The American Association of Clinical Endocrinologists and the American College of Endocrinology

2014 ADVANCED FRAMEWORK FOR A NEW DIAGNOSIS OF OBESITY AS A CHRONIC DISEASE

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Synopsis

- Obesity is a chronic disease

- Emergent Concept 1 (EC.1) from the AACE/ACE Consensus Conference on Obesity (CCO) calls for a new medically meaningful and actionable diagnosis of obesity

- An advanced framework for further discussion and translation of EC.1 is provided

    o The definition of obesity requires anthropometric and clinical descriptors

    o The diagnosis of obesity requires a process of screening, evaluation of complications (using checklist), staging, and algorithmic management

- This advanced framework will be distributed to CCO pillar participants for structured discussion and creation of a final document

The Purpose and Mandate for a New Diagnostic Approach to Obesity

The 2014 AACE/ACE Consensus Conference on Obesity was convened to establish an evidence base that could be used to develop a comprehensive plan to combat obesity. The Conference involved a wide array of national stakeholders (the "Pillars") with a vested interest in obesity, whose concerted participation would be necessary to support an effective overall action plan. A key consensus concept that emerged from the Conference was that a more medically meaningful and actionable definition of obesity was needed. It became clear that the diagnosis based solely on anthropometric measures (e.g., BMI) lacked information needed for concerted action among health care professionals, health care systems, regulators, payers, and employers. Furthermore, the elements for an improved diagnosis should include both the anthropometric criterion together with an indication of the degree to which the weight gain was negatively impacting the health of individual patients.

This document addresses this problem of diagnostic uncertainty, and is the first step in removing this impediment for concerted and comprehensive action. This advanced framework for a new diagnosis of obesity as a chronic disease translates the emergent concept from the AACE Consensus Conference on Obesity into an actionable recommendation. Because concerted action will be necessary, this framework will be submitted to our Pillar partners for comment and recommendations. We will explore with our partners new terminology to improve communication and implementation, and a new diagnostic algorithm that is mapped to evidence-based risk-stratified patient subsets and application of the AACE/ACE complications-centric obesity management algorithm. Upon approval by the AACE Board of Directors, this document will be distributed to the 2014 Consensus Conference on Obesity Pillar representatives with a structured questionnaire for comments. The goal will be to achieve consensus for a medically meaningful and actionable diagnosis of obesity that will support access to rationally delivered interventions for the prevention and treatment of obesity.
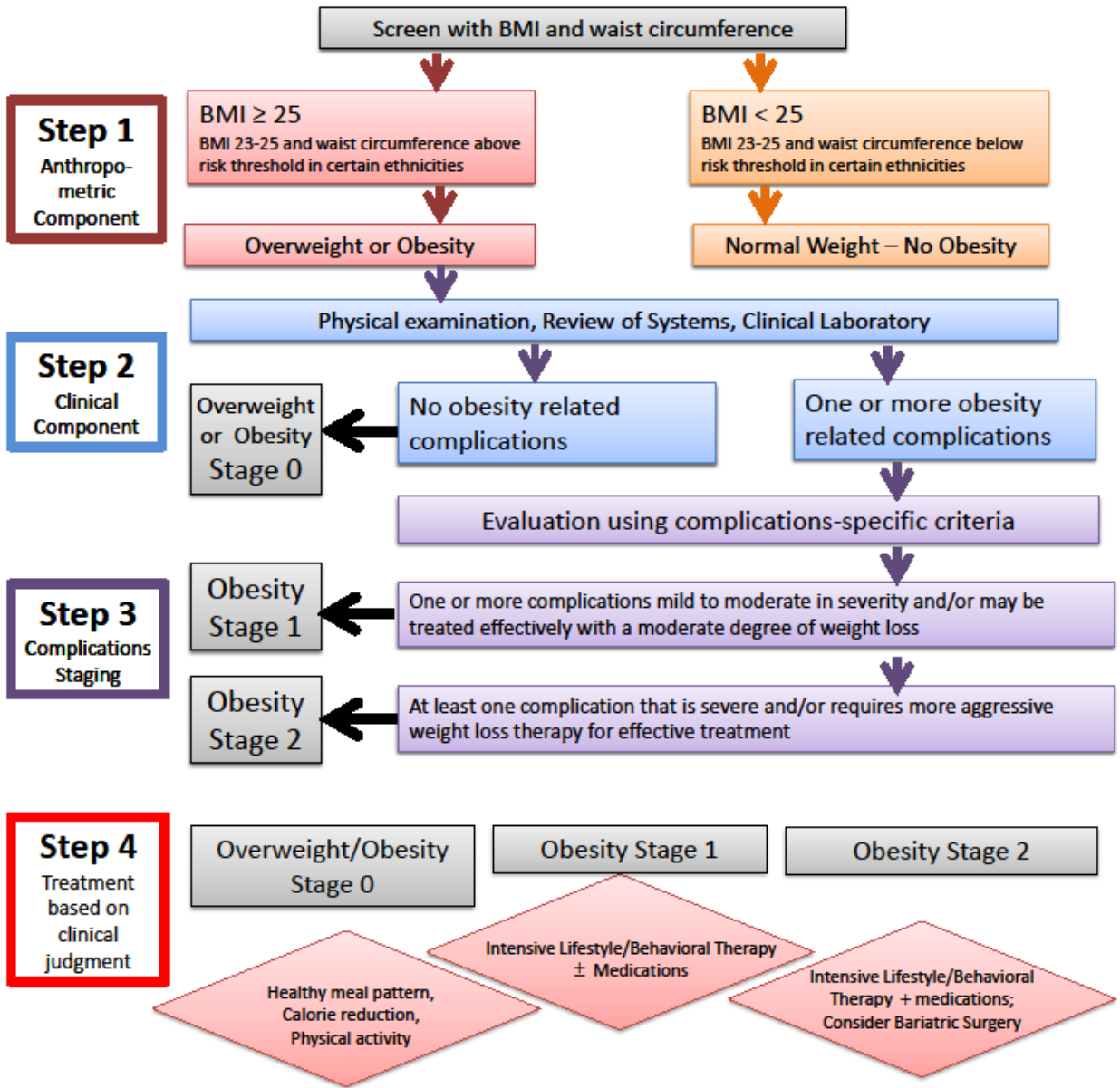
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The Diagnosis of Obesity

A new definition and diagnostic strategy for obesity is required that is actionable, medically-meaningful, and adds value to the health-promoting effects of weight loss. AACE/ACE defines obesity as a chronic disease characterized by pathophysiological processes that result in increased adipose tissue mass and which can result in increased morbidity and mortality. In an environment that interacts with susceptibility genes to promote weight gain (i.e., obesogenic), many individuals have a body mass index (BMI) ≥ 25 kg/m^2, which is associated with increased likelihood for obesity-related complications and risk of progressive obesity. The new obesity diagnostic algorithm incorporates two components: (i) an assessment of body mass including validated ethnicity-adjusted anthropometrics to identify individuals with increased adipose tissue placing them at risk; and (ii) the presence and severity of obesity-related complications. Thus, the complete diagnosis does not simply depend upon BMI level but also the impact of that weight gain on health. Individuals with BMI ≥ 25 kg/m^2 (or BMI 23-25 kg/m^2 with elevated waist circumference) then require evaluation for the presence and severity of specific obesity-related complications to complete the diagnostic process. Each complication is evaluated for severity and impact on the patient's health as Stage 0 (complication not present), Stage 1 (complication is mild-moderate), or Stage 2 (complication is severe) using complication-specific criteria. The staging of complications can be used to guide selection of treatment modality and intensity of weight loss therapy in the context of the AACE obesity management algorithm that is part of the AACE/ACE Comprehensive Diabetes Management Algorithm (1). Therefore, the diagnostic categories for Obesity are: Overweight (BMI 25-29.9) and Obesity Stage 0 (BMI ≥ 30); while these overweight and obese patients do not have complications, intervention may still be required to prevent progressive weight gain and the development of complications. Obesity Stage 1 is indicative of patients with BMI ≥ 25 and one or more complications that are mild-moderate in severity (but no severe complications). Obesity Stage 2 is indicative of patients with BMI ≥ 25 and one or more severe complications. The identification and staging of obesity-related complications is based on complication-specific criteria. In summary, a 4-step approach is recommended for all patients: (i) screening with BMI with adjustments for ethnic differences, (ii) clinical evaluation for the presence of obesity-related complications using a checklist, (iii) staging for the severity of complications using complication-specific criteria, and (iv) selection of prevention and/or intervention strategies targeting specific complications as guided

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by the AACE/ACE obesity management algorithm. These recommendations have been translated from concepts and evidence derived from the AACE/ACE Consensus Conference on Obesity on March 23-24, 2014 in Washington, DC (2).

DIAGNOSIS	Anthropometric Component	Clinical Component
Normal Weight	BMI < 25 kg/m^2 (BMI < 23 in certain ethnic groups)	
Overweight	BMI ≥ 25 – 29.9 kg/m^2 (BMI 23-25 and elevated waist circumference in certain ethnic groups)	No obesity-related complications
Obesity Stage 0	BMI ≥ 30 kg/m^2	No obesity-related complications
Obesity Stage 1	BMI ≥ 25 kg/m^2 (BMI 23-25 and elevated waist circumference in certain ethnic groups)	Presence of one or more obesity related complications that are Stage 1 in severity (mild to moderate)
Obesity Stage 2	BMI ≥ 25 kg/m^2 (BMI 23-25 and elevated waist circumference in certain ethnic groups)	Presence of at least one obesity related complication that is Stage 2 in severity (severe)

AACE/ACE Diagnostic Algorithm for the Disease of Obesity

Screen with BMI and waist circumference

Step 1
Anthropometric Component

BMI ≥ 25 BMI 23-25 and waist circumference above risk threshold in certain ethnicities	BMI < 25 BMI 23-25 and waist circumference below risk threshold in certain ethnicities
Overweight or Obesity	**Normal Weight – No Obesity**

Physical examination, Review of Systems, Clinical Laboratory

Step 2
Clinical Component

Overweight or Obesity Stage 0 ← No obesity related complications

One or more obesity related complications

Evaluation using complications-specific criteria

Step 3
Complications Staging

Obesity Stage 1 ← One or more complications mild to moderate in severity and/or may be treated effectively with a moderate degree of weight loss

Obesity Stage 2 ← At least one complication that is severe and/or requires more aggressive weight loss therapy for effective treatment

Step 4
Treatment based on clinical judgment

Overweight/Obesity Stage 0	Obesity Stage 1	Obesity Stage 2
Healthy meal pattern, Calorie reduction, Physical activity	Intensive Lifestyle/Behavioral Therapy ± Medications	Intensive Lifestyle/Behavioral Therapy + medications; Consider Bariatric Surgery

Rationale, Principles, and Development of the Diagnostic Approach

<u>The 2014 AACE/ACE Consensus Conference on Obesity.</u>

The 2014 AACE/ACE Consensus Conference on Obesity was predicated on a belief that concerted action among a diverse array of stakeholders is required for significant reduction in obesity prevalence growth rates. The Conference convened on March 23-24, 2014 in Washington, DC, and resulted in a portfolio of "affirmed concepts" (AC) representing the validation of previously held concepts and practices, and "emergent concepts" (EC) that became apparent only through the vigorous analyses and discussions emanating from the multidisciplinary cohort of attendees that included insights from health care professionals, government/regulatory entities, pharmaceutical industry, large employers, large payers, lay and professional organizations, educational organizations, and research sponsors (2). The principal finding, reflected in EC.1, was that the diagnostic definition of obesity needs to be improved. The justification for this is that conference participants, representing a broad base of stakeholders in the American healthcare system with a vested interest in the problem of obesity, identified the current definition as a major obstacle to concerted action. Despite the paradigm shift suggested by increased numbers of organizations recognizing obesity as a chronic disease, the diagnosis of obesity has not changed. The old diagnosis primarily relied on the anthropomorphic measure of BMI (3,4), with uncertainties regarding how an increase in BMI affects individual health. AACE/ACE has developed a new definition and diagnostic algorithm, which is actionable and medically meaningful, and represents a translation of the findings of the Consensus Conference on Obesity. The lack of a medically-meaningful strategy and poor translation of accumulating scientific data regarding the pathogenesis of obesity as a chronic disease have also limited the effectiveness of public health initiatives.

<u>Rationale and Underlying Principles.</u>

This new strategy is based upon current scientific evidence indicating that pathogenesis of obesity conforms to the chronic disease model; that is, a disease that arises from the interaction of susceptibility genes, environment, and behavior with overlapping or additional subsets of gene-environment interactions determining the severity of the disease, impact on health, and development of complications. The new strategy addresses these issues and specifically incorporates the following attributes of an obesity chronic disease model:

- Obesity as a chronic disease (5);

- Obesity results from the complex interaction of multiple biological factors (e.g., susceptibility genes), environmental factors (e.g., built environment), and behavior;

- High prevalence rates and an obesogenic environment place a majority of individuals in many societies at some level of risk; therefore, all individuals must be screened;

- Screening should include BMI, but not exclude other measures that more directly quantify adipose tissue mass, in a preventive care model, including adjustments for ethnic differences in risk thresholds and modifiers to account for epidemiological, behavioral, and physiological differences among individuals;

- The diagnosis of obesity prioritizes organ dysfunction resulting in discernible complications as a marker of disease and disease severity;

- A complication-centric approach to management will target increasingly aggressive therapeutic approaches to those patients with obesity-related complications who will most benefit from treatment, thus optimizing patient outcomes, benefit/risk ratio of intervention, and cost effectiveness (1,6);

- There is an emphasis on obesity-related complications that can be ameliorated by weight loss therapy;

- Screening, diagnosis, and staging are relevant to management options, as directed by the AACE/ACE Obesity Algorithm (1), which treats complications as the end point of weight loss therapy, not BMI.

Development of the diagnostic approach: Questions to be vetted by Pillar partners.

The new obesity diagnosis will require input from multiple stakeholders to assure broad-based acceptance and concerted action in a comprehensive plan to combat obesity. Therefore, our pillar participants will be asked for feedback. Some questions requiring vetting are included below.

a. **Alternative medical term other than 'obesity'.** The term obesity has been widely used in multiple contexts, and conveys a sense of stigmatization for patients. Do we need new terminology when approaching the prevention and treatment of this disease and its complications from a clinical perspective? Should consideration be given to re-naming the chronic disease state in a format that effectively reflects the concept of weight-driven disease, for example **"adiposity-based chronic disease (ABCD)"**; this concept is consistent with the use of alternative diagnostic labels for diseases identified by eponyms, popular references, or antiquated terminology ("obesity" derived from *obesitas, obdere,* or *ob + edere* all meaning "fatness" or "to overeat" and not reflecting a pathophysiology).

b. **Role of waist circumference measurement.** What is the optimal use of waist circumference. Should it be used as an essential criterion for the anthropometric component in all patients or in subgroups of patients, and what is its role in evaluating patients for risks of cardiometabolic conditions (e.g., prediabetic states, cardiovascular disease risk, etc).

c. **Incorporation of overweight and obesity designations.** What is the rationale for discriminating between patients with overweight (BMI 25-29.9) and obesity (BMI ≥ 30) in a medically meaningful diagnostic algorithm? Should patients who are overweight by BMI (i.e., BMI 25-29.9) never be referred to as patients with obesity even if they have complications (e.g., Obesity Stage 1 or Stage 2)? Isn't an overweight patient with a given complication just as deserving of weight loss therapy as an obese patient with the same complication, and, therefore, the distinction between overweight and obesity should not be retained? On the other hand, is this differentiation warranted because the prevalence of many obesity-related complications will increase as the BMI increases? Other thoughts?

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d. **Concept of 'pre-obesity'.** Is there any advantage to adopting a diagnosis of pre-obesity for overweight or obese patients without complications?

e. **Cost effectiveness.** The diagnostic approach should facilitate an economically viable model for obesity care. The process must not dilute resources needed for high-risk individuals requiring care and not expand aggressive interventions to lower-morbidity patient populations beyond the capacity of our healthcare system, while at the same time taking into account the 'value' of obesity care in enhancing quality of life and disease prevention.

f. **Elderly patients.** How should the diagnostic and treatment paradigm for obesity be modified for elderly patients (e.g., > 70 years of age)?

Screening, Diagnosis, Complications Staging, and Management of Obesity as a Disease

STEP 1.   SCREENING and THE ANTHROPOMETRIC COMPONENT OF DIAGNOSIS

1.1   All Americans must be screened using BMI.

1.2   BMI ≥ 25 kg/m^2 is one component of the diagnosis of obesity. Individuals with BMI ≥ 25 kg/m^2 meet the criterion for Overweight (BMI 25-29.9) or Obesity (BMI ≥ 30), and then must be assessed for the clinical component (see Step 2) to complete the diagnostic process. Patients with BMI ≥ 25 can have obesity-related complications treatable by weight loss therapy whether they are overweight or obese.

1.3   In certain ethnic groups (e.g., South Asians), individuals with BMI 23-25 kg/m^2 can still be diagnosed as Overweight on the basis of elevated waist circumference using population and ethnicity specific threshold values as delineated by the International Diabetes Federation (3,4,7,11).

1.4   If an individual is edematous, elderly with sarcopenic obesity, or highly muscular, then clinical judgment and/or DXA should be employed to identify individuals with high risk for obesity based on fat mass with attention to gender differences in body composition.

Ethnic Specific Values for Waist Circumference: International Diabetes Federation Consensus World Wide Definition of Metabolic Syndrome www.idf.org		
Population	Male	Female
United States	≥ 102 cm or 40 in	≥ 88 cm or 35 in
Europids (Caucasians)	≥ 94 cm or 37 in	≥ 80 cm or 31 in
South Asians, Chinese, Japanese	≥ 90 cm or 35 in	≥ 80 cm or 31 in
South and Central Americans	Use South Asian criteria until more specific data are available	
Sub-Saharan Africans, Eastern Mediterranean and Middle East (Arab)	Use Europid criteria until more specific data are available	

1.5   Individuals who meet the anthropometric criterion for the diagnosis of overweight or obesity would then be evaluated for obesity-related complications, i.e., the clinical criterion that constitutes the second component of the diagnostic algorithm. In this way, the anthropometric criterion is necessary but not sufficient for a complete diagnosis, which requires, in addition, the pathophysiological component as reflected in complications or risk of complications.

STEP 2.   THE CLINICAL COMPONENT OF DIAGNOSIS and OBESITY-RELATED COMPLICATIONS

2.1.   Individuals who meet the anthropometric criterion for overweight or obesity must then undergo evaluation for the presence or absence of obesity-related complications, the clinical criterion, to complete the diagnosis of obesity.

2.2.   Initial evaluation would include history, physical examination, review of systems, blood pressure, waist circumference, fasting glucose, fasting lipid panel (total cholesterol, LDL-c, HDL-c, triglycerides), electrolytes, creatinine, hepatic transaminases, in addition to assessment of diet, meal pattern preferences, and physical activity.

2.2.   Diagnostic evaluation includes a stepped evaluation protocol and checklist for the presence of obesity-related complications based on information from the initial evaluation, with an emphasis on those complications that can be ameliorated using weight loss therapy (Table 1).   The initial basic clinical evaluation is sufficient to determine whether many obesity related complications are present or absent. In many instances, further evaluation may be necessary in Step 3 to stage the severity of the complications.

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STEP 3.   DISEASE STAGING and COMPLICATIONS-CENTRIC APPROACH

3.1.   If any obesity-related complications are identified, individuals should undergo further evaluation to stage the severity of each complication.

3.2.   Staging is completed for each of the identified complications using complications-specific criteria (see Table 2 below) and staged as:
- Overweight and Obesity Stage 0 represent diagnoses for those patients who satisfy the anthropometric criterion, BMI 25-29.9 for Overweight and BMI ≥ 30 for Obesity, and who do not have obesity-related complications (Stage 0).
- Obesity Stage 1 represents the diagnosis of obesity for those patients who satisfy the anthropometric criterion (e.g., BMI ≥ 25 kg/m^2) and have one or more obesity related complications of mild-to-moderate severity (but none severe).
- Obesity Stage 2 represents the diagnosis of obesity for those patients who satisfy the anthropometric criterion (e.g., BMI ≥ 25 kg/m^2) and have one or more obesity related complications that are severe.
- For patients with Obesity Stage 1 and Obesity Stage 2, no distinction is made for patients with overweight or obesity based on BMI alone since excess weight in either case is adversely affecting health and all patients have one or more complications that can be treated by weight loss therapy.

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STEP 4. **TREATMENT: IMPLEMENT AACE/ACE OBESITY MANAGEMENT ALGORITHM IMMEDIATELY AFTER DIAGNOSIS AND COMPLICATION STAGING ARE COMPLETE (figure 1)**

4.1 Steps 1-3 diagnose obesity on the basis of both anthropometric criteria and clinical criteria that reflect the impact of weight gain on health as manifest by the presence and severity of obesity-related complications. The staging of complications in Step 3 helps guide treatment decisions in the context of the Obesity Treatment Algorithm shown in Figure 1, which is part of the AACE/ACE Comprehensive Diabetes Treatment Algorithm (1). Obesity management never precludes specific complication-related treatment outside of weight loss therapy when needed.

4.2 Overweight and Obesity Stage 0 are indicative of the absence of obesity-related complications. From the perspective of cardiometabolic disease, these patients have been referred to as the "healthy obese" (8,9), and, in this instance, biomechanical and other complications of obesity would similarly not be present. While therapy should be individualized and based on clinical decision-making, patients with Overweight/Obesity Stage 0 would generally be treated with lifestyle modification employing eating patterns that promote health (10), behavior modification, and increased physical activity primarily intended to prevent progressive weight gain and/or the emergence of complications in the future. More emphasis on weight reduction and hypocaloric diets may be warranted with BMI ≥ 30 or in patients with rapid increases in body weight.

4.3 Obesity Stage 1 is indicative of the presence of one or more obesity-related complications, each of which are mild-moderate in severity, based on complication-specific criteria. Effective treatment of these complications can generally be accomplished by moderate weight loss (e.g., 3-10% weight loss). While therapy should be individualized based on clinical judgment, in general, patients with Obesity Stage 1 would be effectively treated with intensive lifestyle/behavioral therapy or the combination of a lifestyle modification program that emphasizes caloric reduction in conjunction with a weight loss medication. Obesity Stage 1 includes both overweight and obese patients with one or more mild-moderate complications that can be ameliorated by weight loss. The emphasis, therefore, is on improving the patient's health and treating both weight and weight-related complications and not just weight or the BMI level per se.

4.4 Obesity Stage 2 is indicative of the presence of one or more obesity-related complications that are severe based on complications-specific criteria (see Table 3). Stage 2 complications generally have a more adverse impact on individual health, and/or require more aggressive obesity management with a greater degree of weight loss (e.g., ≥ 10% weight loss) in order to effectively or optimally treat the obesity-related complication. While therapy should be individualized and based on judgment, in general, patients with Obesity Stage 2 would effectively be treated with intensive lifestyle/behavioral therapy in conjunction with a weight loss medication or with bariatric surgery. Obesity Stage 2 includes both overweight and obese patients with one or more severe complications that can be ameliorated by weight loss. The emphasis, therefore, is on improving the patient's health and treating complications and not the BMI level per se.

4.5 Patients meeting the diagnosis for Obesity, whether Stage 0, 1, or 2, have a lifelong disease and will need ongoing follow-up and re-assessment for both anthropometric and clinical components of the diagnosis. For example, a current diagnosis of Obesity Stage 0 does not assure the perpetual absence of complications; these patients may convert to Stage 1 or Stage 2 in the future indicating the need for more aggressive weight loss

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therapy. Similarly patients with Overweight are at risk of future weight gain in our obesogenic environment, and require lifestyle modifications and ongoing follow-up.

Table 1.   Checklist of Obesity Related Complications.*

	Obesity Related Complication	Identification based on information available in initial evaluation	Possible secondary tested needed to confirm presence of complication, stage complication, or guide therapy
☑	Metabolic Syndrome	waist circumference, blood pressure, triglycerides, HDL cholesterol, fasting glucose (ATPIII criteria)	initial evaluation completes diagnosis; screen for cardiovascular disease
☑	Prediabetes	fasting glucose	Repeat fasting glucose completes diagnosis of impaired fasting glucose, but patient should be further evaluated with 2-hour oral glucose tolerance test to identify Prediabetes due to impaired glucose tolerance or Diabetes based on elevated 2-hour glucose value and/or with HbA1c; screen for cardiovascular disease
☑	Type 2 Diabetes Mellitus	fasting glucose	Overtly elevated or repeat fasting glucose completes diagnosis, but patients with moderate elevations in glycemia may require further evaluation with 2-hour oral glucose tolerance glucose value or HbA1c or both; screen for cardiovascular disease and microvascular complications
☑	Dyslipidemia	fasting triglycerides and HDL-c with lipid panel	initial evaluation completes diagnosis; lipoprotein subclasses may further define risk
☑	Hypertension	systolic and diastolic sitting blood pressures	initial evaluation completes diagnosis; further testing may include ambulatory blood pressure monitoring; screen for complications of hypertension
☑	Non-Alcoholic Fatty Liver Disease	liver examination, liver function tests	additional studies are needed for diagnosis: imaging, liver biopsy as indicated
☑	Polycystic Ovary Syndrome	physical exam, review of systems	additional studies are needed for diagnosis: hormonal testing
☑	Obstructive Sleep Apnea	physical exam, review of systems	additional studies are needed for diagnosis: neck circumference, sleep study
☑	Osteoarthritis	physical exam, review of systems	additional studies are needed for diagnosis: radiographic imaging
☑	Urinary Stress Incontinence	physical exam, review of systems	additional studies may be indicated: urine culture, urodynamic testing
☑	Gastroesophageal Reflux Disease	physical exam, review of systems	additional studies may be indicated: endoscopy, esophageal motility
☑	Disability/Immobility	physical exam, review of systems	initial evaluation may complete diagnosis, functional testing may be needed
☑	Psychological Disorder and/or Stigmatization	physical exam, review of systems	additional studies may be needed: psychological testing
☑	Obesity secondary to genetic syndromes, hormonal disease, iatrogenic medications	physical exam, review of systems, review medications and supplements, family history	additional studies may be needed: genetic testing, hormonal testing

Other obesity related complications or disease processes that could be treated with weight loss therapy:
Improvement in Risk of Surgery and Anesthesia; Idiopathic Intracranial Hypertension/Pseudotumor cerebri; Primary Prevention of Cancer in high risk individuals and families; Secondary Prevention of Breast Cancer; Congestive Heart Failure; Infertility not associated with PCOS; "Low Testosterone"/Hypogonadism; Back Pain; Lower Extremity Venous Stasis and Edema; Thrombophlebitis; Prior to pregnancy to improvement in maternal/fetal outcomes; Chronic Lung Disease including Asthma; Gout; Chronic Kidney Disease/Renal Protection.

* Initial evaluation in patients with Obesity (BMI ≥ 25 kg/m^2) includes: history, physical examination, review of systems, blood pressure, waist circumference, fasting glucose, fasting lipid panel (total cholesterol, LDL-c, HDL-c, triglycerides), electrolytes, creatinine, hepatic transaminases.

Table 2.   Staging of Obesity-Related Complications That Can Be Improved by Weight Loss.*

A]   Prediabetes, Metabolic Syndrome, and Type 2 Diabetes.

Stage 0 (none)	No risk factors related to insulin resistance (WC, BP, HDL, TG, fasting Glucose). This is equivalent to Cardiometabolic Disease Stage 0 (CMDS) (9)
Stage 1 (mild-moderate)	1 or 2 risk factors (WC, BP, HDL, TG; CMDS stage 1)
Stage 2 (severe)	Prediabetes, Metabolic Syndrome, or Type 2 Diabetes (CMDS stages 2-4)

B]   Hypertension

Stage 0 (none)	Blood Pressure < 130/85 mm/Hg
Stage 1 (mild-moderate)	BP ≥ 130/85 mm/Hg in absence of other risk factors
Stage 2 (severe complication)	BP target not met despite use of anti-hypertensive medication(s)
	BP ≥ 130/85 mm/Hg in high risk individual: CMDS 2-4, smoking, African American, congestive heart failure

C]   Hypertriglyceridemia/Dyslipidemia

Stage 0 (none)	TG < 150 and HDL-c ≥ 40 in male and ≥ 50 in female
Stage 1 (mild-moderate)	TG 150-399 and/or HDL-c < 40 in male and < 50 in female in absence of other risk factors
Stage 2 (severe)	TG ≥400 in absence of other risk factors
	TG ≥ 150 and HDL-c < 40 in male and < 50 in female in high risk individual: CMDS stage 2-4

D]   Sleep Apnea

Stage 0 (none)	No symptoms, Apnea Hypopnea Index (AHI) < 5
Stage 1 (mild-moderate)	AHI 5-29 with no or mild symptoms
Stage 2 (severe)	AHI ≥ 30
	AHI 5-29 with severe symptoms and/or clinical consequences

E]   Non-Alcoholic Fatty Liver Disease

Stage 0 (none)	No steatosis
Stage 1 (mild-moderate)	Presence of steatosis but no inflammation or fibrosis
Stage 2 (severe)	Steatohepatitis (NASH)

F]   Polycystic Ovary Disease

Stage 0 (none)	Does not meet criteria, absence of PCOS
Stage 1 (mild-moderate)	1 or 2 risk factors (WC, BP, HDL, TG: CMDS stage 1) and no infertility/anovulation
Stage 2 (severe)	Infertility/anovulation
	Oligomenorrhea; Menorrhagia
	Prediabetes/Metabolic Syndrome/T2DM (CMDS stage 2-4)

G]   Osteoarthritis

Stage 0 (none)	No symptoms and no radiographic joint changes
Stage 1 (mild-moderate)	Mild-moderate symptoms and functional impairment (e.g., validated questionnaire) and/or mild-moderate anatomical joint changes
Stage 2 (severe)	Moderate-severe symptoms and functional impairment (e.g., validated questionnaire) and/or moderate-severe anatomical joint changes
	S/P knee or hip replacement surgery

H]   Stress and Urge Urinary Incontinence

Stage 0 (none)	No symptoms and/or normal urodynamics
Stage 1 (mild-moderate)	Mild-moderate symptom severity score
Stage 2 (severe)	Severe symptom severity score

I]   Gastroesophageal Reflux Disease

Stage 0 (none)	No symptoms or findings
Stage 1 (mild-moderate)	Mild-moderate symptoms
Stage 2 (severe)	Severe symptoms
	Erosive esophagitis
	Barrett's Esophagus (if not accompanied by progressive weight loss)

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J] Disability/Immobility
> Stage 0 (none), Stage 1 (mild-moderate), Stage 2 (severe)

K] Psychological Disorder/Stigmatization
> Stage 0 (none), Stage 1 (mild-moderate), Stage 2 (severe)

L] Other Complications

Specific staging criteria could also be established for the following complications and other disease processes that can be prevented and/or treated using weight loss therapy:

- Idiopathic Intracranial Hypertension/Pseudotumor cerebri; Primary Prevention of Cancer in high risk individuals and families; Secondary Prevention of Breast Cancer; Congestive Heart Failure; Infertility not associated with PCOS; "Low Testosterone"/Hypogonadism; sexual function related to the mechanical aspects of coitus; Back Pain; Lower Extremity Venous Stasis and Edema; Thrombophlebitis; Deep Vein Thrombosis; Gastric Ulcers; Maternal/Fetal Risk of Pregnancy; Improvement in Risk of Surgery and Anesthesia; Chronic Lung Disease including Asthma; Gout; Chronic Kidney Disease/Renal Protection.

* While there is an evidence base for the complications-specific criteria below that are used to stage the severity of obesity-related complications, several criteria may require additional expert scrutiny, critique, and research for optimization.

Table 3.	Diagnosis and Management of Obesity		
Diagnosis		**Complications-Specific[†] Staging and Treatment**	
Step 1	Step 2	Step 3	Step 4
Anthropometric Component – BMI*	**Clinical Component**	**Complications-Specific Staging[†]**	**Suggested Therapeutic Interventions [Δ]** (based on clinical judgment)

25-29.9	**Presence or Absence of Obesity Related Complications**
	
	• Metabolic Conditions
	  → Prediabetes
	  → Metabolic Syndrome
	  → T2DM
	  → Hypertension
	  → Dyslipidemia
	  → NAFLD/NASH
	• Sleep Apnea
	• PCOS
	• Osteoarthritis
	• Stress Incontinence
	• GERD
	• Disability/Immobility
	• Psychological Disorder or Stigmatization
		Overweight	• Healthy Meal Pattern & Physical Activity
			• Lifestyle Modification/ Reduced Calorie Meal Plan/ Physical Activity

≥ 30		Obesity Stage 0	• Lifestyle Modification/ Reduced Calorie Meal Plan/ Physical Activity • Intensive Behavioral and Lifestyle Therapy
≥25		Obesity Stage 1 (one or more mild-moderate complications)	• Lifestyle Modification/ Reduced Calorie Meal Plan/ Physical Activity • Intensive Behavioral and Lifestyle Therapy • Consider adding weight loss medications to lifestyle therapy program if BMI ≥ 27[‡]
≥25		Obesity Stage 2 (at least one severe complication)	• Intensive Behavioral and Lifestyle Therapy • Intensive Behavioral and Lifestyle Therapy with Medications if BMI ≥ 27[‡] • Consider Bariatric Surgery in patients with T2DM and BMI 35-39.9 • Consider Bariatric Surgery in patients with BMI ≥ 40

Note: All patients with BMI ≥ 25 have either Overweight, Obesity Stage 0, Obesity Stage 1, or Obesity Stage 2 depending on the initial clinical evaluation for presence and severity of complications. These patients should be followed over time and evaluated for changes in both anthropometric and clinical diagnostic components. The diagnoses of Overweight/Obesity Stage 0, Obesity Stage 1, and Obesity Stage 2 are not static, and disease progression may warrant more aggressive weight loss therapy in the future. Patients with elevated BMI due to muscularity should be excluded.

*   In certain ethnic populations, waist circumference should be assessed if the BMI is 23-25 kg/m². If the waist circumference is elevated using ethnic population-specific cutoff values, this positive risk factor identifies a patient who could benefit from weight loss and meets the criteria for an Obesity Stage 1 diagnosis. Waist circumference is also used in the clinical evaluation of all patients for Metabolic Syndrome, and, if elevated per se, indicates Overweight Stage 1.

†   Stages are determined using criteria specific to each obesity-related complication. Stage 0 = no complication; Stage 1 = mild-to-moderate; Stage 2 = severe

Δ   Treatment plan should be individualized; suggested interventions are appropriate for obtaining the

sufficient degree of weight loss generally required to treat the obesity-related complication(s) at the specified stage of severity

‡ The BMI ≥ 27 is consistent with the prescribing information mandated by the Food and Drug Administration for weight loss medications.

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