



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of



DECISION

MPA/167836

PRELIMINARY RECITALS

Pursuant to a petition filed August 07, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on November 19, 2015, at Ladysmith, Wisconsin. Hearings scheduled for September 25, 2015, and October 12, 2015, were rescheduled at the petitioner's request. The record was left open for 14 days at the petitioner's request.

The issue for determination is whether the Office of Inspector General correctly denied the petitioner's request for a gastric bypass because she did not prove that she had a comorbid condition.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:



Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: [Redacted] M.D.
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Michael D. O'Brien
Division of Hearings and Appeals

FINDINGS OF FACT

- 1. The petitioner (CARES # [Redacted]) is a resident of Rusk County.

2. The petitioner with the Marshfield Clinic requested a Lap Sleeve Gastrectomy on June 9, 2015, at a cost of \$8,059. The Office of Inspector General denied her request on June 24, 2015.
3. The petitioner is 5'3" tall and weighs 255 pounds. Her body mass index is 45.2. http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html.
4. The petitioner has not established that she has sleep apnea, poorly controlled Diabetes Mellitus while compliant with appropriate medication regimen, poorly controlled hypertension while compliant with appropriate medication regimen, or obesity-related cardiomyopathy

DISCUSSION

The petitioner seeks approval of gastric bypass surgery to overcome morbid obesity. The department's approval process for this procedure is an attempt to harmonize a mishmash of logically inconsistent directives found in Wisconsin's statutes and administrative code. Wisconsin statutes specifically bar payment for a gastric bypasses or similar weight-reduction surgery "unless it is performed because of a medical emergency." Wis. Stat. § 49.46(2)(f). Emergency services are those "necessary to prevent the death or serious impairment of the health of the individual." Wis. Admin. Code, § DHS 101.03(52). Surgery that normally requires prior authorization can be reimbursed even if the request for authorization is denied or it is not obtained before receiving the service "in emergency circumstances." Wis. Admin. Code, § DHS 107.03(9). From this, one might assume that because gastric bypass surgery may only occur if there is an emergency, and prior authorization is unnecessary if an emergency exists, there is no need for prior authorization for gastric bypass surgery. But this assumption would be wrong. The department requires prior authorization for "[a]ll...surgical...services aimed specifically at weight control or reduction." Wis. Admin. Code, § DHS 107.06(2)(b).

The department has tried several times over the last decade and a half to make sense of these conflicting directives. Before 2001, it followed these various laws and regulations down the logical abyss and issued guidelines and interpretations of those guidelines that made approval of the procedure nearly impossible. Reading the law literally, it argued in its letters to the Division of Hearings and Appeals supporting its denials that the medical emergency requirement meant that the person's weight had to pose an immediate threat to her life. It further argued that if this threat did occur, prior authorization was unnecessary, which created a procedure that required prior authorization but that could only be approved without prior authorization.

In 2001, the *Prior Authorization Guidelines Manual*, § 117.014.02, changed the approval criteria to the following more attainable requirements:

- 1) The patient must have acceptable operative risks and be able to participate in treatment and long-term follow-up; *and*
- 2)
 - (a) The BMI [body mass index] is 40 or greater; *or*
 - (b) The BMI is between 35 and 39 with high-risk, co-morbid medical conditions clinically judged to be life-threatening, such as documented sleep apnea, Pickwickian syndrome, obesity-related cardiomyopathy, severe diabetes mellitus.

[emphasis in original]

These regulations allowed many recipients who had not attempted to lose weight through more conventional means to receive the surgery. Because conventional means of losing weight are cheaper than surgery, this guideline was at least somewhat inconsistent with administrative code requirements that the division consider the cost of the service and the "extent to which less expensive alternative services are

available,” as well as whether it is “cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient.” Wis. Admin. Code §§ DHS 107.02(3)(e) and 101.03(96m)(b)8. New guidelines issued on July 8, 2005, addressed these problems. Those guidelines were revised once more in December 2005 to correct a typographical error and to require that those with a BMI of greater than 40 show a co-morbid medical condition that has not responded to appropriate treatment and threatens the patient’s life. Those approval criteria stated:

A.

1. The BMI is 40 or greater, and there is at least one (or more) diagnosed comorbid medical condition(s) that has not responded to appropriate treatment and threatens the patient’s life or
2. The BMI is between 35 and 39 with documented high-risk co-morbid medical conditions that have not responded to medical management and are a threat to life, such as but not limited to: clinically significant obstructive sleep apnea, Pickwickian syndrome, obesity-related cardiomyopathy, coronary heart disease, or medically refractory hypertension.

and

- B. The candidate has attempted weight loss in the past without successful long-term weight reduction. These attempts may include, but are not limited to diet restrictions/supplements, behavior modification, physician supervised plans, physical activity program, commercial or professional programs, pharmacological therapy, etc.

and

- C. All candidates should have clinically documented evidence of a minimum of six months of demonstrated adherence to a physician-supervised weight management program including at least three consecutive months of participation in a weight management program prior to the date of surgery in order to improve surgical outcomes, reduce the potential for surgical complications and establish the candidate’s ability to comply with post-operative medical care and dietary restrictions. A physician’s summary letter is not sufficient documentation. Documentation should include assessment of the patient’s participation and progress throughout the course of the program. The patient must also agree to attend a medically supervised post-operative weight management program for a minimum of six months post surgery for the purpose of ongoing dietary, physical activity, behavioral/psychological, and medical education and monitoring.

and

- D. The candidate should receive a pre-operative evaluation by an experienced and knowledgeable multidisciplinary bariatric treatment team composed of health care providers with medical, nutritional and psychological experience. This evaluation should include at a minimum:
1. a complete history and physical examination, specifically evaluating for obesity-related comorbidities that would require preoperative management.
 2. evaluation for any correctable endocrinopathy that might contribute to obesity
 3. psychological/psychiatric evaluation and clearance to determine the stability of the patient in terms of tolerating the operative procedure and post-operative sequelae, as well as the likelihood of the patient participating in an ongoing weight management program following surgery
 4. dietary assessment and counseling

and

- E. The recipient must be 18 years of age or older and have completed growth.

Prior Authorization Guidelines Manual, § 117.014.03 and .04. [emphasis in original]

The Department still was not satisfied with the regulation, and in February 2008 it amended the criteria, this time primarily to clarify the conditions that qualify as comorbid and to set up a new approval category for those with a body mass index of at least 50.

Those approval criteria stated:

The recipient must meet Criteria A or B or C. If any of these are met the recipient must then also meet the requirements in D and E and F and G.

- A. The BMI is over 40kg/m² **and** there is clinical documentation that a continued morbidly obese status will lead to serious impairment of the patient's health because of comorbid conditions that cannot be optimally corrected with current therapy or demonstrated and documented trial of a minimum of three months.

Such comorbid conditions undergoing current appropriate therapy trial would include, but not be restricted to, congestive heart failure, recurrent venous thrombosis with [or] without pulmonary emboli, uncontrolled diabetes mellitus or demonstrated coronary artery disease with hemodynamically significant arteriolar occlusion leading to documented myocardial dysfunction.

or

- B. The BMI is between 35 and 39 with documented high-risk co-morbid medical conditions that have not responded to medical management and are a threat to life, such as but not limited to: clinically significant obstructive sleep apnea, Pickwickian syndrome, obesity-related cardiomyopathy, coronary heart disease, or medically refractory hypertension. [unchanged from previous regulation]

or

- C. The recipient must have a BMI ≤ 50 kg/m² for approval of procedure codes 43770 – 43774.

and

- D. All candidates should have clinically documented evidence of a minimum of six months of demonstrated adherence to a physician-supervised weight management program including at least three consecutive months of participation in a weight management program prior to the date of surgery in order to improve surgical outcomes, reduce the potential for surgical complications and establish the candidate's ability to comply with post-operative medical care and dietary restrictions. A physician's summary letter is not sufficient documentation. Documentation should include assessment of the patient's participation and progress throughout the course of the program. The patient must also agree to attend a medically supervised post-operative weight management program for a minimum of six months post surgery for the purpose of ongoing dietary, physical activity, behavioral/psychological, and medical education and monitoring. [unchanged from previous regulation]

and

- E. The candidate should receive a pre-operative evaluation by an experienced and knowledgeable multidisciplinary bariatric treatment team composed of health care providers with medical, nutritional and psychological experience. This evaluation should include at a minimum:
1. a complete history and physical examination, specifically evaluating for obesity-related comorbidities that would require preoperative management.
 2. evaluation for any correctable endocrinopathy that might contribute to obesity
 3. psychological/psychiatric evaluation and clearance to determine the stability of the patient in terms of tolerating the operative procedure and post-operative sequelae, as well as the likelihood of the patient participating in an ongoing weight management program following surgery
 4. patients receiving active treatment for a psychiatric disorder must receive evaluation by their treatment provider prior to bariatric surgery, and be cleared for bariatric surgery.
 5. dietary assessment and counseling

and

- F. The recipient must be 18 years of age or older and have completed growth.
 G. The bariatric center requesting the prior authorization must be approved by CMS/ASBS guidelines as a Center of Excellence.

[emphasis in original]

In August 2011, responding to new research, the Department issued a major revision of the guidelines. The latest guidelines reduce the level of obesity required for approval but no longer allow those with a body-mass index of at least 50 to receive the surgery without demonstrating a comorbid condition.

The latest approval criteria, which are found in *ForwardHealth Update No. 2011-44*. (August 2011) and went into effect on September 1, 2011, state in their entirety:

The approval criteria for prior authorization (PA) requests for covered bariatric surgery procedures include *all* of the following:

- ✓ The member has a body mass index greater than 35 with at least one documented high-risk, life-limiting comorbid medical conditions capable of producing a significant decrease in health status that are demonstrated to be unresponsive to appropriate treatment. There is evidence that significant weight loss can substantially improve the following comorbid conditions:
 - Sleep apnea.
 - Poorly controlled Diabetes Mellitus while compliant with appropriate medication regimen.
 - Poorly controlled hypertension while compliant with appropriate medication regimen.
 - Obesity-related cardiomyopathy.
- ✓ The member has been evaluated for adequacy of prior efforts to lose weight. If there have been no or inadequate prior dietary efforts, the member must undergo six months of medically supervised weight reduction program. This is separate from and not satisfied by the dietician counseling required as part of the evaluation for bariatric surgery.

- ✓ The member has been free of illicit drug use and alcohol abuse or dependence for the six months prior to surgery.
- ✓ The member has been obese for at least five years.
- ✓ The member has had medical evaluation from the member's primary care physician that assessed his or her preoperative condition and surgical risk and found the member to be an appropriate candidate.
- ✓ The member has received a preoperative evaluation by an experienced and knowledgeable multidisciplinary bariatric treatment team composed of health care providers with medical, nutritional, and psychological experience. This evaluation must include, at a minimum:
 - A complete history and physical examination, specifically evaluating for obesity-related comorbidities that would require preoperative management.
 - Evaluation for any correctable endocrinopathy that might contribute to obesity.
 - Psychological or psychiatric evaluation to determine appropriateness for surgery, including an evaluation of the stability of the member in terms of tolerating the operative procedure and postoperative sequelae, as well as the likelihood of the member participating in an ongoing weight management program following surgery.
 - For members receiving active treatment for a psychiatric disorder, an evaluation by his or her treatment provider prior to bariatric surgery. The treatment provider is required to clear the member for bariatric surgery.
 - At least three consecutive months of participation in a weight management program prior to the date of surgery, including dietary counseling, behavioral modification, and supervised exercise, in order to improve surgical outcomes, reduce the potential for surgical complications, and establish the candidate's ability to comply with post-operative medical care and dietary restrictions. A physician's summary letter is not sufficient documentation.
 - Agreement by the member to attend a medically supervised post-operative weight management program for a minimum of six months post surgery for the purpose of ongoing dietary, physical activity, behavioral/psychological, and medical education and monitoring.
- ✓ The member is 18 years of age or older and has completed growth.
- ✓ The member has not had bariatric surgery before or there is clear evidence of compliance with dietary modification and supervised exercise, including appropriate lifestyle changes, for at least two years.
- ✓ The bariatric center where the surgery will be performed has been approved by Centers for Medicare and Medicaid Services/American Society for Bariatric Surgery (ASBS) guidelines as a Center of Excellence and meet one of the following requirements:
 - The center has been certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center.
 - The facility has been certified by the ASBS as a Bariatric Surgery Center of Excellence.

The petitioner is 5'3" tall and weighs 255 pounds, giving her a body-mass index is 45.2kg/m^2 . The Office of Inspector General denied her request for bariatric surgery because she did not document a comorbid condition that would not respond to appropriate treatment. She has a number of problems related to her weight, the most serious of which is diabetes. The inspector general acknowledges that her diabetes was once uncontrolled but says recent evidence indicates this is no longer true. She disagrees. To resolve this question, the record was left open for 14 days so she could submit additional medical evidence. More than 14 days have passed, and she has not submitted any more evidence. She has the burden of proving by the preponderance of the credible evidence that the surgery is medically necessary. The only medical documentation I have now offers no proof that her diabetes remains uncontrolled. As a result, she has not

proved by the preponderance of the credible evidence that she has a comorbid condition. Without this proof, I must uphold the agency's denial of her surgery.

CONCLUSIONS OF LAW

The requested gastric bypass surgery is not medically necessary because the petitioner has not shown that it is cost-effective.

THEREFORE, it is **ORDERED**

The petitioner's appeal is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 4th day of December, 2015

\sMichael D. O'Brien
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator
Suite 201
5005 University Avenue
Madison, WI 53705-5400

Telephone: (608) 266-3096
FAX: (608) 264-9885
email: DHAmail@wisconsin.gov
Internet: <http://dha.state.wi.us>

The preceding decision was sent to the following parties on December 4, 2015.

Division of Health Care Access and Accountability