

A Comprehensive Review of the Veterans Affairs (VA)-Department of Defense (DoD) Clinical Practice Management Guidelines for Adult Obesity

LTC Sky Graybill, M.D. Clinical Communities Speaker Series 24 September 2020



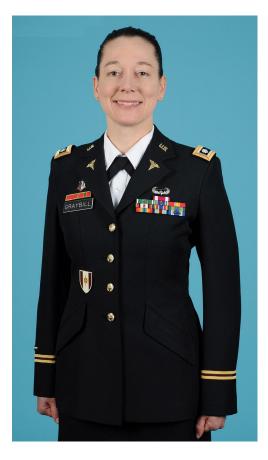
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At the conclusion of this activity, participants will be able to:

- 1. Outline the three components of comprehensive lifestyle intervention: behavioral, dietary, physical activity.
- 2. Illustrate pharmacotherapy options for the management of overweight and obesity.
- 3. Identify patients appropriate for referral or evaluation for bariatric surgery.

Overweight & Obesity



	Overweight	Obesity	Total
US Adult Population	32%	40%	72%
Active Duty Service Members ²	51%	15%	66%
Veterans in VA Care ³	36%	44%	80%

Overweight: Body mass index (BMI) 25 to 29.9 kg/m² Obesity: BMI 30 kg/m² or higher

(Hales et al., 2017) (Meadows et al., 2015) (VA, n.d.)

Conditions Associated with Overweight and Obesity



- Hypertension (HTN)
- Type 2 Diabetes and prediabetes
- Dyslipidemia
- Metabolic syndrome
- Obstructive sleep apnea

- Osteoarthritis
 (OA)/degenerative joint disease (DJD)
- Non-alcoholic fatty liver disease
- Gastroesophageal reflux disease (GERD)

Cancer



Evidence-based

- Provide decision support
- Standardize care
- Offer recommendations
- Contain algorithm for care
- Include support tools

VA/DoD CPG Process



- Develop key questions
- Conduct evidence review
- Working group
 - Evaluates strength of evidence
 - □ Formulates recommendations
- Review by internal and external stakeholders
- Finalize, publish and disseminate

2020 VA/DoD CPG for Overweight & Obesity



■ Published in 2006, updated in 2014

- New evidence regarding efficacy of treatments
 - Comprehensive Lifestyle Intervention (CLI)
 - Pharmacotherapy
 - □ Bariatric surgery and other procedures

2020 Obesity CPG Recommendations



18 Evidence-Based Recommendations					
Long-Term Management (15)	Short-Term Weight Loss (3)				
Comprehensive lifestyle intervention	Intragastric balloon				
Pharmacotherapy	Low carbohydrate diet				
Dietary supplements/nutraceuticals					
Bariatric procedures					



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.

Comprehensive Lifestyle Intervention: Modalities and Intensity



- Can be delivered in an individual or group setting, inperson, by telephone, or through synchronous video.
- Insufficient evidence to recommend a specific number of sessions
- However, most offer at least 12 intervention sessions in the first 12 months of intervention

Recommendation #6



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.



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.



- Dietary component is a core element of comprehensive lifestyle intervention
- Variety of evidence-based dietary approaches
- Based on patient preferences and medical conditions
- Negative energy balance is key



We suggest offering prescribed pharmacotherapy (specifically liraglutide, naltrexone/bupropion, orlistat, or phentermine/topiramate) for long-term weight loss in patients with a BMI ≥30 kg/m² and for those with a BMI ≥27 kg/m² who also have obesity-associated conditions, in conjunction with a comprehensive lifestyle intervention.

Recommendation #9



- BMI: \geq 30 or \geq 27 + obesity-associated condition
- Medications:
 - □liraglutide (Saxenda)
 - Inaltrexone/bupropion (Contrave)
 - Orlistat (Xenical, Alli)
 - Dphentermine/topiramate (Qsymia)
- Use in conjunction with comprehensive lifestyle intervention
- Reassess response
- Anticipate weight regain from discontinuation

Recommendation #9



Weight Loss and Adverse Event Outcomes with Medications for Long-term Weight Loss

Medication	Mean weight loss vs placebo	<u>></u> 5% weight loss	Discontinuation due to an adverse event
phentermine/ topiramate	-8.80 kg	75%	10%
liraglutide	-5.24 kg	63%	12%
naltrexone/ bupropion	-4.95 kg	55%	13%
orlistat	-2.63 kg	44%	8%

Note: lorcaserin is not included in this table as it was requested to be removed from the U.S. market in February, 2020.

(Khera, Murad, & Chandar, 2016)

Weight loss Medications



Table 3: Prescribing Information for Chronic Weight Management Medications		Orlistat (Xenical®, Alli®) [120 mg; 60 mg (OTC) capsules]			
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: • Xenical®: 120 mg 3 times daily	/with a	with a Contraindications: Pregnancy;	
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; increase to 15mg/92 mg daily for 12 weeks. If 5% baseline weight loss is not achieved, discontinue by slow taper. <u>Renal/Hepatic Impairment</u> (CrCl <50 mb brie or Child Duck 3.0% Manufaces 3.5	Contraindications: Pregnancy; REMS; Glaucoma; MAOI use during or within 14 days; Hyperthyroidism Warnings: ↑ heart rate, mood & sleep disorders, suicidal behavior/ideation, ↑ creatinine, metabolic acidosis, cognitive impairment, nephrolithiasis, drug abuse, hypokalemia. • Taper slowly to discontinue (1 dose every other day for ≥1 week) to	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 <u>Renal/Hepatic Impairment</u> : No adjustments provided by manufacturer		Cholestasis Warninga: Hepatotoxicity; cholelithiasis; ↑ urine oxalate and nephrolithiasis; decreased absorption of fat-soluble vitamins, cyclosporine, thyroid hormone, and anticonvulsants; adjust hypoglycemic drugs to avoid hypoglycemia	
mL/min or Child-Pugh 7-9): Max dose: 7.5 every other day for 21 week) to mg/46 mg daily prevent seizure. Discontinue if glaucoma or myopia develop	Liraglutide (Saxenda®) [6 mg/mL, 3mL injection for subcutaneous use]				
Naltrexone/Bupropion ER (Contrave®) [8 mg/90 mg tablet]		Dosing: Initiate 0.6 mg daily for 1 week; increase by 0.6 mg	Contraindications: Pregnancy; Personal or family history of medullary thyroid carcinoma or		
 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. <u>Renal Impairment</u> (moderate/severe): Max dose: 1 tablet twice daily Not recommended for use in patients with ESRD. 	Contraindications: Opioid use; Pregnancy; Uncontrolled hypertension; Seizure disorder; Bulimia & anorexia nervosa; Abrupt stop of alcohol; acute opioid withdrawal; MAOI's Warnings: Suicidal thinking/ behavior [Boxed Warning]; Seizures, ↑ heart rate & blood pressure; neuropsychiatric symptoms; hepatotoxicity; may precipitate withdrawal if receiving	per week to target dose of 3 mg; slow tibration may improve tolerability Goal: 4% weight loss within 16 weeks. Discontinue if unsuccessful. <u>Renal Impairment</u> : Use with caution	MEN2 [E Warning (Disconti suicidal I hypoglyc secretag 50%) or	MEN2 [Boxed Warning] Warnings: Thyroid C-cell Tumors [Boxed Warning]; gallbladder disease; pancreatitis (Discontinue); ↑ heart rate; renal impairment; suicidal behavion/ideation; to reduce the risk for hypoglycemia, decrease concomitant secretagogue (ie. sulfonylureas) dose (e.g., by 50%) or insulin	
Hepatic Impairment: Max dose: 1 tablet in the morning.	In February 2020, the FDA requested the withdrawal of the weight-loss drug lorcaserin (Belviq, Belviq XR) from the US market citing potential risk of cancer outweighs the benefits of use.				

(<u>www.healthquality.va.gov/guidelines/CD/obesity</u>, n.d.)

Recommendation #11



We suggest against using dietary supplements or nutraceuticals for clinically meaningful short-term weight loss or long-term weight management.



- Nutraceutical a food or dietary supplement that is believed to provide health benefits
- Not studied in conjunction with comprehensive lifestyle intervention
- Low quality of evidence
 - Several limitations and confounders
- Marketing may lead to unrealistic expectations



We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, to patients with a BMI \geq 30 kg/m² and type 2 diabetes mellitus.



- Most durable modality to affect long-term weight loss
- Potential remission of type 2 diabetes without the use of medications



We suggest offering intragastric balloons in conjunction with a comprehensive lifestyle intervention to patients with obesity (BMI ≥30 kg/m²) who prioritize short-term (up to six months) weight loss.



Intragastric balloons may be effective for shortterm weight loss

□Food and Drug Administration (FDA) approved usage for six months

- Consultation with a bariatric surgeon
 - Placement
 - □Management



Putting CPG Recommendations into Clinical Practice



- Setting weight loss, diet and physical activity goals
- Addressing barriers to change
- Self-monitoring
- Problem-solving to maintain lifestyle changes

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)

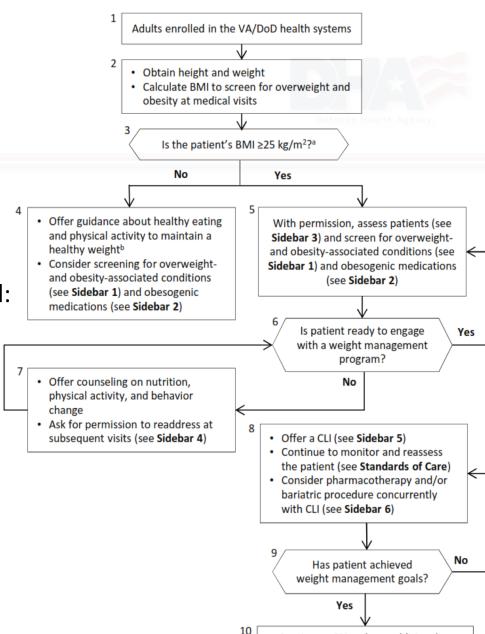


- Specific diet less important than calorie deficit
- Any evidence-based diet can be chosen based on the patient's medical condition and likelihood of adherence
- Evidence-based diets include: low carbohydrate, Dietary Approaches to Stop Hypertension (DASH), low fat, low calorie
- Consider consult with registered dietitian



- Recommend at least 150 minutes per week in conjunction with diet to lose weight
- Recommend 200-300 minutes per week to maintain weight loss
- Short bursts of activity or a single longer episode

Algorithm



 Continue a CLI and any additional therapy for weight maintenance
 Reassess periodically including for

management

pharmacotherapy and follow-up for long-term post-bariatric procedure

- For patients of Asian descent: is BMI
 ≥23 kg/m²?; for patients >65 years old: consider individualized assessment
- See, for example, 2015-2020 Dietary Guidelines for Americans, 8th edition, available at:

https://health.gov/dietaryguidelines/2015/ and Physical Guidelines for American, 2nd Edition, available at:

https://health.gov/paguidelines/second-edition/

(www.healthquality.va.gov/guidelines/CD/obesity, n.d.)



- Thirty year-old staff sergeant presents for failing to meet body fat standards despite exercise
- Past Medical History (PMHx): knee osteoarthritis
- Physical Exam (PE): obesity, muscle strength 5/5 throughout, no wide/purple stretch marks
- Thyroid function tests: unremarkable



- Discuss significance of obesity related conditions
- Ask what he would like to do over the next three to six months with his diet and exercise
- Patient thinks he could tolerate riding a bike and using an elliptical better than running
- Patient thinks his diet is generally healthy but is not aware of intake amount
- Encourage food log for portion control

Case 1: Treatment Course



- Army Wellness Center for dietitian and exercise physiologist coaching
- Integrated behavioral health clinician for sleep hygiene
- Six months later, meets body fat standards and is released from the Army Body Composition Program
- Holistic Health and Fitness (H2F) system for unit's athletic trainer and dietician to avoid weight regain



- Ten years after patient retires, BMI is 33 kg/m² despite attempts at diet and exercise modification
- PMHx: OA, GERD, HTN, hyperlipidemia (HLD), and type 2 diabetes
- Medications: omeprazole, lisinopril, atorvastatin, metformin, exenatide, empagliflozin
- HbA1c: 10%
- Unremarkable laboratory results: complete blood count (CBC), liver function test (LFT), electrolytes, parathyroid hormone (PTH), albumin, iron, ferritin, zinc, vitamin A, vitamin B1, vitamin B12, vitamin D and folate.
- Patient is interested in bariatric/metabolic surgery and you decide he is a reasonable candidate

Case 1: Shared Decision-Making



Risks

- □ Major surgery, though peri-operative mortality < 0.5%
- Morbidity < 4% for strictures/ulcer, bowel obstruction, bleeding, venous thromboembolism (VTE), infection, self-harm, malabsorption</p>
- Benefits
 - □ Most effective and durable weight loss adjunct to diet and exercise
 - Mortality benefit over time
 - □ Improvement in cardiovascular disease (CVD), T2DM, HLD, and HTN
- Shared Decision: Roux-en Y Gastric Bypass
 - □ Slightly better weight loss and diabetes remission rates than gastric sleeve
 - Gastric sleeve could worsen GERD



■ Veteran is a 62 year-old woman

- PMHx: type 2 diabetes complicated by neuropathy, high blood pressure
- BMI is 36 kg/m²
- First step: Ask for permission!

"I am concerned about how your weight might be affecting your health. Is this something you feel comfortable discussing today?"

Case #2: Obesogenic Agent Review



Next: Review medication list

 \rightarrow Look for culprits making weight loss harder

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Next: Review medication list

 \rightarrow Look for culprits making weight loss harder

- 1. Glipizide 10mg twice daily
- 3. Metoprolol tartrate 25 mg twice daily
- 5. Gabapentin 600mg three times daily

AVOID iatrogenic weight GAIN!

Case #2



Select Medications and Potential Effects on Weight			
Category	Potential for Weight Gain	Alternative to Consider	
Antidepressants	Tricyclic antidepressants (amitriptyline, nortriptyline); mirtazapine; SSRIs (paroxetine); Monoamine oxidase inhibitors	bupropion; desvenlafaxine; venlafaxine	
Antipsychotics	quetiapine; clozapine; olanzapine; risperidone; thioridazine	aripiprazole; haloperidol; ziprasidone	
Antiepileptics or mood stabilizers	gabapentin; pregabalin; carbamazepine; divalproex; lithium; valproic acid; vigabatrin	topiramate; lamotrigine; zonisamide	
Antihyperglycemic agents	Insulin; Sulfonylureas; Meglitinides; Thiazolidinediones	GLP-1 agonists; SGLT2 inhibitors; metformin; Alpha- glucosidase inhibitors; pramlintide; DPP-4 inhibitors	
Beta-Blockers	metoprolol; atenolol; propranolol	carvedilol; nebivolol Other drug classes available (ACEIs, ARBs, CCBs, diuretics) per indication	
Alpha-Blockers	terazosin	BPH: doxazosin, alfuzosin, tamsulosin	
Glucocorticoids	prednisone; methylprednisolone; hydrocortisone	NSAIDs, biologics/DMARDs, nontraditional therapies	
Hormonal agents	Progestins	For contraception, consider alternative methods (e.g., copper IUD)	
Antihistamines	cetirizine; cyproheptadine	Depending on symptoms, consider decongestants, inhalers, nasal irrigation	





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Category	Potential for Weight Gain	Alternative to Consider
Antidepressants	Tricyclic antidepressants (amitriptyline, nortriptyline); mirtazapine; SSRIs (paroxetine); Monoamine oxidase inhibitors	bupropion; desvenlafaxine; venlafaxine
Antipsychotics	quetiapine; clozapine; olanzapine; risperidone; thioridazine	aripiprazole; haloperidol; ziprasidone
Antiepileptics or mood stabilizers	<mark>gabapentin;</mark> pregabalin; carbamazepine; divalproex; lithium; valproic acid; vigabatrin	topiramate; lamotrigine; zonisamide
Antihyperglycemic agents	Insulin; Sulfonylureas; Meglitinides; Thiazolidinediones	GLP-1 agonists; SGLT2 inhibitors; metformin; Alpha-glucosidase inhibitors; pramlintide; DPP-4 inhibitors
Beta-Blockers	metoprolol; atenolol; propranolol	carvedilol; nebivolol Other drug classes available (ACEIs, ARBs, CCBs, diuretics) per indication
Alpha-Blockers	terazosin	BPH: doxazosin, alfuzosin, tamsulosin
Glucocorticoids	prednisone; methylprednisolone; hydrocortisone	NSAIDs, biologics/DMARDs, nontraditional therapies
Hormonal agents	Progestins	For contraception, consider alternative methods (e.g., copper IUD)
Antihistamines	cetirizine; cyproheptadine	Depending on symptoms, consider decongestants, inhalers, nasal irrigation

Case #2: Obesogenic Agent Alternatives



- Consider regimen that does not include a beta blocker if no CV event history
- Consider SWITCH from glipizide (sulfonylurea) to alternative hypoglycemic agent (SGLT2i or GLP-1 agonist associated with weight loss; DPP4i weight neutral)
- Suggest WEAN DOWN on gabapentin while adding one or more:
 - Topiramate (OFF label; Warnings/Precautions include: nephrolithiasis and acute closed angle glaucoma, teratogenic)
 - Duloxetine (FDA indication for diabetic neuropathy)
 - Capsaicin cream (usually not monotherapy)
 - Topical lidocaine
 - Topical NSAID

^{*}Refer to respective VA or DoD formulary listings, pre-authorization requirements, criteria for use, or other clinical recommendations.



- Ask about weight history: weight loss attempts, barriers and facilitators to success
- Ask if she would be interested in considering referral to the MOVE! program for CLI.
- Simultaneously, is she interested in considering starting a medication for weight loss?
- Would she be interested in more information regarding bariatric surgery option?

Case #2: Weight Management Pharmacotherapy Considerations



Obtain history:
 Kidney stone in the past
 Seizure as a child
 Trying to quit smoking
 Insomnia

Resources and Links



- Clinical Practice Guideline and Tools: <u>www.healthquality.va.gov</u>
- MOVE! <u>www.move.va.gov</u>
- DoD toolkit and programming <u>www.qmo.amedd.army.mil</u>
- VA Pharmacotherapy Criteria for Use: <u>https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx</u> <u>https://www.pbm.va.gov/</u>
- VA Academic Detailing Service Documents and Resources: <u>https://vaww.portal2.va.gov/sites/ad/SitePages/WeightManagement.aspxhttps</u> ://vaww.portal2.va.gov/sites/ad/Education%20Materials/Weight%20Managem <u>ent/WM_Provider_QuickReferenceGuide_IB101159.pdf</u>

Key Takeaways



- Obesity is a chronic disease that requires lifelong management
- Shared decision-making is fundamental to weight management
- Review medications and eliminate obesogenic agents used to treat other medical illnesses
- Consider weight neutral agents or those that promote weight loss.
- Comprehensive lifestyle intervention (CLI) is central to successful and sustained weight loss and maintenance
- Negative energy balance should be achieved through decreased caloric intake and increased physical activity

Key Takeaways



- Dietary supplements or nutraceuticals do not contribute to clinically meaningful weight loss or weight management
- Pharmacotherapy and/or bariatric procedures are options in conjunction with CLI; both require long-term follow-up
- Individualize FDA-approved medications for weight loss based on efficacy, safety, potential side effects, patient tolerability, and preference
- Bariatric procedures are effective for weight loss and particularly helpful for Type 2 diabetes
- Combining CLI, pharmacologic, and surgical options simultaneously can enhance weight loss and maintenance





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Questions?

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- 1. Go to URL: <u>https://www.dhaj7-cepo.com/content/clinical-communities-speaker-series-military-health-care-select-promising-practices-24-sept</u>
- 2. Click on the REGISTER/TAKE COURSE tab.
 - a. If you have previously used the CEPO CMS, click login.
 - b. If you have not previously used the CEPO CMS click register to create a new account.
- 3. Follow the onscreen prompts to complete the post-activity assessments:
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 - b. Complete the Evaluation
 - c. Take the Posttest
- 4. After completing the posttest at 80% or above, your certificate will be available for print or download.
- 5. You can return to the site at any time in the future to print your certificate and transcripts at https://www.dhaj7-cepo.com/
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