

---

# CMS Manual System

## Pub. 100-03 Medicare National Coverage Determinations

Transmittal 23

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Date: OCTOBER 1, 2004

---

CHANGE REQUEST 3502

### SUBJECT: Treatment of Obesity

**I. SUMMARY OF CHANGES:** Current language in Pub. 100-03, National Coverage Determinations Manual (NCDM) states “obesity itself cannot be considered an illness.” This language is being removed, and the remaining language revised, as the NCDM is intended to address the coverage of particular care and services rather than the definition of illness. The change in the manual language will not directly affect current Medicare coverage of obesity treatments. Services in connection with the treatment of obesity are covered services only when an integral and necessary part of a course of treatment for a medical condition. Treatment of obesity unrelated to such a medical condition remains non-covered.

(This revision to §40.5 of Pub. 100-03 is an NCD. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

**NEW/REVISED MATERIAL - EFFECTIVE DATE: October 1, 2004**

**\*IMPLEMENTATION DATE: October 1, 2004**

### II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/40.5/Treatment of Obesity (Effective October 1, 2004)

### \*III. FUNDING:

**These instructions shall be implemented within your current operating budget.**

### IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

**\*Medicare contractors only**



# Attachment - Business Requirements

Pub. 100-03	Transmittal: 23	Date: October 1, 2004	Change Request 3502
-------------	-----------------	-----------------------	---------------------

**SUBJECT: Treatment of Obesity**

## I. GENERAL INFORMATION

**A. Background:** Current language in Pub. 100-03, National Coverage Determinations Manual (NCDM) states “obesity itself cannot be considered an illness.” This language is being removed, and the remaining language revised, as the NCDM is intended to address the coverage of particular care and services rather than the definition of illness. The change in the manual language will not directly affect current Medicare coverage of obesity treatments. Services in connection with the treatment of obesity are covered services only when an integral and necessary part of a course of treatment for a medical condition. Treatment of obesity unrelated to such a medical condition remains non-covered.

**B. Policy:** The removal of the “illness” definition in the NCDM does not directly affect current Medicare coverage. Treatments for obesity alone remain noncovered, and treatments of diseases resulting in or exacerbated by obesity remain unchanged. However, removal of the language permits interested parties to submit NCD requests for anti-obesity interventions to CMS to determine if scientific and medical evidence demonstrate their effectiveness in improving Medicare beneficiaries’ health outcomes.

**C. Provider Education:** A Medlearn Matters provider education article related to this instruction will be available at [www.cms.hhs.gov/medlearn/matters](http://www.cms.hhs.gov/medlearn/matters) shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their website and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers				Other
		I	H	a	M	F	M	V	C	
			H	r	E	I	C	M	W	
			I	i	R	S	S	S	F	
				e	C					
				r						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3502.1	Providers shall note that the definition of obesity stating “obesity itself cannot be considered an illness” has been removed from §40.5 of the NCDM.									Providers
3502.2	Providers shall understand that the removal of the definition of obesity described in 3502.1 above does not change current Medicare coverage policy on obesity; i.e., treatments for obesity alone remain non-covered and treatments of diseases resulting in or exacerbated by obesity remain unchanged.									Providers
3502.3	Providers shall note that removal of the definition of obesity described in 3502.1 above allows interested parties to request that CMS review NCDs for anti-obesity interventions to determine if scientific and medical evidence demonstrate their effectiveness in improving Medicare beneficiaries’ health outcomes.									Providers

**III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS**

**A. Other Instructions: N/A**

X-Ref Requirement #	Instructions

**B. Design Considerations: N/A**

X-Ref Requirement #	Recommendation for Medicare System Requirements

**C. Interfaces: N/A**

**D. Contractor Financial Reporting /Workload Impact: N/A**

**E. Dependencies: N/A**

**F. Testing Considerations: N/A**

**IV. SCHEDULE, CONTACTS, AND FUNDING**

<b>Effective Date*:</b> October 1, 2004 <b>Implementation Date:</b> October 1, 2004 <b>Pre-Implementation Contact(s):</b> Kate Tillman, 410-786-9252, Pat Brocato-Simons, 410-786-0261 <b>Post-Implementation Contact(s):</b> Regional offices	<b>Medicare contractors shall implement these instructions within their current operating budgets.</b>
---	--

**\*Unless otherwise specified, the effective date is the date of service.**

## 40.5 - Treatment of Obesity

*(Rev.23, Issued: 10-01-04, Effective: 10-01-04, Implementation: 10-01-04)*

### A. General

*Obesity may be caused by medical conditions* such as hypothyroidism, Cushing's disease, and hypothalamic lesions, or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these *medical conditions*.

*However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined to be reasonable and necessary.*

*In addition*, supplemented fasting is a type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins, and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein.

### B. Nationally Covered Indications

*Services performed in connection with the treatment of obesity are covered by Medicare when such services are an integral and necessary part of a course of treatment for diseases such as hypothyroidism, Cushing's disease, hypothalamic lesions, cardiovascular diseases, respiratory diseases, diabetes, and hypertension.*

### C. Nationally Noncovered Indications

- 1. The treatment of obesity unrelated to such a medical condition (see section B. above) is not considered reasonable and necessary and is not covered under the Medicare program.*
- 2. Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).*

### D. Other

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient *is eligible for local coverage determination through individual contractor discretion*. The risks associated

**with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.**

*(This NCD last reviewed September 2004.)*

*See §§ 100.1, 100.8, 100.11*