” VOLUME 27, ISSUE 11, P1139-1148, July 11, 2021. <a href="https://doi.org/10.1016/j.eprac.2021.07.004">https://doi.org/10.1016/j.eprac.2021.07.004</a></li> <li>• Meyer H. Medicare Diabetes Prevention: Enrollment Short of Projections. Health Affairs [Internet] 2021 [cited 2023 Mar 15];40(11):1682–7. Available from: <a href="https://doi.org/10.1377/hlthaff.2021.01292">https://doi.org/10.1377/hlthaff.2021.01292</a> (Average duration of AOM use is 81 days)</li> <li>• Suissa K, Schneeweiss S, Kim DW, Paterno E. Prescribing trends and clinical characteristics of patients starting antiobesity drugs in the United States. Diabetes, Obesity and Metabolism [Internet] 2021 [cited 2023 Mar 15];23(7):1542–51. Available from: <a href="https://doi.org/10.1111/dom.14367">https://doi.org/10.1111/dom.14367</a></li> <li>• Persistence of newer anti-obesity medications in a real-world setting - PubMed (nih.gov)</li> <li>• Antiobesity Medication Use Among Overweight and Obese Adults in the United States: 2015–2018 - ScienceDirect</li> <li>• Antiobesity Medication Use in 2.2 Million Adults Across Eight Large Health Care Organizations: 2009–2015 - PubMed (nih.gov)</li> </ul> | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p> |



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| <p><b>Commenter:</b> Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association</p> |   |  |
|   | <ul style="list-style-type: none"> <li>Weight-Loss Maintenance for 10 Years in the National Weight Control Registry - ScienceDirect</li> <li>Effectiveness of anti-obesity medications approved for long-term use in a multidisciplinary weight management program: a multi-center clinical experience   International Journal of Obesity (nature.com)</li> </ul>   |  |
| <p><b>References</b></p>  | <p><u>New innovative therapies research</u></p> <ul style="list-style-type: none"> <li>Tirzepatide Once Weekly for the Treatment of Obesity   NEJM</li> <li>Purcell M, Stanley E, Wu S, et al. Unlocking the Obesity Challenge: a &gt;\$50bn Market [Internet]. Morgan Stanley; 2022. Available from: <a href="https://khn.org/wp-content/uploads/sites/2/2022/09/Morgan-Stanley_Unlocking-the-Obesity-Challenge.pdf">https://khn.org/wp-content/uploads/sites/2/2022/09/Morgan-Stanley_Unlocking-the-Obesity-Challenge.pdf</a> (Payer rebates in the range of 50%.5)</li> <li>Weight Loss Outcomes Associated With Semaglutide Treatment for Patients With Overweight or Obesity   Lifestyle Behaviors   JAMA Network Open   JAMA Network (the limited uptake in the large Mayo Clinic Health System and near clinical trial efficacy from real-world evidence)</li> <li>Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial   Nature Medicine (utilization of AOMs is barely 1%)</li> <li>Kathleen M. Robinson, Mark Vander Weg, Helena H. Laroche, Margaret Carrel, Jason Wachsmuth, Krista Kazembe, Mary Vaughan Sarrazin, "Obesity treatment initiation, retention, and outcomes in the Veterans Affairs MOVE! Program among rural and urban veterans" 01 June 2022 <a href="https://doi.org/10.1002/osp4.622">https://doi.org/10.1002/osp4.622</a></li> </ul>  | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p> |
| <p><b>References</b></p>  | <ul style="list-style-type: none"> <li><a href="https://watermark.silverchair.com/dc23s008.pdf?token=AQ_ECAHi208BE49Ooan9kKhW_Ercy7Dm3ZL_9Cf3qfKAc485y_sgAAA0owggNGBgkqhkiG9w0BBwagggM3MIIDMwIBADC_CAYwGCSqGSib3DQEHATAeBgIghkgBZQMEAS4wEQQMxMeSKK-8brgA-AZzAgEQgIIC_T5izpSJJGhtQSGJ3fBIKYvodYQLLjqfBLtcWRx8Fm8Rf1oVYs5s0IWmR3JZp2mjdps_JWGZz5i2riY8P9dqmiJ0Ch6ulj3ktVTIEhCvppqoFGYntqjZZ7aLLB8aNKutQ9EnhIKoRNH9DKgR52PLmeXkWUwbNiyhwHT656-xG-_IuvHfcDLd0SBKhQ7cj4248B4EjZO_Z59k2uEyzL8jKrm4IsQ-Q-VwPAIjPYYQR8wcCNTgbzoEnHu4JiTmJ6KKC0yN1rz71zPMkU1yt8M5L9elbVHw39yPTbc1nSrijaz6RJa27d1W983daJXJglYL_qNg-9AdNCsMXE87eCXqhoE0zkUdeMD5hG7wC2h9bM1-ColUB-JdCLt7sePxmS01qN8rt4ZBxUWR8pkJRYR6ybtDt2ujHyDhk_y0uEkmwKeU4w6rs3P4sfNxMaDyYQS2khgzZdLlySY7zeTV">https://watermark.silverchair.com/dc23s008.pdf?token=AQ_ECAHi208BE49Ooan9kKhW_Ercy7Dm3ZL_9Cf3qfKAc485y_sgAAA0owggNGBgkqhkiG9w0BBwagggM3MIIDMwIBADC_CAYwGCSqGSib3DQEHATAeBgIghkgBZQMEAS4wEQQMxMeSKK-8brgA-AZzAgEQgIIC_T5izpSJJGhtQSGJ3fBIKYvodYQLLjqfBLtcWRx8Fm8Rf1oVYs5s0IWmR3JZp2mjdps_JWGZz5i2riY8P9dqmiJ0Ch6ulj3ktVTIEhCvppqoFGYntqjZZ7aLLB8aNKutQ9EnhIKoRNH9DKgR52PLmeXkWUwbNiyhwHT656-xG-_IuvHfcDLd0SBKhQ7cj4248B4EjZO_Z59k2uEyzL8jKrm4IsQ-Q-VwPAIjPYYQR8wcCNTgbzoEnHu4JiTmJ6KKC0yN1rz71zPMkU1yt8M5L9elbVHw39yPTbc1nSrijaz6RJa27d1W983daJXJglYL_qNg-9AdNCsMXE87eCXqhoE0zkUdeMD5hG7wC2h9bM1-ColUB-JdCLt7sePxmS01qN8rt4ZBxUWR8pkJRYR6ybtDt2ujHyDhk_y0uEkmwKeU4w6rs3P4sfNxMaDyYQS2khgzZdLlySY7zeTV</a></li> </ul> | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p> |

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| <p><b>Commenter:</b> Carissa Kemp, Director, State Government Affairs (AK, CO, ID, MN, MT, ND, NV, OR, SD, UT, WA, WY), American Diabetes Association</p> |   |          |
|   | <p><a href="#">FlekiMY7bgdUO4RnxbsN3DLVF1eA2k-9Y4oDZHjldA_jSI7agvfwT0BhhoEAhk48RFlafTgJWF2wOYuG6_ZKo14schn9zv0HADhOtYzSYW477KRyc61KgIBVyR1OLwLUP_wtqtm8Gddy3elTVKe_gvjY00Wwxllw-LvMO2He-A2GTn_45Xe5ovhpKri7EI8Wk8rUzQVZ681f6E3tHD7ZgcJ3DgmlH8wNdxrYUFHFh5fe25c8CRZ_OAbGGxZ3pmbSIsAEwW68LiXlh_o6Ff6ip7t2vvZPFTTrREQaLYrvHeIEjTir0txDWO_SwCObgNPUx5srhGP35ly_8v_fm7CQD0uLmAGeat4APE_TpaY4uPJSfEb3BojaJ2MPnMDDr0U_imQMz-KAsTMjxC1qqWaJI09LNFLvwUsufFKIFB2QAWMLCo0GUGIsor9pXq2LU2xdN_D4hNX68Ay27cxeXRzqr16oJDOVLclX4so5G30WAYI6fQ7fvpvlyQQDa2VeYFRu708FdIBD5bl-x04o3TrHYIEKp10Wztu7TqE2Kq1dLybOrlIZw</a></p> <ul style="list-style-type: none"> <li>• <a href="https://doh.wa.gov/data-and-statistical-reports/diseases-and-chronic-conditions/obesity">https://doh.wa.gov/data-and-statistical-reports/diseases-and-chronic-conditions/obesity</a></li> <li>• <a href="https://www.obesityaction.org/wp-content/uploads/Washington2023-1">https://www.obesityaction.org/wp-content/uploads/Washington2023-1</a></li> <li>• Centers for Disease Control and Prevention. <a href="https://www.cdc.gov/cancer/obesity/index">https://www.cdc.gov/cancer/obesity/index</a>. Accessed April 26, 2023</li> <li>• Benefits of Medicare Coverage for Weight Loss Drugs. By Alison Sexton Ward, PhD, Bryan Tysinger, PhD, PhuongGiang Nguyen, Dana Goldman, PhD and Darius Lakdawalla, PhD. USC Schaeffer, 2023.</li> </ul> |          |

| Comments   |  | Response  |
|--|--|---|
| <p><b>Commenter:</b> Marina Kurian, MD FACS FASMBMS, President, American Society for Metabolic and Bariatric Surgery</p> |  |   |
| <p><b>General comments:</b></p>  |  |   |
|  | <p>Dear Members of the Washington State Health Care Authority:<br/>On behalf of the American Society for Metabolic and Bariatric Surgery (ASMBS), please see our attached comments in response to the October 18, 2023, notice regarding proposed topics for review by the Washington State Health Care Authority’s (HCA) Health Technology Assessment (HTA) program. Our comments focus specifically on bariatric surgery.</p>                | <p>Thank you for your comments.<br/>Please see detailed responses to specific points below.</p> |
| <p><b>Specific comments:</b></p>   |  |   |
| <p><b>Background and Context</b></p>   | <p>RE: WA State HCA’s HTA Review of Metabolic and Bariatric Surgery<br/>Dear Members of the Washington State Health Care Authority:<br/>On behalf of the American Society for Metabolic and Bariatric Surgery (ASMBS), I am pleased to provide comments in response to the October 18, 2023, notice regarding proposed topics for review by the Washington State Health Care Authority’s (HCA) Health Technology Assessment (HTA) program.</p> | <p>Thank you for your comment.</p>  |

| Comments  | Response  |  |
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| <p><b>Commenter:</b> Marina Kurian, MD FACS FASMBS, President, American Society for Metabolic and Bariatric Surgery</p> |   |  |
|   | <p>The HCA selected metabolic and bariatric surgery (MBS) coverage for rereview to evaluate the effectiveness, safety, and cost-effectiveness of MBS in adults and children who are affected by overweight or obesity. This evidence review is designed to help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use of metabolic and bariatric surgery in adults and children.</p> <p>The ASMBS is the largest organization for bariatric surgeons in the United States. It is a nonprofit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of severe obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in bariatric surgery, while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for patients with severe obesity.</p>  |  |
| <p><b>Guidelines and Standards</b></p>  | <p><b>Adoption of Latest Clinical Guidelines Surrounding Metabolic and Bariatric Surgery</b></p> <p>MBS coverage is expanding everyday given the evolving science behind new populations for whom surgical intervention could be beneficial. Therefore, we are pleased that the Washington State HCA has included these new guidelines as part of its consideration of expanding MBS coverage to these new critical populations.</p> <p>For example, the 2022 ASMBS/International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Guidelines on Indications for Metabolic and Bariatric Surgery. These new guidelines are meant to replace a consensus statement developed by the National Institutes of Health more than 30 years ago that set standards most insurers and doctors still rely upon to make decisions about who should get weight-loss surgery, what kind they should get, and when they should get it.</p> <p>The ASMBS/IFSO Guidelines now recommend metabolic and bariatric surgery for individuals with a BMI of 35 or more “regardless of presence, absence, or severity of obesity-related conditions” and that it be considered for people with a BMI 30-34.9 and metabolic disease and in “appropriately selected children and adolescents.” But even without metabolic disease, the guidelines say weight-loss surgery should be considered starting at BMI 30 for people who do not achieve substantial or durable weight loss or obesity disease-related improvement using nonsurgical methods.</p> <p>The ASMBS/IFSO Guidelines are just the latest in a series of new recommendations from medical groups calling for expanded use of metabolic surgery. In 2016, 45 professional societies, including the American Diabetes Association (ADA), issued a joint statement that metabolic surgery should be considered for patients with type 2 diabetes and a BMI 30.0–34.9 if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable</p> | <p>Thank you for your comment.</p> <p>We will review these guidelines as part of report development.</p> |

| Comments   | Response  |  |
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| <b>Commenter:</b> Marina Kurian, MD FACS FASMBS, President, American Society for Metabolic and Bariatric Surgery |   |  |
|  | <p>medications. This recommendation is also included in the ADA's "Standards of Medical Care in Diabetes – 2022."</p>   |  |
| <b>Guidelines and Standards</b>  | <p><b>MBSAQIP Standards Improve Quality &amp; Culture of Care</b></p> <p>ASMBS joined with the American College of Surgeons (ACS) in creating a national standard for bariatric surgery accreditation programs in 2012 called the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). This program accredits inpatient and outpatient bariatric surgery centers in the U.S. and Canada that have undergone an independent, voluntary, and rigorous peer evaluation in accordance with nationally recognized bariatric surgical standards.</p> <p>Being an accredited center means you are held to the highest bariatric surgical standards and have quality improvement initiatives in place. Accredited centers are required to report their treatment outcomes and participate in regular evaluations of their surgical programs, ensuring they are meeting safety requirements, consistently improving processes, applying multidisciplinary approaches, and implementing standards of care defined by MBSAQIP.</p> <p>MBSAQIP accreditation goes beyond reporting, to culture, as well. An accredited center must strive for excellence in fostering patient-centered culture. When it comes to bariatric surgery, it is incredibly important that patients feel comfort and respect in and out of the operating room.</p> | <p>Thank you for your comment.</p> <p>We will review this standard of care as part of report development.</p>                                    |
| <b>References</b>  | <p><b>Effectiveness, Safety, and Cost-Effectiveness of Metabolic and Bariatric Surgery</b></p> <p>Metabolic and bariatric surgery is already widely covered by Medicare, TRICARE, the Federal Employees Health Benefits program, and nearly every State Medicaid and State employee plan. In addition, studies show MBS is as safe or safer than some of the most commonly performed operations in America including gallbladder surgery, appendectomy and knee replacement. We are pleased that Washington State can be counted among these states that recognize the benefits associated with metabolic and bariatric surgery for their state employees and Medicaid recipients.</p> <p>Finally, to assist the Washington State HCA, we have attached a spreadsheet of the latest studies that evaluate the clinical significance and cost effectiveness of metabolic and bariatric surgery.</p> <p>Again, we appreciate the opportunity to provide these comments and ASMBS looks forward to working with the Washington State HCA during its clinical review process surrounding coverage of MBS.</p>   | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review protocol as part of report development.</p> |
| <b>References</b>  | <ul style="list-style-type: none"> <li>• Lauren. Estimated Cost-effectiveness of Medical Therapy, Sleeve Gastrectomy, and Gastric Bypass in Patients With Severe Obesity and Type 2 Diabetes.. JAMA Network Open. 5(2):e2148317, 2022 02 01.</li> <li>• Chaturvedi . The Long-term Value of Bariatric Surgery Interventions for American Adults With Type 2 Diabetes</li> </ul>   | <p>Thank for providing these references.</p> <p>We will check these for inclusion against our review</p>   |

| Comments  | Response                                       |
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| <p><b>Commenter:</b> Marina Kurian, MD FACS FASMBS, President, American Society for Metabolic and Bariatric Surgery</p>   |  |
| <p>Mellitus.. Ann Surg. 2022;10.1097/SLA.0000000000005517. doi:10.1097/SLA.0000000000005517</p> <ul style="list-style-type: none"> <li>• Noparatayaporn. Incremental Net Monetary Benefit of Bariatric Surgery: Systematic Review and Meta-Analysis of Cost-Effectiveness Evidences. [Review]. Obesity Surgery. 31(7):3279-3290, 2021 07.</li> <li>• Rajbhandari-Thapa. In-patient obesity diagnosis, use of surgical treatment and associated costs by payer type in the United States: Analysis of the National Inpatient Sample, 2011 through 2014.. Clinical Obesity. 10(5):e12385, 2020 Oct.</li> <li>• Xia. Health state utilities for economic evaluation of bariatric surgery: A comprehensive systematic review and meta-analysis.. Obesity Reviews. 21(8):e13028, 2020 08.</li> <li>• Hoerger. Economics and Policy in Bariatric Surgery. [Review]. Current Diabetes Reports. 19(6):29, 2019 04 29.</li> <li>• Krishna. Weight Loss Surgery Reduces Healthcare Resource Utilization and All-Cause Inpatient Mortality in Morbid Obesity: a Propensity-Matched Analysis.. Obesity Surgery. 28(10):3213-3220, 2018 10.</li> <li>• Palli. Bariatric Surgery Coverage: a Comprehensive Budget Impact Analysis from a Payer Perspective.. Obesity Surgery. 28(6):1711-1723, 2018 06.</li> <li>• Alsumali. Systematic assessment of decision analytic models for the cost-effectiveness of bariatric surgery for morbid obesity.. Surgery for Obesity &amp; Related Diseases. 14(7):1041-1059, 2018 07.</li> <li>• Alsumali. Cost-Effectiveness Analysis of Bariatric Surgery for Morbid Obesity.. Obesity Surgery. 28(8):2203-2214, 2018 08.</li> <li>• Cohen. What is the impact on the healthcare system if access to bariatric surgery is delayed?. [Review]. Surgery for Obesity &amp; Related Diseases. 13(9):1619-1627, 2017 Sep.</li> <li>• Klebanoff. Cost-effectiveness of Bariatric Surgery in Adolescents With Obesity.. JAMA Surgery. 152(2):136-141, 2017 02 01.</li> <li>• Sinha. Are we operating too late? Mortality Analysis and Stochastic Simulation of Costs Associated with Bariatric Surgery: Reconsidering the BMI Threshold.. Obesity Surgery. 26(1):219-28, 2016 Jan.</li> <li>• Warren. Cost-effectiveness of Bariatric Surgery: Increasing the Economic Viability of the Most Effective Treatment for Type II Diabetes Mellitus.. American Surgeon. 81(8):807-11, 2015 Aug.</li> <li>• Lewis. Comparing Medical Costs and Use After Laparoscopic Adjustable Gastric Banding and Roux-en-Y Gastric Bypass.. JAMA Surgery. 150(8):787-94, 2015 Aug.</li> <li>• Broderick. Increasing the Value of Healthcare: Improving Mortality While Reducing Cost in Bariatric Surgery.. Obesity Surgery. 25(12):2231-8, 2015 Dec.</li> </ul> | <p>protocol as part of report development.</p> |

| Comments  |  | Response |
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| <p><b>Commenter:</b> Marina Kurian, MD FACS FASMBS, President, American Society for Metabolic and Bariatric Surgery</p> |  |          |
|   | <ul style="list-style-type: none"> <li>• Wang. Cost-effectiveness of bariatric surgical procedures for the treatment of severe obesity.. European Journal of Health Economics. 15(3):253-63, 2014 Apr.</li> <li>• Gesquiere. Medication cost is significantly reduced after Roux-en-Y gastric bypass in obese patients.. Obesity Surgery. 24(11):1896-903, 2014 Nov.</li> <li>• Neovius. Health care use during 20 years following bariatric surgery.. JAMA. 308(11):1132-41, 2012 Sep 19.</li> <li>• Hoerger. Cost-effectiveness of bariatric surgery for severely obese adults with diabetes.. Diabetes Care. 33(9):1933-9, 2010 Sep.</li> <li>• Makary. Medication utilization and annual health care costs in patients with type 2 diabetes mellitus before and after bariatric surgery.. Archives of Surgery. 145(8):726-31, 2010 Aug.</li> <li>• Campbell. Cost-effectiveness of laparoscopic gastric banding and bypass for morbid obesity.. American Journal of Managed Care. 16(7):e174-87, 2010 Jul 01.</li> <li>• Mullen. Longitudinal cost experience for gastric bypass patients.. Surgery for Obesity &amp; Related Diseases. 6(3):243-8, 2010 May-Jun.</li> <li>• Ikramuddin. Cost-effectiveness of Roux-en-Y gastric bypass in type 2 diabetes patients.. American Journal of Managed Care. 15(9):607-15, 2009 Sep.</li> <li>• Christou. Impact of obesity and bariatric surgery on survival.. World Journal of Surgery. 33(10):2022-7, 2009 Oct.</li> <li>• Cremieux. A study on the economic impact of bariatric surgery.. American Journal of Managed Care. 14(9):589-96, 2008 Sep.</li> <li>• Hawkins. Paid work increases and state benefit claims decrease after bariatric surgery.. Obesity Surgery. 17(4):434-7, 2007 Apr.</li> <li>• Snow. The effect of Roux-en-Y gastric bypass on prescription drug costs.. Obesity Surgery. 14(8):1031-5, 2004 Sep.</li> <li>• Craig. Cost-effectiveness of gastric bypass for severe obesity.. American Journal of Medicine. 113(6):491-8, 2002 Oct 15.</li> </ul> |          |

| Comments   |   | Response   |
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| <p><b>Commenter:</b> Joseph Nadglowski, Jr., OAC President and CEO</p> |   |  |
| <p><b>General comments:</b></p>  |   |  |
|  | <p>Dear Members of the Washington State Health Care Authority:</p> <p>On behalf of the Obesity Action Coalition (OAC), I am pleased to provide the attached comments in response to the October 18, 2023, notice regarding proposed topics for review by the Washington State Health Care Authority’s (HCA) Health Technology Assessment (HTA) program. The OAC’s comments will focus on metabolic and bariatric surgery (MBS) for those affected by obesity.</p> | <p>Thank you for your comments.</p> <p>Please see detailed responses to specific points below.</p> |

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| <b>Commenter:</b> Joseph Nadglowski, Jr., OAC President and CEO |   |  |
| <b>Specific comments:</b>                                       |   |  |
| <b>Background and Context</b>                                   | <p>RE: WA State HCA’s HTA Review of Metabolic and Bariatric Surgery</p> <p>Dear Members of the Washington State Health Care Authority:</p> <p>On behalf of the Obesity Action Coalition (OAC), I am pleased to provide comments in response to the October 18, 2023, notice regarding proposed topics for review by the Washington State Health Care Authority’s (HCA) Health Technology Assessment (HTA) program. The OAC’s comments will focus on metabolic and bariatric surgery (MBS) for those affected by obesity. The HCA selected MBS coverage for rereview to evaluate the effectiveness, safety, and cost-effectiveness of bariatric surgery in adults and children who are affected by overweight or obesity. The evidence review will help inform Washington’s independent Health Technology Clinical Committee as it determines coverage regarding the use of bariatric surgery in adults and children.</p> <p>The OAC is the leading national non-profit dedicated to serving people living with obesity through awareness, support, education, and advocacy. Our vision is to create a society where all individuals are treated with respect and without discrimination or bias regardless of their size or weight. We strive for those affected by the disease of obesity to have the right to access safe and effective treatment options. And we educate all individuals to understand that when it comes to health, weight matters. OAC has a strong and growing membership of over 80,000 individuals living with obesity, across the United States and more than 1,425 members in Washington State.</p> | <p>Thank you for your comment.</p>   |
| <b>Guidelines and Standards</b>                                 | <p><b>Metabolic and Bariatric Surgery is Safe &amp; Widely Covered</b></p> <p>MBS is already widely covered by Medicare, TRICARE, the Federal Employees Health Benefits program, and nearly every State Medicaid and State employee plan. In addition, studies show MBS is as safe or safer than some of the most commonly performed operations in America including gallbladder surgery, appendectomy and knee replacement. We are pleased that Washington State can be counted among these states that recognize the benefits associated with metabolic and bariatric surgery for their state employees and Medicaid recipients.</p> <p>MBS coverage is expanding everyday given the evolving science behind new populations for whom surgical intervention could be beneficial. OAC is pleased that the Washington State HCA has included these new guidelines as part of its consideration of expanding MBS coverage to these new critical populations.</p> <p>For example, the American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) issued new Guidelines on Indications for Metabolic and Bariatric Surgery in 2022. The new ASMBS/IFSO guidelines are meant to replace a consensus</p>  | <p>Thank you for your comment.</p> <p>We will review these guidelines as part of report development.</p> |

| Comments  | Response  |   |
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| <b>Commenter:</b> Joseph Nadglowski, Jr., OAC President and CEO |   |   |
|   | <p>statement developed by the National Institutes of Health more than 30 years ago that set standards most insurers and doctors still rely upon to make decisions about who should get weight-loss surgery, what kind they should get, and when they should get it.</p> <p>The ASMBS/IFSO Guidelines now recommend metabolic and bariatric surgery for individuals with a BMI of 35 or more “regardless of presence, absence, or severity of obesity-related conditions” and that it be considered for people with a BMI 30-34.9 and metabolic disease and in “appropriately selected children and adolescents.” But even without metabolic disease, the guidelines say weight-loss surgery should be considered starting at BMI 30 for people who do not achieve substantial or durable weight loss or obesity disease-related improvement using nonsurgical methods.</p> <p>The ASMBS/IFSO Guidelines are just the latest in a series of new recommendations from medical groups calling for expanded use of metabolic surgery. In 2016, 45 professional societies, including the American Diabetes Association (ADA), issued a joint statement that metabolic surgery should be considered for patients with type 2 diabetes and a BMI 30.0–34.9 if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. This recommendation is also included in the ADA’s “Standards of Medical Care in Diabetes – 2022.”</p> |   |
| <b>Guidelines and Standards</b>                                 | <p><b>MBSAQIP Standards Improve Quality &amp; Culture of Care</b></p> <p>The American College of Surgeons (ACS) and the ASMBS together created a national standard for bariatric surgery accreditation programs in 2012 called the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). This program accredits inpatient and outpatient bariatric surgery centers in the U.S. and Canada that have undergone an independent, voluntary, and rigorous peer evaluation in accordance with nationally recognized bariatric surgical standards. Being an accredited center means you are held to the highest bariatric surgical standards and have quality improvement initiatives in place. Accredited centers are required to report their treatment outcomes and participate in regular evaluations of their surgical programs, ensuring they are meeting safety requirements, consistently improving processes, applying multidisciplinary approaches, and implementing standards of care defined by MBSAQIP. MBSAQIP accreditation goes beyond reporting, to culture, as well. An accredited center must strive for excellence in fostering patient-centered culture. When it comes to bariatric surgery, it is incredibly important that patients feel comfort and respect in and out of the operating room.</p>  | <p>Thank you for your comment.</p> <p>We will review this standard of care as part of report development.</p> |



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| <b>Commenter:</b> Joseph Nadglowski, Jr., OAC President and CEO |   |  |
| <b>Language</b>   | <p><b>Weight Bias &amp; Discrimination</b></p> <p>Weight-based bias and discrimination are widely prevalent toward people living with obesity. It can be shown in many ways, but one of the most popular was it is shown is through the absence of people-first language. Labeling people as “obese” creates negative feelings toward individuals with obesity and perpetuates weight bias. Using terminology such as, “a person living with obesity” or “people living with obesity” are recommended to authors, editors, and scientific writers. OAC is happy to provide resources to support authors. We kindly request that the Washington State HCA uses people-first language in writing reports and statements.</p> <p>Again, we appreciate the opportunity to provide these comments and we look forward to working with the Washington State HCA during its clinical review process surrounding coverage of MBS.</p> | <p>Thank you for your comment.</p> <p>We will work with our editorial team to ensure we use people-first language in the final report.</p> |