

**Health Technology Clinical Committee
Draft Findings and Decision**

Topic: Bariatric Surgery

Meeting Date: May 15, 2015

Final Adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterial

Number and Coverage Topic:

20150515B – Bariatric Surgery

HTCC Coverage Determination:

Bariatric Surgery for patients aged 18 and older is a **covered benefit with conditions**.

HTCC Reimbursement Determination:

Limitations of Coverage

For patients age \geq 18 years of age bariatric surgery is covered for the following conditions:

- Body Mass Index (BMI) \geq 40.
- BMI 35 to $<$ 40 for those patients with at least one obesity-related co-morbidity.
- BMI 30 to $<$ 35 with Type II Diabetes Mellitus.
- When covered, patients must abide by all other agency surgery program criteria (e.g., specified centers or practitioners; pre-operative psychological evaluation; participating in pre- and post-operative multidisciplinary care programs).

Non-Covered Indicators

- BMI 30 to $<$ 35 without Type II Diabetes Mellitus
- BMI $<$ 30
- Patients $<$ 18 years of age

Agency Contact Information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

HTCC Coverage Vote and Formal Action

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on Bariatric Surgery demonstrates that there is sufficient evidence to cover. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Bariatric Surgery.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Bariatric Surgery	0	10	0

Discussion

The Chair called for discussion of conditions of coverage for Bariatric Surgery following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

Limitations

Patients ≥ 18 years of age:

1. **Cover** for BMI of ≥ 40
2. **Cover** for BMI of 35 to < 40 for those patients with at least one obesity related co-morbidity
3. **Covered** for BMI 30 to < 35 with Type II Diabetes Mellitus
4. **Non-Covered** for BMI 30 to < 35 w/o Type II Diabetes Mellitus
5. **Non-Covered** for BMI < 30.
6. **Non-Covered:** Patients under 18 years of age.
7. When covered, patients must abide by all other agency surgery program criteria (e.g., specified centers or practitioners; pre-op psychological evaluation; participating in pre- and post-operative multidisciplinary care programs).

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is an NCD for bariatric surgery; the committee’s decision includes coverage beyond the conditions included in the NCD, based on more recent evidence and interpretation of that evidence.

The committee discussed clinical guidelines and training standards identified for bariatric surgery. These included:

- American Heart Association/ American College of Cardiology/ The Obesity Society
- American Association of Clinical Endocrinologist/ The Obesity Society/ American Society for Metabolic and Bariatric Surgery
- U.W. Department of Veteran’s Affairs/ Department of Defense
- Original NIH-based Criteria

Draft

National Heart, Lung, and Blood Institute
Guidelines for Pediatric Surgery
Endocrine Society
National Institute for health and Care Excellence, UK
Canadian Medical Association

The Chair noted consistency with the guidelines with differences due to interpretation of the evidence.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Bariatric Surgery reflective of the majority vote for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Bariatric Surgery

Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Bariatric Surgery**.

Timeline

Phase	Date	Public Comment Days
Technology Recommendations published	February 28, 2014	
Public comments	February 28 – March 20, 2014	21
Selected Technologies published	April 4, 2014	
Public comments	April 4 – May 5, 2014	31
Draft Key Questions published	October 8, 2014	
Public comments	October 8 – 22, 2014	14
Final Key Questions published	November 7, 2014	
Draft Report published	February 9, 2015	
Public comments	February 9 – March 13, 2015	33
Final Report published	April 12, 2015	
Public Meeting	May 15, 2015	
Draft Findings & Decision published	June 3, 2015	
Public comments	June 3 – 17, 2015	14

Overview

Category	Comment Period <i>June 3 – 17, 2015</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	1	1
Professional society & advocacy organization	0	0
Total	1	1

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. John deCsepel, MD, FACS Vice President of Global Medical Affairs Chief Medical Officer, Surgical Innovations	Medtronic	Yes
<input type="checkbox"/>	2.		
<input type="checkbox"/>	3.		
<input type="checkbox"/>	4.		
<input type="checkbox"/>	5.		



Medtronic
Minimally Invasive Therapies Group
555 Long Wharf Drive
New Haven, CT 06511
www.medtronic.com

June 11, 2015

Dorothy F. Teeter, MHA
Director
Washington State Health Care Authority
626 8th Avenue, SE
P.O. Box 42712
Olympia, WA 98504-2712

Submitted via Email: shtap@hca.wa.gov

Dear Ms. Teeter,

On behalf of Medtronic's Minimally Invasive Therapies Group (MITG) we appreciate the opportunity to submit a comment on the Washington State Health Care Authority Health Technology Assessment and draft decision regarding coverage for bariatric surgery (number 200150515B).

Medtronic MITG (formerly Covidien) is a manufacturer of medical devices and medical supplies, and treatment of obesity, including bariatric surgery, is a key area of focus for our company. We agree with the Health Technology Clinical Committee's conclusion that upon a thorough review of the scientific evidence, public comment, and state agency utilization information, bariatric surgery should be a covered benefit for qualified patients.

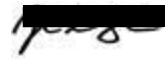
Although Washington ranks 32nd in state prevalence of obesity, obesity rates in the state are growing rapidly, rising from a 10% adult obesity rate in 1990 to 27.2% in 2013. Per the Washington State's Health Care Authority Health Technology Assessment Final Evidence Report, serious and costly co-morbid conditions are associated with obesity including Type 2 diabetes, coronary artery disease, hypertension, and sleep apnea which increase the risk of premature death. We agree that patients with a body mass index > 40, and patients with a body mass index between 35 and 40 with at least one obesity-related co-morbidity should be provided access to bariatric surgery. Numerous prospective randomized studies have demonstrated significant benefits of bariatric surgery on Type 2 diabetes resolution (Schauer et al, N Engl J Med 2014; Ikramuddin et al, JAMA 2013; Mingrone et al, N Engl J Med 2012). Therefore we were particularly pleased to see, and fully agree with, the HTCC's recommendation to cover bariatric surgery for individuals with a body mass index between 30 and 35 with T2D.

The economic burden of obesity is well documented (\$147 billion in the US in 2008, Finkelstein et al, Health Affairs, 2009). While bariatric surgery has been demonstrated to reduce healthcare spending largely due to resolution of co-morbidities, the time to full "return on investment" for the cost of the surgery has not been agreed upon. We were encouraged by the Institute for Clinical and Economic Review's (ICER) approach and conclusion regarding the economic benefit of bariatric surgery, which considers improved quality of life as a real and measurable benefit. We believe the demonstrated healthcare economic benefits associated with bariatric surgery will continue to improve over time with more surgeon experience and improvements in technology.

In conclusion we are pleased that, upon a thorough review by the HTCC including the comprehensive ICER technology assessment, the committee arrived at the decision to cover bariatric surgery for qualified patients. We believe this decision will have a substantial positive impact on many Washingtonians suffering with severe obesity and related life threatening conditions.

Thank you for the opportunity to submit comment on the draft decision. Please contact Michael Morseon (michael.p.morseon@medtronic.com, 716-662-2280) if you have questions or if you need additional information.

Sincerely,

A black rectangular redaction box covers the signature area. Below the box, the handwritten signature "John deCsepel" is visible in blue ink.

John deCsepel, MD, FACS
Vice President of Global Medical Affairs
Chief Medical Officer
Surgical Innovations
Medtronic
555 Long Wharf Drive
New Haven, CT 06511