



American Diabetes Association

7. Obesity Management for the Treatment of Type 2 Diabetes: Standards of Medical Care in Diabetes—2018

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The American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” includes ADA’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA’s clinical practice recommendations, please refer to the Standards of Care Introduction. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

There is strong and consistent evidence that obesity management can delay the progression from prediabetes to type 2 diabetes (1,2) and may be beneficial in the treatment of type 2 diabetes (3–8). In overweight and obese patients with type 2 diabetes, modest and sustained weight loss has been shown to improve glycemic control and to reduce the need for glucose-lowering medications (3–5). Small studies have demonstrated that in obese patients with type 2 diabetes more extreme dietary energy restriction with very-low-calorie diets can reduce A1C to <6.5% (48 mmol/mol) and fasting glucose to <126 mg/dL (7.0 mmol/L) in the absence of pharmacologic therapy or ongoing procedures (7,9,10). Weight loss–induced improvements in glycemia are most likely to occur early in the natural history of type 2 diabetes when obesity-associated insulin resistance has caused reversible β -cell dysfunction but insulin secretory capacity remains relatively preserved (5,8,10,11). The goal of this section is to provide evidence-based recommendations for dietary, pharmacologic, and surgical interventions for obesity management as treatments for hyperglycemia in type 2 diabetes.

ASSESSMENT

Recommendation

- At each patient encounter, BMI should be calculated and documented in the medical record. **B**

At each routine patient encounter, BMI should be calculated as weight divided by height squared (kg/m^2) (12). BMI should be classified to determine the presence of overweight or obesity, discussed with the patient, and documented in the patient record. In Asian Americans, the BMI cutoff points to define overweight and obesity are lower than in other populations (**Table 7.1**) (13,14). Providers should advise overweight and obese patients that, in general, higher BMIs increase the risk of

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Table 7.1—Treatment options for overweight and obesity in type 2 diabetes

Treatment	BMI category (kg/m ²)				
	25.0–26.9 (or 23.0–26.9*)	27.0–29.9	30.0–34.9 (or 27.5–32.4*)	35.0–39.9 (or 32.5–37.4*)	≥40 (or ≥37.5*)
Diet, physical activity, and behavioral therapy	†	†	†	†	†
Pharmacotherapy		†	†	†	†
Metabolic surgery			†	†	†

*Cutoff points for Asian American individuals. †Treatment may be indicated for selected motivated patients.

cardiovascular disease and all-cause mortality. Providers should assess each patient's readiness to achieve weight loss and jointly determine weight loss goals and intervention strategies. Strategies include diet, physical activity, behavioral therapy, pharmacologic therapy, and metabolic surgery (Table 7.1). The latter two strategies may be prescribed for carefully selected patients as adjuncts to diet, physical activity, and behavioral therapy.

DIET, PHYSICAL ACTIVITY, AND BEHAVIORAL THERAPY

Recommendations

- Diet, physical activity, and behavioral therapy designed to achieve >5% weight loss should be prescribed for overweight and obese patients with type 2 diabetes ready to achieve weight loss. **A**
- Such interventions should be high intensity (≥16 sessions in 6 months) and focus on diet, physical activity, and behavioral strategies to achieve a 500–750 kcal/day energy deficit. **A**
- Diets should be individualized, as those that provide the same caloric restriction but differ in protein, carbohydrate, and fat content are equally effective in achieving weight loss. **A**
- For patients who achieve short-term weight-loss goals, long-term (≥1 year) comprehensive weight maintenance programs should be prescribed. Such programs should provide at least monthly contact and encourage ongoing monitoring of body weight (weekly or more frequently), continued consumption of a reduced-calorie diet, and participation in high levels of physical activity (200–300 min/week). **A**
- To achieve weight loss of >5%, short-term (3-month) interventions that use very-low-calorie diets (≤800 kcal/day) and total meal replacements may be prescribed for

carefully selected patients by trained practitioners in medical care settings with close medical monitoring. To maintain weight loss, such programs must incorporate long-term comprehensive weight maintenance counseling. **B**

Among overweight or obese patients with type 2 diabetes and inadequate glycemic, blood pressure, and lipid control and/or other obesity-related medical conditions, lifestyle changes that result in modest and sustained weight loss produce clinically meaningful reductions in blood glucose, A1C, and triglycerides (3–5). Greater weight loss produces even greater benefits, including reductions in blood pressure, improvements in LDL and HDL cholesterol, and reductions in the need for medications to control blood glucose, blood pressure, and lipids (3–5).

Look AHEAD Trial

Although the Action for Health in Diabetes (Look AHEAD) trial did not show that an intensive lifestyle intervention reduced cardiovascular events in overweight or obese adults with type 2 diabetes (15), it did show the feasibility of achieving and maintaining long-term weight loss in patients with type 2 diabetes. In the Look AHEAD intensive lifestyle intervention group, mean weight loss was 4.7% at 8 years (16). Approximately 50% of intensive lifestyle intervention participants lost ≥5%, and 27% lost ≥10% of their initial body weight at 8 years (16). Participants randomly assigned to the intensive lifestyle group achieved equivalent risk factor control but required fewer glucose-, blood pressure-, and lipid-lowering medications than those randomly assigned to standard care. Secondary analyses of the Look AHEAD trial and other large cardiovascular outcome studies document other benefits of weight loss in patients with type 2 diabetes, including improvements in mobility, physical and sexual

functioning, and health-related quality of life (17). A post hoc analysis of the Look AHEAD study suggests that heterogeneous treatment effects may have been present. Participants who had moderately or poorly controlled diabetes (A1C 6.8% or higher) as well as both those with well-controlled diabetes (A1C less than 6.8%) and good self-reported health were found to have significantly reduced cardiovascular events with intensive lifestyle intervention during follow-up (18).

Lifestyle Interventions

Weight loss can be attained with lifestyle programs that achieve a 500–750 kcal/day energy deficit or provide approximately 1,200–1,500 kcal/day for women and 1,500–1,800 kcal/day for men, adjusted for the individual's baseline body weight. Although benefits may be seen with as little as 5% weight loss (19), sustained weight loss of ≥7% is optimal.

These diets may differ in the types of foods they restrict (such as high-fat or high-carbohydrate foods) but are effective if they create the necessary energy deficit (12,20–22). Use of meal replacement plans prescribed by trained practitioners, with close patient monitoring, can be beneficial. Within the intensive lifestyle intervention group of the Look AHEAD trial, for example, use of a partial meal replacement plan was associated with improvements in diet quality (23). The diet choice should be based on the patient's health status and preferences.

Intensive behavioral lifestyle interventions should include ≥16 sessions in 6 months and focus on diet, physical activity, and behavioral strategies to achieve an ~500–750 kcal/day energy deficit. Interventions should be provided by trained interventionists in either individual or group sessions (19).

Overweight and obese patients with type 2 diabetes who have lost weight during the 6-month intensive behavioral lifestyle intervention should be enrolled in long-term (≥1 year) comprehensive

Table 72—Continued

Generic drug name (proprietary name[s]), dosage, strength, and form	Usual adult dosing frequency	Average wholesale price (per month) ¹³	National Average Drug Acquisition Cost (per month) ¹⁴	1-Year weight change status ¹⁻⁴		Adverse effects ^{1,5-12}	
				Average weight loss relative to placebo	% Patients with $\geq 5\%$ loss of baseline weight	Common ⁶	Serious ⁶
Opioid antagonist/aminoketone antidepressant combination							
Naltrexone/bupropion (Contrave) 8 mg/90 mg tabs	Maximum dose: two tablets of Contrave b.i.d. for a total daily dosage of naltrexone 32 mg/bupropion 360 mg	\$290 (maximum dose)	\$231 (maximum dose)	2.0–4.1 kg (32 mg/360 mg)	36–57%	Nausea, constipation, headache, vomiting	Depression, precipitation of mania, contraindicated in patients with a seizure disorder
Glucagon-like peptide 1 receptor agonist							
Liraglutide (Saxenda) 6 mg/mL prefilled pen	Maintenance dose: 3 mg s.c. q.d.	\$1,385	\$1,105	5.8–5.9 kg	51–73%	Hypoglycemia, nausea, vomiting, diarrhea, constipation, headache	Pancreatitis, thyroid C-cell tumors in rodents, contraindicated in patients with personal/family history of MTC or MEN2, acute renal failure

All medications are contraindicated in women who are or may become pregnant. Women in their reproductive years must be cautioned to use a reliable method of contraception. Caps, capsules; ER, extended release; MEN2, multiple endocrine neoplasia type 2; MTC, medullary thyroid carcinoma; N/A, not applicable; NMS, neuroleptic malignant syndrome; s.c., subcutaneous; tabs, tablets. *Phentermine is FDA-approved as a short-term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction.

¹Physicians' Desk Reference. PDR Network, LLC (electronic version). Truven Health Analytics, Greenwood Village, CO.
²Yanovski SZ, Yanovski JA. Long-term drug treatment for obesity: a systematic and clinical review. *JAMA* 2014;311:74–86 (30).
³Astrup A, Carraro R, Finan N, et al.; NN8022–1807 Investigators. Safety, tolerability and sustained weight loss over 2 years with the once-daily human GLP-1 analog, liraglutide. *Int J Obes (Lond)* 2012;36:843–854.
⁴Wadden TA, Hollander P, Klein S, et al.; NN8022–1807 Investigators. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: the SCALE Maintenance randomized study. *Int J Obes (Lond)* 2013;37:1443–1451.
⁵DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO.
⁶Selective common (defined as an incidence of $> 5\%$) and serious adverse effects are noted. Refer to the medication package inserts for full information about adverse effects, cautions, and contraindications.
⁷Data of common adverse effects for Xenical were derived from seven double-blind, placebo-controlled clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes), but the percentage of patients with type 2 diabetes was not reported. In clinical trials in obese patients with diabetes, hypoglycemia and abdominal distension were also observed.
⁸Data of common adverse effects for Belviq were derived from placebo-controlled clinical trials in patients with type 2 diabetes.
⁹Data of common adverse effects for Qsymia were derived from four clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes); 13% had type 2 diabetes.
¹⁰Data of common adverse effects for Contrave were derived from five double-blind, placebo-controlled clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes); 13% had type 2 diabetes.
¹¹Data of common adverse effects for Saxenda were derived from clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes). Percentage of patients with type 2 diabetes was not reported.
¹²Phentermine. FDA prescribing information, side effects and uses [Internet]. 2017. Available from <https://www.drugs.com/pro/phentermine.html>. Accessed 22 September 2017 (29).
¹³RED BOOK Online. Micromedex 2.0 (electronic version). Truven Health Analytics, Greenwood Village, CO. Accessed 18 July 2017.
¹⁴National Average Drug Acquisition Cost data available at: <https://data.medicare.gov/>. Accessed 19 July 2017.

and nutritional status must be provided to patients after surgery, according to guidelines for postoperative management of metabolic surgery by national and international professional societies. **C**

- People presenting for metabolic surgery should receive a comprehensive mental health assessment. **B** Surgery should be postponed in patients with histories of alcohol or substance abuse, significant depression, suicidal ideation, or other mental health conditions until these conditions have been fully addressed. **E**
- People who undergo metabolic surgery should be evaluated to assess the need for ongoing mental health services to help them adjust to medical and psychosocial changes after surgery. **C**

Several gastrointestinal (GI) operations including partial gastrectomies and bariatric procedures (35) promote dramatic and durable improvement of type 2 diabetes. Given the magnitude and rapidity of the effect of GI surgery on hyperglycemia, and experimental evidence that rearrangements of GI anatomy similar to those in some metabolic procedures directly affect glucose homeostasis (36), GI interventions have been suggested as treatments for type 2 diabetes, and in that context are termed “metabolic surgery.”

A substantial body of evidence has now accumulated, including data from numerous randomized controlled clinical trials, demonstrating that metabolic surgery achieves superior glycemic control and reduction of cardiovascular risk factors in obese patients with type 2 diabetes compared with various lifestyle/medical interventions (35). Improvements in micro- and macrovascular complications of diabetes, cardiovascular disease, and cancer have been observed only in nonrandomized observational studies (37–46). Cohort studies attempting to match surgical and nonsurgical subjects suggest that the procedure may reduce longer-term mortality (38).

On the basis of this mounting evidence, several organizations and government agencies have recommended expanding the indications for metabolic surgery to include patients with inadequately controlled type 2 diabetes and BMI as low as 30 kg/m² (27.5 kg/m² for Asian Americans) (47–50).

Please refer to “Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations” for a thorough review (35).

Randomized controlled trials with postoperative follow up ranging from 1 to 5 years have documented sustained diabetes remission in 30–63% of patients (35). Available data suggest an erosion of diabetes remission over time (51): 35–50% or more of patients who initially achieve remission of diabetes eventually experience recurrence. However, the median disease-free period among such individuals following Roux-en-Y gastric bypass (RYGB) is 8.3 years (52,53). With or without diabetes relapse, the majority of patients who undergo surgery maintain substantial improvement of glycemic control from baseline for at least 5 (54,55) to 15 (38,39,53,56–58) years.

Younger age, shorter duration of diabetes (e.g., <8 years) (59), nonuse of insulin, and better glycemic control are consistently associated with higher rates of diabetes remission and/or lower risk of recidivism (38,57,59). Greater baseline visceral fat area may also help to predict better postoperative outcomes, especially among Asian American patients with type 2 diabetes, who typically have more visceral fat compared with Caucasians with diabetes of the same BMI (60).

Beyond improving glycemia, metabolic surgery has been shown to confer additional health benefits in randomized controlled trials, including greater reductions in cardiovascular disease risk factors (35) and enhancements in quality of life (54,59,61).

The safety of metabolic surgery has improved significantly over the past two decades, with continued refinement of minimally invasive approaches (laparoscopic surgery), enhanced training and credentialing, and involvement of multidisciplinary teams. Mortality rates with metabolic operations are typically 0.1–0.5%, similar to cholecystectomy or hysterectomy (62–66). Morbidity has also dramatically declined with laparoscopic approaches. Major complications rates are 2–6%, with minor complications in up to 15% (62–70), comparing favorably with other commonly performed elective operations (66). Empirical data suggest that proficiency of the operating surgeon is an important factor for determining

mortality, complications, reoperations, and readmissions (71).

Although metabolic surgery has been shown to improve the metabolic profiles of morbidly obese patients with type 1 diabetes, establishing the role of metabolic surgery in such patients will require larger and longer studies (72).

Retrospective analyses and modeling studies suggest that metabolic surgery may be cost-effective or even cost-saving for patients with type 2 diabetes, but the results are largely dependent on assumptions about the long-term effectiveness and safety of the procedures (73,74).

Adverse Effects

Metabolic surgery is costly and has associated risks. Longer-term concerns include dumping syndrome (nausea, colic, diarrhea), vitamin and mineral deficiencies, anemia, osteoporosis, and, rarely (75), severe hypoglycemia from insulin hypersecretion. Long-term nutritional and micronutrient deficiencies and related complications occur with variable frequency depending on the type of procedure and require lifelong vitamin/nutritional supplementation (76,77). Postprandial hypoglycemia is most likely to occur with RYGB (77,78). The exact prevalence of symptomatic hypoglycemia is unknown. In one study, it affected 11% of 450 patients who had undergone RYGB or vertical sleeve gastrectomy (75). Patients who undergo metabolic surgery may be at increased risk for substance use, including drug and alcohol use and cigarette smoking (79).

People with diabetes presenting for metabolic surgery also have increased rates of depression and other major psychiatric disorders (80). Candidates for metabolic surgery with histories of alcohol or substance abuse, significant depression, suicidal ideation, or other mental health conditions should therefore first be assessed by a mental health professional with expertise in obesity management prior to consideration for surgery (81). Individuals with preoperative psychopathology should be assessed regularly following metabolic surgery to optimize mental health management and to ensure psychiatric symptoms do not interfere with weight loss and lifestyle changes.

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