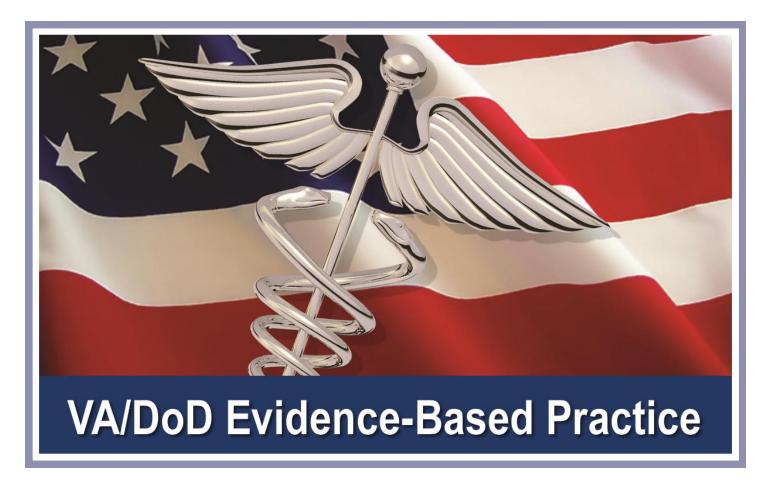
# **VA/DoD Clinical Practice Guidelines**

# THE MANAGEMENT OF ADULT OVERWEIGHT AND OBESITY







# **Provider Summary**





### VA/DOD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF ADULT OVERWEIGHT AND OBESITY

Department of Veterans Affairs

Department of Defense

#### **Provider Summary**

#### **QUALIFYING STATEMENTS**

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review (SR) of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at <a href="https://www.tricare.mil">www.tricare.mil</a> or by contacting your regional TRICARE Managed Care Support Contractor.

Version 3.0 - 2020

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#### Introduction

The Department of Veterans Affairs (VA) and Department of Defense (DoD) Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the Health Executive Committee (HEC) "...on the use of clinical and epidemiological evidence to improve the health of the population..." across the Veterans Health Administration (VHA) and Military Health System (MHS), by facilitating the development of clinical practice guidelines (CPGs) for the VA and DoD populations.[1] This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with overweight or obesity, thereby leading to improved clinical outcomes.

In 2014, the VA and DoD published a CPG for the Screening and Management of Overweight and Obesity (2014 VA/DoD Obesity CPG), which was based on evidence reviewed through February 2013. Since the release of that guideline, a growing body of research has expanded the general knowledge and understanding of overweight and obesity. Consequently, a recommendation to update the 2014 Obesity CPG was initiated in 2018. The updated, 2020 VA/DoD CPG Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020 VA/DoD Obesity CPG) includes objective, evidence-based information on the management of overweight and obesity. It is intended to assist healthcare providers in all aspects of patient care. The system-wide goal of evidence-based guidelines is to improve the patient's health and well-being by guiding health providers who are caring for patients with overweight and obesity along management pathways that are supported by evidence. The expected outcome of successful implementation of this guideline is to:

- Assess the individual's condition and determine, in collaboration with the patient, the best treatment method
- Optimize health outcomes and improve quality of life (QoL)
- Minimize preventable complications and morbidity
- Emphasize the use of patient-centered care

#### **Key Elements of Weight Management**

The key elements of weight loss and weight management that are addressed by this guideline include:

- 1. Obesity is a chronic disease that requires lifelong management.
- Shared decision-making, a process that includes assessment, and re-assessment of patient values, motivation, and interest in weight management options, is fundamental to weight management.
- 3. Reviewing medications carefully and eliminating obesogenic agents used to treat other illnesses is important. Consider first using agents that are weight neutral or promote weight loss when treating a patient with overweight or obesity for any medical concern.
- 4. A comprehensive lifestyle intervention (CLI), defined as the combination of three critical components (i.e., behavioral, dietary, and physical activity) that aim to produce a negative energy balance, is central to successful and sustained weight loss and maintenance.

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- 5. Negative energy balance should be achieved through decreased caloric intake and increased physical activity. There is more than one successful strategy to achieve these goals.
- 6. Dietary supplements or nutraceuticals do not contribute to clinically meaningful weight loss or weight management.
- 7. Pharmacotherapy and/or bariatric procedures may be considered in conjunction with comprehensive lifestyle interventions. Both require long-term follow-up.
- 8. There are several FDA-approved medications with an indication for weight loss. In addition to efficacy and safety, it is important to individualize treatment, taking into consideration the potential for side effects and patient tolerability as well as patient preferences, to optimize long-term adherence to pharmacotherapy. Providers and patients must both be aware that weight regain often results after discontinuation so that long-term use of pharmacotherapy for maintenance of weight loss is often needed.
- 9. Bariatric procedures are effective for weight loss. Type 2 diabetes mellitus especially improves with bariatric procedures. Patient individualization is required.
- 10. A multifaceted approach that combines comprehensive lifestyle intervention, pharmacologic, and surgical options as simultaneous effective treatment strategies can enhance weight loss and maintenance.

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#### Recommendations

The following recommendations were made using a systematic approach considering four domains as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as detailed in the section on Methods and Appendix A in the full text VA/DoD Obesity CPG. These domains include: confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability).

Topic	Sub- topic	#	Recommendation	Strengtha	Category <sup>b</sup>
CCLIS)		1.	We recommend offering an in-person group or individual comprehensive lifestyle intervention that always includes behavioral, dietary, and physical activity components for patients with overweight or obesity.	Strong for	Reviewed, New- replaced
	There is insufficient evidence to recommend a specific num sessions of a comprehensive lifestyle intervention for patie overweight or obesity.			Neither for nor against	Reviewed, new-added
esity	or obesity.  There is insufficient evidence to recommend a specific number of sessions of a comprehensive lifestyle intervention for patients with overweight or obesity.  We suggest offering a comprehensive lifestyle intervention for weight maintenance to patients who have completed a comprehensive lifestyle intervention for weight loss.  We suggest offering an individual or group telephone-delivered comprehensive lifestyle intervention for weight loss, either as an alternative to or in conjunction with an in-person intervention.  There is insufficient evidence for or against offering a comprehensive lifestyle intervention for weight loss that uses technology as its primary mode of delivery.  We suggest choosing one or more of the following as the physical activity component of a comprehensive lifestyle intervention: aerobic,		Weak for	Reviewed, New- replaced	
eight or Ob			comprehensive lifestyle intervention for weight loss, either as an	Weak for	Reviewed, Amended
nt of Overw			lifestyle intervention for weight loss that uses technology as its	Neither for nor against	Reviewed, New- Replaced
Managemer	b. Physical Activity Component of a CLI	We suggest choosing one or more of the following as the physical activity component of a comprehensive lifestyle intervention: aerobic resistance, and/or lifestyle physical activity.		Weak for	Reviewed, New- replaced
	c. Dietary Component of a CLI	7. We recommend offering patients a dietary approach that contributes to a negative energy balance to achieve weight loss as the dietary component of a comprehensive lifestyle intervention.		Strong for	Reviewed, Amended
	c. Dietar) Component oj	8.	We suggest meal replacement (for example portion-controlled shake, protein bar, or meal) as an option to achieve negative energy balance as a component of a comprehensive lifestyle intervention.	Weak for	Reviewed, New- replaced

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Topic	Sub- topic	#	Recommendation	Strength <sup>a</sup>	Category <sup>b</sup>
d. Long-Term Pharmacotherapy		9.	We suggest offering prescribed pharmacotherapy (specifically liraglutide, naltrexone/bupropion, orlistat, or phentermine/topiramate) for long-term weight loss in patients with a body mass index $\geq 30 \text{ kg/m}^2$ and for those with a body mass index $\geq 27 \text{ kg/m}^2$ who also have obesity-associated conditions, in conjunction with a comprehensive lifestyle intervention.	Weak for	Reviewed, New- replaced
ont.)	d. La Pharm	10.	There is insufficient evidence to recommend for or against offering phentermine monotherapy, benzphetamine, diethylpropion, or phendimetrazine, for short-term, long-term, or intermittent weight loss in patients with overweight or obesity.	Neither for nor against	Reviewed, New-added
Management of Overweight or Obesity (cont.)	We suggest against using dietary supplements or nutraceuticals for clinically meaningful short-term weight loss or long-term weight management.			Weak against	Reviewed, New-added
nent of Ov	Devices 15.		We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥30 kg/m² and type 2 diabetes mellitus.	Weak for	Reviewed, New-added
Management of Aetabolic/Bariatric Procedures & Devices		13.	We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a body mass index $\geq$ 40 kg/m² or those with body mass index $\geq$ 35 kg/m² with obesity-associated condition(s).	Weak for	Reviewed, New- replaced
	bolic/B	14.	There is insufficient evidence to recommend for or against metabolic/bariatric surgery to patients over age 65.	Neither for nor against	
	f. Metal	15 Ingroutancous gastrostomy devises for weight loss in nationts with		Neither for nor against	Reviewed, New-added
tht Loss nths)	We suggest offering intragastric balloons in conjunction with a comprehensive lifestyle intervention to patients with obesity (body mass index >30 kg/m²) who prioritize short-term (up to six months)		Weak for	Reviewed, New-added	
Short-Term Weight Loss (Up to Six Months)			Neither for nor against	Reviewed, New-added	
Short- (Up		18.	We suggest offering a low-carbohydrate diet over a low-fat diet as the dietary component of a comprehensive lifestyle intervention for patients who prioritize short-term (up to six months) weight loss.	Weak for	Reviewed, New-added

<sup>&</sup>lt;sup>a</sup> For additional information, please refer to the section on <u>Grading Recommendations</u> in the full text of the VA/DoD Obesity CPG.

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<sup>&</sup>lt;sup>b</sup> For additional information, please refer to the section on <u>Recommendation Categorization and Appendix D</u> in the full text of the VA/DoD Obesity CPG.

#### Algorithm

This CPG includes algorithms designed to facilitate understanding of the clinical pathways and decision-making processes used in managing patients with overweight or obesity. The use of the algorithm format as a way to represent patient management was chosen based on the understanding that such a format may promote more efficient diagnostic and therapeutic decision making; it also has potential to change patterns of resource use. Although the Work Group recognizes that not all clinical practices are linear, the simplified linear approach depicted through the algorithm and its format allows the provider to assess the critical information needed at the major decision points in the clinical process. It includes:

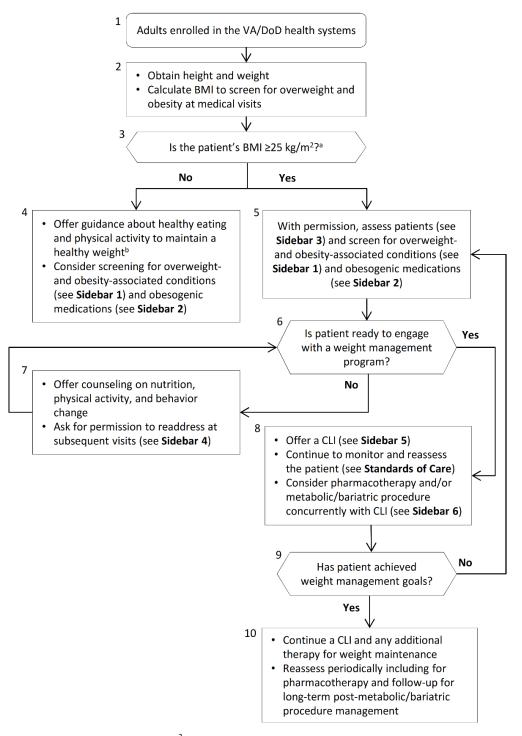
- 1. An ordered sequence of steps of care
- 2. Recommended observations and examinations
- 3. Decisions to be considered
- 4. Actions to be taken

For each VA/DoD CPG, there is a corresponding clinical algorithm that is depicted by a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm, and arrows connect the numbered boxes indicating the order in which the steps should be followed.[2]

Description
Rounded rectangles represent a clinical state or condition
Hexagons represent a decision point in the guideline, formulated as a question that can be answered "Yes" or "No"
Rectangles represent an action in the process of care
Ovals represent a link to another section within the guideline

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#### **Algorithm Module**



<sup>&</sup>lt;sup>a</sup> For patients of Asian descent: is BMI ≥23 kg/m<sup>2</sup>?; [3] for patients >65 years old: consider individualized assessment [4]

Abbreviations: BMI: body mass index; CLI: comprehensive lifestyle intervention; DoD: Department of Defense; kg: kilograms; m: meters; VA: Department of Veterans Affairs

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b See, for example, 2015-2020 Dietary Guidelines for Americans, 8<sup>th</sup> edition, available at: https://health.gov/dietaryguidelines/2015/ and Physical Guidelines for American, 2<sup>nd</sup> Edition, available at: https://health.gov/paguidelines/second-edition/

#### Sidebar 1: Common Overweight- and Obesity-Associated Conditions

- HTN
- T2DM and prediabetes
- Dyslipidemia
- Metabolic syndrome<sup>a</sup>
- OSA
- OA/degenerative joint disease
- NAFLD
- GERD
- Cancer [5]

Abbreviations: GERD: gastroesophageal reflux disease; HTN: hypertension; NAFLD: non-alcoholic fatty liver disease; OA: osteoarthritis; OSA: obstructive sleep apnea; T2DM: type 2 diabetes mellitus

Sidebar 2: Select Medications and their Potential Effects on Weight <sup>a</sup>					
Medication Classes	Medications with Potential for Weight Gain	Medications that may be Weight Neutral or have Potential for Weight Loss			
Antipsychotics	<ul><li> Quetiapine</li><li> Clozapine</li><li> Olanzapine</li><li> Risperidone</li><li> Thioridazine</li></ul>	<ul><li> Aripiprazole</li><li> Haloperidol</li><li> Ziprasidone</li></ul>			
Antidepressants	<ul> <li>Mirtazapine</li> <li>Selective serotonin reuptake inhibitor (e.g., paroxetine, sertraline, citalopram, b escitalopram, b fluoxetineb)</li> <li>MAOIs (e.g., phenelzine)</li> <li>Tricyclic anti-depressants (e.g., amitriptyline, clomipramine, doxepin, imipramine, nortriptyline, protriptylineb)</li> </ul>	<ul><li>Bupropion</li><li>Desvenlafaxine</li><li>Venlafaxine</li></ul>			
Antiepileptic drugs or mood stabilizing agents	<ul> <li>Gabapentin</li> <li>Pregabalin</li> <li>Carbamazepine</li> <li>Divalproex</li> <li>Lithium</li> <li>Valproic acid</li> <li>Vigabatrin</li> </ul>	<ul><li>Topiramate</li><li>Lamotrigine</li><li>Zonisamide</li></ul>			

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<sup>&</sup>lt;sup>a</sup> See National Cholesterol Education Program definition of metabolic syndrome, available at: https://www.nhlbi.nih.gov/files/docs/guidelines/atglance.pdf

Sidebar 2: Select Medications and their Potential Effects on Weight <sup>a</sup>					
Medication Classes	Medications with Potential for Weight Gain	Medications that may be Weight Neutral or have Potential for Weight Loss			
Antihyperglycemic agents	<ul> <li>Insulin</li> <li>Sulfonylureas (e.g., chlorpropamide, glimepiride, glipizide, glyburide)</li> <li>Meglitinides (e.g., nateglinide, repaglinide)</li> <li>Thiazolidinediones (e.g., pioglitazone, rosiglitazone)</li> </ul>	<ul> <li>GLP-1 agonists (e.g., semaglutide, liraglutide, exenatide, dulaglutide, lixisenatide)</li> <li>SGLT2 inhibitors (e.g., empagliflozin, canagliflozin, dapagliflozin, ertugliflozin)</li> <li>Metformin</li> <li>Pramlintide</li> <li>Alpha-glucosidase inhibitors (e.g., acarbose, miglitol)</li> <li>Dipeptidyl-peptidase-4 inhibitors (e.g., alogliptin, linagliptin, saxagliptin, sitagliptin)</li> </ul>			
Beta-blockers	<ul><li>Metoprolol</li><li>Atenolol</li><li>Propranolol</li></ul>	Carvedilol     Nebivolol  Note: Other alternative classes of antihypertensive medications may be an option depending on the indication (e.g., angina, heart failure, HTN, migraine). Consider calcium channel blockers, angiotensin-converting enzyme inhibitors, ARBs, and thiazide or loop diuretics, as indicated.			
Alpha-blockers	Terazosin	For benign prostatic hyperplasia (e.g., doxazosin, alfuzosin, tamsulosin)			
Glucocorticoids	<ul><li>Prednisone</li><li>Methylprednisolone</li><li>Hydrocortisone</li></ul>	Alternatives for rheumatologic disorders:  NSAIDs Biologics/Disease-modifying antirheumatic drugs Nontraditional therapies			
Hormonal agents	Progestins (e.g., medroxyprogesterone, megestrol acetate)	For contraception, consider alternative methods (e.g., copper intrauterine device)			
Antihistamines	<ul><li>Cetirizine</li><li>Cyproheptadine</li></ul>	Depending on symptoms, consider ipratropium nasal spray, decongestants, inhalers, and/or nonpharmacologic measures (e.g., nasal irrigation)			

<sup>&</sup>lt;sup>a</sup> The information provided in the table is not to be considered all-inclusive and is a compilation of information from the medical literature (systematic reviews, meta-analyses, subgroup analysis of clinical trials, cohort studies, reviews), some of which may have included differing comparators with variable results based on length of follow-up, baseline weight, patient comorbidities, etc.; medical and pharmacy resources; and select product information (adverse events, post-marketing and case reports).

Abbreviations: ARB: angiotensin receptor blocker; GLP-1: glucagon-like peptide-1 receptor; HTN: hypertension; MAOI: monoamine oxidase inhibitor; NSAID: nonsteroidal anti-inflammatory drug; SGLT2: sodium-glucose cotransporter 2

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<sup>&</sup>lt;sup>b</sup> Weight gain and weight loss have been reported.

#### Sidebar 3: Assessment of Patients with Overweight or Obesity

- Assess for presence of obesogenic medications (see Sidebar 2 on pharmacotherapy)
- Consider assessing waist circumference for patients with a BMI of 25 29.9 kg/m² (see <u>Standards of Care</u> in the full CPG)
- Assess for common overweight and obesity-associated conditions (see <u>Sidebar 1</u>)
- Assess for secondary causes of overweight or obesity if physical exam and history warrant, including but not limited to: depression, binge eating disorder, hypothyroidism, hypercortisolism (Cushing's disease or syndrome), traumatic brain injury, brain tumor, cranial irradiation, hypogonadism, menopause, acromegaly
- Assess potential benefit of starting pharmacotherapy and/or bariatric procedure
- Assess conditions for which weight loss may not be beneficial (e.g., sarcopenia, active carcinoma, some eating disorders)

Abbreviations: BMI: body mass index; CPG: Clinical Practice Guideline; kg: kilograms; m: meters

#### Sidebar 4: Principles and Core Strategies of Motivational Interviewing

- · Respect autonomy and resist directing
- Understand the patient's motivations
- Listen with empathy
- Empower the patient by building confidence
- Ask Open-ended questions to evoke change talk and provide Affirmations, Reflections, and Summaries (OARS)
- For more information refer to the guide, "Moving Veterans To MOVE!"a
- a Available at: https://www.move.va.gov/

#### **Sidebar 5: Comprehensive Lifestyle Intervention**

- Defined as an intervention that combines behavioral, dietary, and physical activity components together (see Recommendations 1, 6, and 7, and Standards of Care in the full CPG)
- The intervention can be delivered in an individual or group setting, in person, by telephone, or through synchronous video (see <a href="Recommendation 1"><u>Recommendation 4</u></a>)
- Though there is insufficient evidence to recommend a specific number of sessions of comprehensive lifestyle intervention, most CLIs offer at least 12 intervention sessions in the first 12 months of intervention (see Recommendation 2)

Abbreviations: CLI: comprehensive lifestyle intervention; CPG: Clinical Practice Guideline

#### Sidebar 6: Assessment for Pharmacotherapy and/or Bariatric Procedures

- In addition to CLIs, consider pharmacotherapy and/or bariatric procedures in the following scenarios:
- Consider for long-term pharmacotherapy (see Appendix H in the full CPG):
  - Patients with a BMI ≥30 kg/m²
  - Patients with a BMI ≥27 kg/m² and an obesity-related comorbidity (see Table H-1 in the full CPG)
  - Individualize choice of medication to patient-specific comorbidities, dosing, administration, and potential for side effects
- Consider for bariatric procedures (see <u>Appendix I</u> in the full CPG):
  - Patients with a BMI ≥30 kg/m² and T2DM
  - Patients with a BMI ≥35 kg/m<sup>2</sup> and an obesity-related comorbidity
  - Any patient with a BMI ≥40 kg/m<sup>2</sup>

Abbreviations: BMI: body mass index; CLI: comprehensive lifestyle intervention; CPG: Clinical Practice Guideline; kg: kilograms; m: meters; T2DM: type 2 diabetes mellitus

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#### Scope of the CPG

Regardless of setting, any patient in the VA and DoD healthcare system should ideally have access to the interventions that are recommended in this guideline after taking into consideration the patient's specific circumstances.

Guideline recommendations are intended to support the delivery of evidence-based, patient-centered healthcare which occurs at the intersection of best available evidence, patient preference, and practitioner expertise and experience. Effective, open communication between healthcare professionals and the patient is essential and should be supported by evidence-based information tailored to the patient's needs. Use of an empathetic and non-judgmental approach facilitates discussions sensitive to sex, culture, ethnicity, and other considerations. The information that patients are given about treatment and care should be culturally appropriate and available to people with limited literacy skills. Treatment information should also be accessible to people with additional needs such as physical, sensory, or learning disabilities. Family and caregiver involvement should be considered, if appropriate.

This CPG is designed to assist providers in managing or co-managing patients with overweight or obesity. Moreover, the patient population of interest for this CPG is adult patients with overweight or obesity who are eligible for care in the VA and DoD healthcare delivery systems including those who are in the community receiving care from community-based clinicians. It includes Veterans as well as deployed and non-deployed active duty Service, Guard, and Reserve Members and their adult dependents.

#### **Classification of Overweight and Obesity**

For adults, having a BMI of  $25 - 29.9 \text{ kg/m}^2$  is considered overweight, while a BMI of  $30 \text{ kg/m}^2$  or higher is considered obese. The category of "obese" is further divided into subcategories of Class I obesity (BMI  $30.0 - 34.9 \text{ kg/m}^2$ ), Class II obesity (BMI  $35.0 - 39.9 \text{ kg/m}^2$ ), and Class III obesity (BMI  $\geq 40 \text{ kg/m}^2$ ). [6] For individuals of Asian descent, the World Health Organization suggests a lower threshold for overweight (BMI  $\geq 23.0 \text{ kg/m}^2$ ) and obesity (BMI  $\geq 27.5 \text{ kg/m}^2$ ).

An online BMI calculator is available at the CDC website.

#### Methods

The 2020 VA/DoD Obesity CPG is an update to the 2014 VA/DoD Obesity CPG. The methodology used in developing the 2020 VA/DoD Obesity CPG follows the *Guideline for Guidelines*, an internal document of the VA and DoD EBPWG.[1] The *Guideline for Guidelines* can be downloaded from <a href="http://www.healthquality.va.gov/policy/index.asp">http://www.healthquality.va.gov/policy/index.asp</a>. The guideline development process for the 2020 VA/DoD Obesity CPG update consisted of the following steps: formulating and prioritizing key questions (KQs); convening a patient focus group; conducting the systematic evidence review; convening a face-to-face meeting with the CPG Champions and Work Group members; and drafting and submitting a final CPG on the management of obesity to the VA/DoD EBPWG.

The Champions and Work Group used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation: balance of desirable and undesirable outcomes; confidence in the quality of the evidence; patient or provider values and preferences; other implications, as appropriate (e.g., resource use, equity).[7] Using this system, the Champions and Work Group determined the relative strength of

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each recommendation ("Strong" or "Weak"). A "Strong" recommendation generally indicates that the Work Group is highly confident that the desirable effects of an intervention outweigh undesirable effects. If the Work Group is less confident that the desirable effects of an intervention outweigh undesirable effects, they give a "Weak" recommendation. It is important to note that the GRADE terminology used to indicate the assessment across the four domains (i.e., "Strong" versus "Weak") should not be confused with the clinical importance of the recommendation. A "Weak" recommendation may be just as important to the clinical care of a patient as a strong recommendation.

Occasionally, instances may occur when the Work Group feels there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report with conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or "We recommend offering this option ...")
- Weak For (or "We suggest offering this option ...")
- No recommendation for or against (or "There is insufficient evidence ...")
- Weak Against (or "We suggest not offering this option ...")
- Strong Against (or "We recommend against offering this option ...")

The grade of each recommendation made in the 2020 VA/DoD Obesity CPG can be found in the section on Recommendations. Additional information regarding the use of the GRADE system can be found in Appendix A in the full Obesity CPG.

The Work Group developed both new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition, the Work Group considered, without complete review of the relevant evidence, the current applicability of other recommendations that were included in the 2014 VA/DoD Obesity CPG, subject to evolving practice in today's environment. A set of recommendation categories was adapted from those used by National Institute for Clinical Excellence (NICE).[8,9] These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2014 VA/DoD Obesity CPG and can be found in Table 1.

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Table 1. Recommendation Categories and Definitions\*

Evidence Reviewed*	Recommendation Category	Definition
	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
Reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from previous CPG that has been removed based on review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
Not reviewed	Amended	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from previous CPG that has been removed because it was deemed out of scope for the updated CPG

<sup>\*</sup>Adapted from the NICE guideline manual (2012) [8] and Garcia et al. (2014) [9]

Abbreviation: CPG: clinical practice guideline

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#### **Patient-centered Care**

VA/DoD CPGs encourage providers to use a patient-centered care approach that is individualized based on patient needs, characteristics, and preferences. Regardless of setting, all patients in the healthcare system should be able to access evidence-based care appropriate to their specific needs or condition. When properly executed, patient-centered care engages, activates and empowers patients to take a more active role in their health and health care. Patient-centered approaches may decrease patient anxiety, increase trust in clinicians, and improve treatment adherence.[10-12] A patient-centered approach improves patient-clinician communication and supports disclosure of current and future concerns.

As part of the patient-centered approach, providers should ask each patient about any concerns he or she has and barriers to high-quality care he or she has experienced.

#### **Shared Decision Making**

Throughout this VA/DoD CPG, the authors encourage clinicians to focus on shared decision making, a key component of patient-centered care. A shared decision making model was featured in *Crossing the Quality Chasm*, an Institute of Medicine (IOM) (now called the National Academy of Medicine [NAM]) report, in 2001.[13] Patients, together with their clinicians, make decisions regarding their plan of care and management options. Patients with overweight or obesity require sufficient information and time to be able to make informed decisions. Clinicians must be adept at presenting information to their patients regarding risks of overweight and obesity, benefits and potential harms of treatments, expected outcomes, and levels and/or locations of care. Clinicians are encouraged to use shared decision making to individualize treatment goals and plans based on patient capabilities, needs, values, goals, and preferences. See <u>Standards of Care</u> in the full CPG for additional guidance about the use of shared decision making in the care of the overweight and obese patient.

## Dietary Approaches to Support Weight Loss

<b>Dietary Approaches</b>	Description					
Mediterranean	<ul> <li>A dietary pattern that is focused on plant-based food consumption, which includes vegetables, fruits, whole grains, nuts and seeds; minimally processed foods; olive oil as the primary fat source; low to moderate amounts of dairy, fish, and poultry; and minimal amounts of red meat.[15] This dietary approach is evaluated based on the intake of specific food groups with positive health outcomes rather than meeting specific nutrient standards.[14]</li> </ul>					
diet <sup>a</sup> [ <u>14</u> ]	<ul> <li>An SR of five RCTs (n=998) that compared the Mediterranean diet to low-carbohydrate, low-fat, or the American Diabetes Association diet found that at 12 and 48 months, participants on the Mediterranean diet lost an average of between 3.8 and 10.1 kg, lost more weight at ≥12 months, and lost a comparable amount of weight to the remaining diets.[16]</li> </ul>					

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<b>Dietary Approaches</b>	Description		
Dietary Approaches to Stop Hypertension (DASH) diet <sup>b</sup> [17]	The DASH diet is a dietary pattern that focuses on reducing hypertension and promotes the consumption of vegetables, fruits, whole grains, nuts, legumes, seeds, low-fat dairy foods, and lean meats. It also limits the consumption of sugar-sweetened foods and beverages, sodium, caffeine, and alcohol.  The DASH Diet is low in saturated fats and rich in potassium, calcium, magnesium, dietary fiber, and protein. The sodium levels are between 1,500 – 2,300 mg daily. This dietary approach is recognized by the USDA as an ideal eating plan for Americans.  A 2016 SR and meta-analysis of 10 studies (n=1,291) found that participants who followed the DASH diet lost more weight than controls (WMD: -1.42 kg), and that DASH diet with and without energy restriction yielded statistically significant weight loss (WMD: -2.27 kg and -0.85 kg respectively). Studies varied between 8 and 24 weeks. [18]  The definition of low-carbohydrate varies based on the specific dietary approach.  The Dietary Guidelines for Americans recommends that 45 – 65% of calories each day come from carbohydrate and sets the RDA at 130 g.[14] Therefore, any recommendation that is less than 130 g of carbohydrate may be considered low-carbohydrate.  Adherence to modest carbohydrate reductions may be more achievable than more strict carbohydrate reductions, while still promoting weight loss. [19-21]  Low-carbohydrate ketogenic diets (<50 g carbohydrate) are effective for weight loss, but this dietary approach may result in: headache, upset stomach, fatigue and dizzy spells (also called the "keto flu"); constipation; and may require micronutrient supplementation given limitations of vitamin and mineral-rich carbohydrate-containing foods. [22-25]  Typically, low-carbohydrate, ketogenic diets (induction phase of <20 g of carbohydrate) may be best implemented under medical supervision with attention paid to lifestyle and need for monitoring medications and comorbidities. Medications, especially diuretics and antiglycemic agents, may require adjustment on this diet		
Low-carbohydrate diet	<ul> <li>recommendation that is less than 130 g of carbohydrate may be considered low-carbohydrate.</li> <li>Adherence to modest carbohydrate reductions may be more achievable than more strict carbohydrate reductions, while still promoting weight loss.[19-21]</li> <li>Low-carbohydrate ketogenic diets (&lt;50 g carbohydrate) are effective for weight loss, but this dietary approach may result in: headache, upset stomach, fatigue and dizzy spells (also called the "keto flu"); constipation; and may require micronutrient supplementation given limitations of vitamin and mineral-rich carbohydrate-containing foods.[22-25]</li> <li>Typically, low-carbohydrate, ketogenic diets (induction phase of &lt;20 g of carbohydrate) may be best implemented under medical supervision with attention paid to lifestyle and need for monitoring medications and comorbidities. Medications, especially diuretics</li> </ul>		
Low-fat diet	<ul> <li>without formally prescribed energy restriction but with an energy deficit.[26]</li> <li>Studies found that there was significant weight loss in both the low-fat and low-carbohydrate diet groups.[24,27] These findings are consistent with the findings in the 2013 AHA/ACC/TOS Guidelines for the Management of Obesity and Weight</li> </ul>		
Alternate day fasting and Intermittent fasting	<ul> <li>Alternate day fasting and intermittent fasting are both forms of intermittent energy restriction using varied plans for when energy is restricted (by day or in the same day).</li> <li>Current research is limited on this dietary approach.</li> <li>Studies using an alternate day fasting or intermittent fasting methodology yielded the same results, which was that there was no difference in weight loss when compared to an alternate calorie-restriction method.[28-32]</li> </ul>		

<sup>&</sup>lt;sup>a</sup> For further information about the Mediterranean eating pattern see the 2015-2020 Dietary Guidelines for Americans, available at: <a href="https://health.gov/dietaryguidelines/2015/">https://health.gov/dietaryguidelines/2015/</a>

Abbreviations: ACC: American College of Cardiology; AHA: American Heart Association; DASH: Dietary Approaches to Stop Hypertension; g: grams; kg: kilograms; mg: milligrams; RCT: randomized controlled trial; RDA: recommended dietary allowance; SR: systematic review; TOS: The Obesity Society; USDA: United States Department of Agriculture; WMD: weighted mean difference

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<sup>&</sup>lt;sup>b</sup> For further information on the DASH dietary pattern visit: <a href="https://www.nhlbi.nih.gov/health-topics/dash-eating-plan">https://health.gov/dietaryguidelines/2015/resources/2015-2020</a> Dietary Guidelines.pdf

#### Prescribing Information for Chronic Weight Management Medications<sup>a</sup>

### Phentermine/Topiramate ER (Qsymia®) C-IV [3.75 mg/23 mg; 7.5 mg/46 mg; 11.25 mg/69 mg; 15 mg/92 mg capsules]

- Dosing: 3.75 mg/23 mg daily for 14 days; increase to 7.5 mg/46 mg for 12 weeks
- **Goal:** 3% weight loss within 12 weeks. If unsuccessful, increase to 11.25 mg/69 mg for 14 days; then increase to 15 mg/92 mg daily for 12 weeks. If 5% baseline weight loss is not achieved, discontinue by slow taper.
- Renal/Hepatic Impairment (CrCl <50 mL/min or Child-Pugh class B) Max dose: 7.5 mg/46 mg daily
- **Contraindications:** Pregnancy; a REMS program exists to inform prescribers and patients of risks; glaucoma; MAOI use during or within 14 days; hyperthyroidism
- Warnings: increased heart rate, mood & sleep disorders, suicidal behavior/ideation, increased creatinine, metabolic acidosis, cognitive impairment, abuse potential, nephrolithiasis, hypokalemia, adjust hypoglycemic medications to avoid hypoglycemia, tapered discontinuation of anticonvulsants over at least 1 week, avoid concomitant alcohol consumption
- Taper slowly to discontinue (1 dose every other day for ≥1 week) to prevent seizure. Discontinue if glaucoma or myopia develop.

#### Naltrexone/Bupropion ER (Contrave®) [8 mg/90 mg tablet]

- **Dosing:** Week 1: 1 AM tablet; Week 2: 1 AM tablet, 1 PM tablet; Week 3: 2 AM tablets, 1 PM tablet; Weeks 4 12: 2 AM tablets, 2 PM tablets
- Goal: 5% weight loss within 12 weeks. Discontinue if unsuccessful.
- Renal Impairment (moderate/severe) Max dose: 1 tablet twice daily. Not recommended for use in ESRD
- Hepatic Impairment Max dose: 1 tablet every morning
- **Contraindications:** Opioid use (agonists or partial agonists), pregnancy, uncontrolled hypertension, seizure disorder, bulimia & anorexia nervosa, abrupt discontinuation of alcohol, acute opioid withdrawal, concomitant MAOI use or initiation in patients receiving linezolid or IV methylene blue
- Warnings: Suicidal thinking/behavior [Boxed Warning], seizures, increased heart rate & blood pressure, neuropsychiatric symptoms, hepatotoxicity, may precipitate withdrawal if receiving opioids, adjust hypoglycemic medications to avoid hypoglycemia

#### Orlistat (Xenical®, Alli®) [120 mg; 60 mg (OTC) capsules]

- **Dosing:** Xenical®: 120 mg 3 times daily with a fat containing meal (up to 1 hour after meal); omit dose if meal is occasionally missed or contains no fat
- Alli® OTC labeling: 60 mg 3 times daily with a fat containing meal
- Renal/Hepatic Impairment: No adjustments provided by manufacturer
- Contraindications: Pregnancy; chronic malabsorption syndrome; cholestasis
- Warnings: Hepatotoxicity; cholelithiasis; increased urine oxalate and nephrolithiasis; interference with absorption of fat-soluble vitamins, cyclosporine, thyroid hormone, and anticonvulsants; adjust hypoglycemic drugs to avoid hypoglycemia

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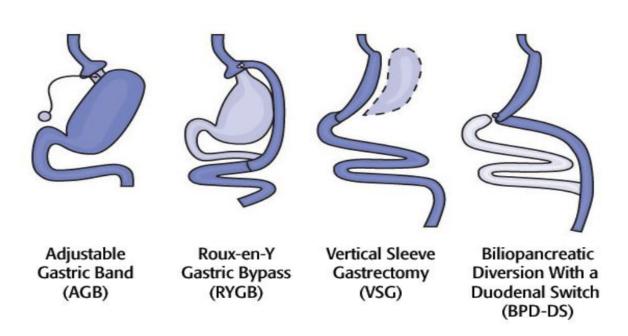
#### Liraglutide (Saxenda®) [6 mg/mL, 3 mL injection for subcutaneous use]

- Dosing: Initiate 0.6 mg daily for 1 week; increase by 0.6 mg per week to target dose of 3 mg; slow titration may
  improve tolerability; consider reducing the dose of the secretagogue (e.g., by 50%) or insulin to avoid
  hypoglycemia
- Goal: 4% weight loss within 16 weeks. Discontinue if unsuccessful.
- Renal Impairment: Use with caution
- Contraindications: Pregnancy; personal or family history of medullary thyroid carcinoma or MEN2 [Boxed Warning]
- Warnings: Thyroid C-cell tumors [Boxed Warning]; injection site and hypersensitivity reactions; gallbladder
  disease; pancreatitis (discontinue); increased heart rate; renal impairment; acute cholelithiasis and cholecystitis;
  acute/chronic renal failure exacerbation; suicidal behavior and ideation; adjust hypoglycemia drugs to avoid
  hypoglycemia
- a If applicable, refer to VA (<a href="http://www.pbm.va.gov">http://www.pbm.va.gov</a>) or DoD (<a href="http://www.health.mil/PandT">http://www.health.mil/PandT</a>) guidance/criteria for further recommendations on use of these agents.
- <sup>b</sup> In February 2020, the FDA requested the withdrawal of the weight-loss drug Belviq, Belviq XR (lorcaserin) from the U.S. market citing potential risk of cancer outweighing the benefits of use.

Abbreviations: CIV: Schedule IV controlled substance; CrCl: creatinine clearance; ER: extended-release; GLP-1: glucagon-like peptide-1 receptor; IV: intravenous; MAOI: monoamine oxidase inhibitor; MEN2: multiple endocrine neoplasia type 2; mg: milligram; min: minute; mL: milliliter; OTC: over-the-counter; REMS: Risk Evaluation and Mitigation Strategy

#### Most Common Types of Bariatric Procedures Performed in the United States [33]

## Surgical Treatments for Obesity



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### Post-Surgical Schedule for Clinical/Biochemical Monitoring [34]

	Pre- operative	1 Month	3 Months	6 Months	12 Months	18 Months	24 Months	Continue Annually
Complete blood count	Х	Х	Х	Х	Х	Х	Х	Х
LFTs	Х	Х	Х	Х	Х	Х	Х	Х
Glucose	Х	Х	Х	Х	Х	Х	Х	Х
Creatinine	Х	Х	Х	Х	Х	Х	Х	Х
Electrolytes	Х	Х	Х	Х	Х	Х	Х	Х
Iron/ferritin	Х			Xa	Xa	Xa	Xa	Xa
Vitamin B12	Х			Xa	Xa	Xa	Xa	Xa
Folate	Х			Xa	Xa	Xa	Xa	Xa
Calcium	Х			Xa	Xa	Xa	Xa	Xa
Intact PTH	Х			Xa	Xa	Xa	Xa	Xa
25-D	Х			Xa	Xa	Xa	Xa	Xa
Albumin/prealbumin	Х			Xa	Xa	Xa	Xa	Xa
Vitamin A	Х						+/-	+/-
Zinc	Х			+/-	+/-		+/-	+/-
Bone mineral density and body composition	Х				Xa		Xa	Xa
Vitamin B1			+/-	+/-	+/-	+/-	+/-	+/-

X: Indicate the suggested schedule for laboratory monitoring after bariatric surgery.

Xa: Examinations should be performed after Roux-en-Y gastric bypass

+/-: optional

Abbreviations: LFT: liver function test; PTH: parathyroid hormone

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#### Recommended Post-Bariatric Surgery Nutritional Supplementation and Medications [35]

- 1. Daily (lifelong) multivitamin (bariatric/pre-natal) with the following requirements:
  - Thiamine (B1) 50 100 mg
  - Cobalamin (B12) 350 1,000 μg (if duodenum bypassed then recommend 1,000 ug sublingual or parenteral (intramuscular/subcutaneous) administration to maintain normal levels
  - Folate 400 800 μg (800 1,000 μg in women of child-bearing age)
  - Iron 18 mg males/45 60 mg elemental iron in menstruating females or with duodenal bypass
  - Calcium 1,200 1,500 mg/day
  - Vitamin D (D3) 3,000 IU/day
  - Vitamin A 5,000 10,000 IU/day
  - Vitamin E 15 mg/day
  - Vitamin K 90 120 μg/day
  - Zinc 100 200% recommended dietary allowance (8 22 mg/day)
  - Copper 100 200% recommended dietary allowance
- 2. Ursodiol 300 mg twice a day for six months (if gallbladder present without stones) for gallstone prophylaxis during acute weight loss
- 3. Chemical venous thromboembolism prophylaxis no clear consensus on dosage or postoperative length of treatment
- 4. Proton pump inhibitors for Roux-en-Y gastric bypass/biliopancreatic diversion with duodenal switch to prevent marginal ulceration. Not indicated for SG unless development of symptomatic reflux.
- Avoidance of ALL potential ulcerogenic medications (i.e., nonsteroidal anti-inflammatory drugs/ acetylsalicylic acid)
- 6. Diabetes medications will likely stop or at least substantially reduce after surgery
- 7. Weight-based medication doses will likely decrease over time

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Access to the full guideline and additional resources are available at the following link:

<a href="https://www.healthquality.va.gov/guidelines/CD/obesity/">https://www.healthquality.va.gov/guidelines/CD/obesity/</a>

