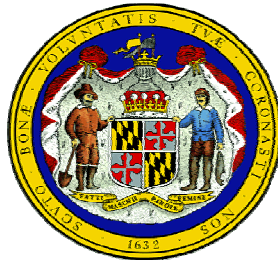
Required Under Senate Bill 333 (2005)
Health Insurance-Treatment of Morbid Obesity

Update on the Utilization Review of the Surgical Treatment of Morbid Obesity



December 2007

Marilyn Moon, Ph.D.
Chair

Rex W. Cowdry, M.D.
Executive Director

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Members and Affiliations of the 2004 Task Force

Cathy Carr-Dadin, R.N., Chair (Maryland Hospital Association)

Michelle Engelmann, Vice-Chair (Maryland WLS Legislative Action Committee)

Gregory Alexander, M.D. (Kaiser Permanente)

Les Chalmers, R.N. (CareFirst Blue Cross Blue Shield)

Vera Dvorak, M.D. (MAMSI)

Maureen Fama, APRN/PMH (Washington Adventist Hospital)

Richard Fornadel, M.D. (Aetna)

Sally Mae Pinkstaff, M.D. (LifeBridge Health/Sinai)

Michael Schweitzer, M.D. (Johns Hopkins University)

Mansur Shomali, M.D. (MedStar Health/Union Memorial)

Kuldeep Singh, M.D. (St. Agnes)

Ben Steffen (Maryland Health Care Commission)

David Von Rueden, M.D. (Greater Baltimore Medical Center)

Introduction

Chapter 486 of the 2004 Acts of the General Assembly clarified the mandate on the surgical treatment of morbid obesity and established a Task Force to Study Utilization Review of the Surgical Treatment of Morbid Obesity (Task Force). In December of 2004 that Task Force issued a report to the General Assembly that recommended a set of guidelines that are appropriate for utilization review of the surgical treatment of morbid obesity and reasonable procedures for documenting patient compliance with the guidelines or criteria. The General Assembly took action on the Task Force's recommendations in the 2005 session (Senate Bill 333). Chapter 568 of the Laws of 2005 reenacted and removed the abrogation date of the mandate and the Task Force was directed to:

1) Review the literature on the surgical treatment of morbid obesity;

2) Report on the number of complaints filed with the Administration relating to the denial of coverage for the surgical treatment of morbid obesity;
   (a) Identify the health insurance carrier that denied coverage and the reason given for the denial; and
   (b) Whether the Administration upheld or reversed the denial of coverage and the basis of the decision.

3) Recommend any additional guidelines or criteria that are appropriate for the utilization review of the surgical treatment of morbid obesity, and additional reasonable procedures for documenting patient compliance with the guidelines and criteria.

The Task Force must report its findings and recommendations in accordance with Section 2-1246 of the State Government Article, to the Senate Finance Committee, and the House Health and Government Operations Committee on or before December 1, 2007. The law required that the Maryland Health Care Commission and the Maryland Insurance Administration (MIA) provide staffing for the Task Force.

MHCC initially assessed whether the standard setting organizations, including the National Institutes of Health (NIH) and the American Society for Metabolic and Bariatric Surgery (ACBS) had developed new guidelines for surgical treatment of morbid obesity. MHCC also consulted with several individual Task Force members to determine if evolving standards of care for the treatment of morbid obesity since 2004 would affect the 2007 recommendations. Based on our own research and the comments of Task Force members, MHCC concluded that reconvening the Task Force was not warranted. MHCC has provided a report on the status of the 2004 recommendations and an examination of utilization, given the requirements in the law.

Background

In the United States, obesity has reached epidemic proportions in the last 25 years. Obesity prevalence doubled among adults aged 20 years and older, between 1980 and 2004.[1] The latest findings from the National Health and Nutrition Examination Survey revealed that more than one-third of U.S. adults were obese[2] in 2005-2006.[3] There has been no significant change in the prevalence since 2003-2004; obesity levels remain high.

Morbid obesity, also referred to as "clinically severe obesity" or "extreme obesity," is a condition that substantially increases risk of morbidity for a number of health conditions, including hypertension, coronary heart disease, type 2 diabetes, cancer, stroke, asthma, osteoarthritis, sleep apnea and respiratory problems.[4] Afflicting about five percent of adults in the U.S., morbid obesity is associated with increased risk of death.

In 2006, an estimated 1 million, or 25 percent, of Maryland adults were obese, and of these, 14 percent were morbidly obese.[5] Of particular concern is that the prevalence of obesity climbed from 20 percent in 2000 to 25 percent in 2006 and morbid obesity rates rose from 2 percent to 4 percent during the same period.

Bariatric surgery is currently the most effective treatment for morbid obesity that can provide significant and sustained weight loss and improvements in co-existing medical conditions. A recent meta-analysis[6] found that bariatric surgery has led to substantial reductions in excess weight and improvements in conditions such as type 2 diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea.[7] Bariatric surgery for morbid obesity is also associated with decreased overall mortality.[8,9] Two long-term studies recently published in the *New England Journal of Medicine* showed a significant survival benefit for severely obese patients who had undergone bariatric surgery[10,11] Bariatric

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[1] Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the Unite States, 1999-2004. JAMA. 2006 Apr 5;295(13):1549-55.
[2] See Appendix A for weight classifications by BMI.
[3] Ogden CL, Carroll MD, McDowell MA, Flegal KM. Obesity among adults in the United States—no change since 2003-2004. NCHS data brief no 1. Hyattsville, MD: National Center for Health Statistics, 2007.
[4] National Institutes of Health, National Heart, Lung, and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults, 1998; Sept. NIH publication No. 98-4083. Available from http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf.
[5] MHCC Analysis of Centers for Disease Control's Behavioral Risk Factor Surveillance System (BRFSS). Obesity prevalence estimates based on self-reported weight and height tend to be underestimates.
[6] The meta-analysis included 136 fully extracted studies for a total of 22,094 bariatric patients.
[7] Buchwald, H, Avidor, Y, Braunwald, E, Jensen, M, Pories, W, Fahrbach, K, Schoelles, K. A systematic review and meta-analysis," JAMA. 2004 Oct 13:292(14):1724-1728.
[8] Flum DR, Dellinger EP. Impact of gastric bypass operation on survival: a population-based analysis. J Am Coll Surg 2004;199:543-51.
[9] Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg 2004;240;416-23.
[10] Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. N Engl J Med 2007;357:753-61.
[11] Sjostrom L, Narbro K, Sjostrom CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med 2007;357:741-52.

patients had a 30 to 40 percent lower risk of death within seven to ten years of the surgery, compared with severely obese persons who did not have surgery.

In the face of a growing obesity epidemic, utilization of bariatric surgeries has surged in Maryland and nationally in recent years. The growing prevalence of obesity, the availability of effective surgical treatment, and the cost of the procedure triggered efforts on the part of insurance carriers to manage utilization. The creation of the Task Force in 2004 reflected the General Assembly's belief that developing standards on use would be to the benefit of patients, providers, and payers.

Utilization Review Criteria

The Task Force recommendations for the utilization review process of primary bariatric surgery for carriers and private review agents remain unchanged from 2004. The recommendations were derived from the National Institutes of Health guidelines, which remain the only nationally recognized guidelines for the treatment of overweight and obesity. No significant changes have been made to the NIH guidelines for surgical treatment of morbid obesity.

Implementation and Regulations

The 2004 Task Force recommended that the MIA adopt regulations governing the utilization review requirements for surgical treatment of morbid obesity. In 2006, the MIA adopted regulations that clarified the applicability of the National Institutes of Health's guidelines to the utilization review process for surgical treatment of morbid obesity (Code of Maryland Regulations 31.10.33[12]). The regulations also established acceptable documentation requirements for structured diet programs.

A review of the number of complaints filed with the MIA relating to the denial of coverage for the surgical treatment of morbid obesity revealed a declining trend from 2004 to 2006 (Table 1). During the six-month reporting period covering June 2004 through November 2004, the MIA received a total of thirty complaints, approximately five complaints a month. Complaints decreased to approximately three per month in 2005 and slightly over two per month in 2006.

The MIA upheld the carrier's denial of coverage in most cases. From June 2004 to November 2006, 31 out of 52 of the denials that were upheld (60 percent) involved individuals covered under the Comprehensive Standard Health Benefit Plan for small employers or the Maryland Health Insurance Plan, neither of which is subject to the mandated benefit for the surgical treatment of morbid obesity.[13] In 35 percent of the cases in which the MIA upheld denial of coverage during the entire period, the

[12] See Appendix B for specified regulations.

[13] In accordance with Insurance Article §15-1207(e)(1), exclusion of mandated benefits is allowed for the Comprehensive Standard Health Benefit Plan and the Limited Heath Benefit Plan. However, CSHBP and MHIP may cover bariatric surgery when deemed medically necessary.

complainant needed to exhaust the carrier's internal grievance process before filing a complaint with the MIA. A small fraction of denials upheld by the MIA involved cases in which the MIA determined the service was not medically necessary or a participating provider was available.

For complainants subject to the mandate of surgical treatment of morbid obesity, the most common reason for denials by the carrier was individuals not meeting the utilization review criteria. The MIA lacked jurisdiction over a number of these complaints to take action. From June 2004 to November 2006, the MIA did not have jurisdiction in 22 cases or 24 percent of all complaints. In these instances, denials from employer self-funded ERISA plans and certain Federal employee plans were not subject to state insurance regulations.[14]

Table 1: Complaints Filed with the Maryland Insurance Administration Relating to the Denial of Coverage for the Surgical Treatment of Morbid Obesity, Reporting Period 2004-2006

	REPORTING PERIOD				
	6/1/04-11/30/04	**1/1/05-11/30/05**	**12/1/05-11/30/06**	**ALL**	**PERCENT FOR ALL COMPLAINTS FILED**
NUMBER OF COMPLAINTS FILED	**30**	**35**	**27**	**92**	**100%**
OUTCOME					
Reversal	3	6	4	**13**	**14%**
Upheld Carrier	19	18	15	**52**	**57%**
CSHBP/MHIP	8	13	10	31	34%
Had not exhausted grievance process	9	4	5	18	20%
Participating provider available	2	-	-	2	2%
Service not medically necessary	-	1	-	1	1%
No jurisdiction	6	8	8	**22**	**24%**
Insufficient claim	2	3	-	**5**	**5%**

Source: Maryland Insurance Administration
Note: CSHBP stands for Comprehensive Standard Health Benefit Plan and MHIP stands for the Maryland Health Insurance Plan.

[14]Enacted in 1974, the Employee Retirement Income Security Act (ERISA) established certain federal requirements that preempt employer-sponsored health coverage from direct state regulation, but maintain states' role in regulating insurance. Thus, insured health plans are subject to state-mandated benefit laws; self-funded health plans are not. Federal Employees Health Benefits Program (FEHBP), although not self-funded, is also not subject to state-mandated benefits.

Bariatric Surgery Utilization

Total number of bariatric surgeries performed at Maryland hospitals more than quadrupled from 2001 to 2006 (Table 2). During this period, Maryland hospitals experienced growth in bariatric surgeries, regardless of source of payer. However, the number of bariatric surgeries for Medicare and Medicaid slightly declined in 2006. Private payers covered more than 85 percent of bariatric surgeries from 2001 to 2006.

Table 2: Frequency of Inpatient Bariatric Surgeries in Maryland Hospitals by Source of Payer, 2001-2006

SOURCE OF PAYER	2001	2002	2003	2004	2005	2006
ALL	**402**	**773**	**1213**	**1594**	**1881**	**1903**
Private	362	692	1035	1403	1630	1650
Medicare	23	44	69	66	89	77
Medicaid	7	15	20	25	48	46
Self-Pay	7	16	77	86	91	96
Other	3	6	12	14	23	34

Source: Maryland Hospital Discharge Data
Note: Count of bariatric surgeries with the following ICD-9-CM all-listed procedure codes 44.31, 44.38, 44.39, 44.68, 44.95, 44.96, 44.97, 44.98, 44.5, 44.5 with DRG 288, 44.99 with DRG 288
Exclusions: ICD-9-CM diagnostic codes 150.0-159.9 stomach and intestinal cancers, 230.1-230.9 in-situ cancers, and cases without any of the following ICD-9-CM obesity diagnosis codes: 278.01, 278.0, 278.00, V778

Between 2001 and 2006, the annual rate of growth in bariatric surgeries performed in Maryland hospitals declined (Table 3). A similar trend existed for bariatric surgeries covered by private payers. The slowing rate of growth can be attributed to several factors. First, as a medical intervention becomes more broadly available, the rate of growth slows even as the number of individuals receiving the intervention continues to increase. Second, treatment of the condition has begun to migrate to the outpatient setting. Laparoscopic adjustable gastric banding and other less invasive bariatric surgical procedures are increasingly being performed on low risk patients in outpatient settings. At the present time, measuring the growth of bariatric surgery in the outpatient setting is extremely difficult because of data reporting limitations.

Table 3: Annual Rate of Growth of Inpatient Bariatric Surgeries in Maryland Hospitals among the Privately Insured, 2001-2006

SOURCE OF PAYER	ANNUAL RATE OF GROWTH OF BARIATRIC SURGERIES				
	2001-2002	2002-2003	2003-2004	2004-2005	2005-2006
ALL	92%	57%	31%	18%	1%
Private	91%	50%	36%	16%	1%

Source: Maryland Hospital Discharge Data
Note: Count of bariatric surgeries with the following ICD-9-CM all-listed procedure codes 44.31, 44.38, 44.39, 44.68, 44.95, 44.96, 44.97, 44.98, 44.5, 44.5 with DRG 288, 44.99 with DRG 288
Exclusions: ICD-9-CM diagnostic codes 150.0-159.9 stomach and intestinal cancers, 230.1-230.9 in-situ cancers, and cases without any of the following ICD-9-CM obesity diagnosis codes: 278.01, 278.0, 278.00, V778

Among the privately insured, patients age 18-54 accounted for 87 percent of all surgeries in 2006, while near elderly (age 55-64) accounted for 13 percent (Table 4). Adolescents and the elderly accounted for the remaining 1 percent. Between 2001 and 2006, the share of bariatric surgeries shifted slightly toward older patients. The fastest growth in bariatric surgeries occurred among the near elderly, for whom the number of surgeries increased more than 9 times (data not shown).

The distribution of men and women undergoing bariatric surgery in Maryland hospitals was fairly static among the privately insured from 2001 to 2006 (data not shown), with women undergoing more bariatric surgeries than men. Women accounted for 83 percent of privately insured surgeries in 2006. Between 2001 and 2006, the numbers of bariatric surgeries increased over five times for women and over four times for men.

Table 4: Distribution of Bariatric Surgery Use among the Privately Insured by Age, 2001-2006

AGE	2001	2002	2003	2004	2005	2006
<18	0%	<0.5%	<0.5%	<0.5%	<0.5%	<0.5%
18-34	31%	29%	24%	26%	25%	25%
35-44	35%	32%	32%	31%	33%	33%
45-54	28%	27%	31%	31%	30%	29%
55-64	6%	11%	12%	12%	12%	13%
65+	0%	<0.5%	<0.5%	<0.5%	<0.5%	<0.5%

Source: Maryland Hospital Discharge Data
Note: Count of bariatric surgeries with the following ICD-9-CM all-listed procedure codes 44.31, 44.38, 44.39, 44.68, 44.95, 44.96, 44.97, 44.98, 44.5, 44.5 with DRG 288, 44.99 with DRG 288
Exclusions: ICD-9-CM diagnostic codes 150.0-159.9 stomach and intestinal cancers, 230.1-230.9 in-situ cancers, and cases without any of the following ICD-9-CM obesity diagnosis codes: 278.01, 278.0, 278.00, V778

Bariatric Surgery Centers of Excellence

Hospitals and surgical groups qualify for designation as a Bariatric Surgery Center of Excellence (BSCOE) by satisfactorily meeting standards set forth by the American Society for Metabolic and Bariatric Surgery. The selection criteria for the Centers for Excellence focus on the following areas:

- Pre- and post-surgical education for patients and follow-up care planning
- Ongoing quality management and improvement programs
- Appropriate equipment and facilities to manage the care of morbidly obese patients
- 24/7 access to the full range of medical specialties and services
- The experience, credentials, and number of bariatric surgeries performed by both the treating physician and the hospital
- Morbidity/mortality rates

In Maryland, there are currently six BSCOE at the following hospitals:

- Greater Baltimore Medical Center,
- Johns Hopkins Bayview Medical Center,
- Peninsula Regional Medical Center,
- St. Agnes Healthcare,
- Shady Grove Adventist Hospital, and
- Sinai Hospital of Baltimore.

In 2006, 72 percent of bariatric surgeries were performed at Maryland hospitals with a BSCOE designation.

Conclusion

This report concludes the work of the Task Force, but it does not end the state oversight of this service or the broader problem of obesity in Maryland. Since the Task Force released its recommendations in 2004, complaints regarding denial of coverage for the surgical treatment of morbid obesity have been infrequent and surgeries appear to occur when medically necessary. New MIA regulations clarified the utilization review process allowing for widespread access to bariatric surgery to appropriately selected candidates. As the process for utilization review of surgical treatment has been defined in Maryland law, further monitoring by the Task Force is not needed.

The certification of six Bariatric Surgery Centers of Excellence is an especially promising development. Centers now exist in central, southern, and eastern Maryland. Certification of a bariatric center in western Maryland would give residents in all areas of the state access to providers that use recognized standards of practice developed by the ASMBS, the largest and most recognized society of bariatric surgeons. Most payers are working to direct patients requiring surgery to those centers. As noted in this report, 72 percent of all inpatient surgeries were performed at Centers of Excellence in 2006.

Attacking the causes of obesity thereby reducing the demand for the procedure is as important as ensuring that there is an ample supply of qualified providers. Recently, private carriers and public agencies in Maryland have increased their efforts to reduce obesity in the state.

Appendix A

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI		
	Obesity Class	**BMI (kg/m^2)**
Underweight		<18.5
Normal		18.5-24.9
Overweight		25.0-29.9
Obesity	I	30.0-34.9
	II	35.0-39.9
Extreme Obesity	III	$\geq$40

Appendix B

MARYLAND INSURANCE ADMINISTRATION
HEALTH INSURANCE—GENERAL

Utilization Review of Surgical Treatment of Morbid Obesity
(COMAR 31.10.33)

Authority: Insurance Article, §§2-109(a)(1) and 15-893, Annotated Code of Maryland; Ch. 301, Acts of 2005

.01 Scope

This chapter establishes the manner in which carriers and private review agents acting on behalf of carriers may apply utilization review criteria and impose documentation requirements to the surgical treatment of the morbid obesity benefit mandated by Insurance Article, §15-839, Annotated Code of Maryland.

.02 Definitions

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Body mass index" has the meaning stated in Insurance Article, §15-839, Annotated Code of Maryland.

(2) "Carrier" means an insurer, a nonprofit health service plan, or a health maintenance organization.

(3) "Commissioner" means the Maryland Insurance Commissioner.

(4) "Health maintenance organization" has the meaning stated in Health-General Article, §19-701, Annotated Code of Maryland.

(5) "Insurer" has the meaning stated in Insurance Article, §1-101, Annotated Code of Maryland.

(6) "Member" means an individual who is covered by a contract that:

(a) Is issued or delivered by a carrier in the State; and

(b) Includes a benefit for the surgical treatment of morbid obesity.

(7) "Morbid obesity" has the meaning stated in Insurance Article, §15-839, Annotated Code of Maryland.

(8) "Nonprofit health service plan" means a person who has received a certificate of authority from the Commissioner to act as a nonprofit health service plan in the State.

(9) "Private review agent" has the meaning stated in Insurance Article, §15-10B-01, Annotated Code of Maryland.

(10) "Utilization review" has the meaning stated in Insurance Article, §15-10B-01, Annotated Code of Maryland.

.03 Utilization Review Criteria for Surgical Treatment of Morbid Obesity

A. When establishing utilization review criteria for the surgical treatment of morbid obesity as a covered benefit under Insurance Article, §15-839, Annotated Code of Maryland, a carrier or a private review agent acting on behalf of a carrier:

(1) Shall limit the criteria to the permissible criteria listed in §B of this regulation; and

(2) May not use any criteria that is more restrictive to the member than the criteria listed in §B of this regulation.

B. Permissible Criteria for Utilization Review Decisions.

(1) Body Mass Index.

(a) Except as permitted under §B(1)(b) of this regulation, a carrier or a private review agent acting on behalf of a carrier shall consider a member to meet the body mass index criterion if the member has a body mass index greater than 40 kilograms per meter squared.

(b) If the member has a comorbid medical condition, the carrier or private review agent acting on behalf of the carrier may not impose the criterion described in §B(1)(a) of this regulation, but shall consider the member to meet the body mass index criterion if the member has a body mass index equal to or greater than 35 kilograms per meter squared.

(c) In determining whether the member has a comorbid medical condition under §B(1)(b) of this regulation, the carrier or the private review agent acting on behalf of the carrier shall consider the member to have a comorbid condition if the member has one of the following conditions:

(i) Hypertension;
(ii) A cardiopulmonary condition;
(iii) Sleep apnea;
(iv) Diabetes; or
(v) Any life threatening or serious medical condition that is weight induced.

(2) The carrier or private review agent acting on behalf of the carrier may establish a utilization review criterion that limits the benefit for surgical treatment of morbid obesity to adults who are 18 years old or older.

(3) The carrier or private review agent acting on behalf of the carrier may establish a utilization review criterion that requires the member to complete a psychological examination of the member's readiness and

fitness for surgery and the necessary postoperative lifestyle changes before undergoing surgical treatment of morbid obesity.

(4) Completion of a Structured Diet Program.

(a) If a carrier or a private review agent acting on behalf of a carrier establishes a criterion that requires a member to complete a structured diet program, the carrier or private review agent acting on behalf of the carrier may not establish a criterion that is more restrictive than described in §B(4)(b) of this regulation.

(b) The carrier or the private review agent acting on behalf of the carrier shall consider the member to have completed a structured diet program, if the member completes either of the following in the 2-year period that immediately precedes the request for the surgical treatment of morbid obesity:

(i) One structured diet program for 6 consecutive months; or
(ii) Two structured diet programs for 3 consecutive months.

(c) A carrier or a private review agent acting on behalf of a carrier shall use flexibility with regard to defining a structured diet program.

(d) A carrier or a private review agent acting on behalf of a carrier shall consider commonly available diet programs, such as Weight Watchers or Jenny Craig, to be structured diet programs.

Effective date: April 10, 2006