# Guidance for Managing Scarce Weight Management Medication Resources in VA

Developed by VA Pharmacy Benefits Management Services (PBM) Scarce Resource Allocation Workgroup

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## Background

The Department of Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline for Management of Adult Overweight and Obesity (VA/DoD CPG) recommends offering weight management medications (WMM) that are U.S. Food and Drug Administration (FDA)-approved for chronic weight management along with comprehensive lifestyle intervention to Veterans with body mass index (BMI) $\geq$ 27 kg/m$^2$ with a weight-related condition and Veterans with a BMI $\geq$ 30.

Given that as of September 2023 an estimated 2.9 Million (M) Veterans were identified out of the overall Veteran population receiving care within VA to be potentially eligible for WMM based on BMI, VA's considerations for management of scarce WMM is *population health* focused. This approach aims to minimize potential health inequities in the context of scarce resources by providing consistent guidance for the health care system. It emphasizes the importance of shared decision-making between Veterans and their health care team that personalizes evidence-based care in consideration of each Veteran's health status, needs, goals, values, and preferences.

## Rationale for this Guidance

The availability of newer, more effective FDA-approved WMM is associated with increased interest in WMM for individuals with higher body weights. In VHA, WMM utilization increased 177% in 2023 compared with 2022, with this increase primarily attributed to FDA approval of an additional WMM in 2021. The increase likely would have been greater if not for the limited supply from the manufacturer. With FDA approval of additional WMM expected, utilization will likely continue to increase. Although this represents a significant step forward in providing Veterans with treatments needed to effectively lose and manage weight, additional resources are needed to support utilization.

Based on current trends both within and outside of VHA, four potential sources of scarcity have been identified that could affect availability of weight management medications in VHA: (1) drug supply chain, (2) providers to prescribe and support WMM pharmacotherapy, (3) access to MOVE! comprehensive lifestyle intervention, (4) budgetary constraints. Given that these sources of scarcity will likely vary by VISN and VA medical facility, and that one or more could be exerting influence at any point in time, this guidance was developed to be used when resources are scarce, regardless of the specific source.

## Ethical Approach

Augmenting resources is more ethically desirable than prioritizing patients for treatment. Therefore, VHA and its facilities should augment resources to meet clinical needs prior to implementing practices that limit patient access to treatment. However, given the potential resource constraints described above, an approach to WMM allocation when resources are insufficient to treat all patients for whom treatment is clinically indicated is of paramount importance for our nation's Veterans and the VA Healthcare system.

Resource constraints that limit the availability of WMM for all eligible Veterans present VA with significant ethical challenges for how to provide treatment fairly to Veterans with higher body weights. VA's mission, I CARE values, and ethics principles obligate VA to articulate and use a transparent allocation framework informed by the best available clinical evidence. An ethically grounded approach for allocation of WMM centered on principles of beneficence and utility serves as the basis for consistent, accountable, and equitable decision making across the system.

## General Clinical Considerations for Use of WMM

- Patient engagement in comprehensive lifestyle intervention should be emphasized as a foundational component of all weight management strategies, including pharmacotherapy. Combining WMM and comprehensive lifestyle intervention optimizes the potential benefit of WMM in both the short and long term for Veterans with overweight and obesity while promoting effective use of VA resources.
- Patients who may benefit from metabolic and bariatric surgery as an option for weight management should be identified and engaged in shared decision-making regarding this option of care.
- Medications that may contribute to weight gain or impede weight loss should be identified with consideration for discontinuation, alternate therapy selection, or dose reduction.
- Ongoing follow-up after WMM therapy initiation, including safety and efficacy monitoring, should always occur. WMM should be modified or discontinued when response is inadequate or when safety concerns exist.
- WMM are indicated for chronic therapy. Interruption or discontinuation of effective therapy increases the risk for weight regain.

## How to Use This Guidance

This guidance provides a framework to VA medical facilities for how to approach allocation of WMM resources when there are scarce resources. This framework does not replace the PBM Criteria for Use (CFU); rather it should be used in tandem with the CFU. Specifically, CFU should be applied first to determine eligibility for a WMM, then this framework may be consulted based on local resources. In recognition that each VISN and associated VA medical facility will have unique compositions, strengths, and constraints, this guidance is NOT prescriptive or binding. It is intended to facilitate fair, transparent, and consistent decision-making across the VA system.

This guidance is intended for use *going forward*; it is dynamic and based on evidence, resources, and monitoring of use. It is intended to be implemented flexibly at the facility level. It is expected that exceptions will be made collaboratively by the health care team based on individual patient factors and clinical considerations. This guidance applies to new therapy initiation only. Patients already on effective therapy are recommended to continue. Facilities should determine when resources are sufficient to proceed with initiating therapy; similarly, facilities should determine when resources are limited to the extent that therapy initiation should be paused.

## Decision-Making Tier Framework

The following tier framework is based on current medical evidence, ethical principles relevant to scarce resource allocation, and VA subject matter expertise. The content is dynamic and will be adapted as new relevant information becomes available. The purpose is to promote transparency and consistency in practitioners' clinical decision-making and standardize and improve the quality of patient care in the context of scarce resources.

The tiers provide an allocation framework for use of WMM when there are more patients with a clinical indication for a WMM than resources to treat them. The framework, based on the ethical principles of beneficence, utility, and equity, is designed to identify patients most likely to medically benefit from WMM treatment and least harmed medically by delaying treatment, to enable prioritization for the sickest patients who would be most harmed by delaying treatment. The tier framework must be used within the context of the VA PBM CFU for WMM. The use of these medications for other established primary indications (e.g., diabetes) is outside the scope of this guidance document.

Within each tier, there are sub-tiers that describe the hierarchy. For example, Tier 1a is higher than 1b. Most tiers are further stratified by BMI to provide additional means to prioritize within each sub-tier. The tiers are intended to provide population-level guidance. Clinicians should use this population-level guidance and interpret it in the clinical context of the individual patient. For guidance to assist clinicians in evaluating impact of obesity at an individual patient level, this reference may be helpful: Clinical evaluation of patients living with obesity - PMC (nih.gov) .

**Tier 1: Patients for whom treatment with a WMM will likely reduce short-term mortality risk.**
1a: Patients with life-threatening, weight-related conditions. Clinicians should consider how directly the mortality threat correlates with excess weight, likelihood of short-term harm if WMM therapy is delayed, and how amenable the condition(s) will be to treatment with a WMM. For Tier 1a, BMI stratification is omitted and short-term mortality risk is defined as a reasonable risk of death within a short timeframe (for example, within 12 months) if WMM therapy is not initiated. These are expected to be rare scenarios allowing for compassionate use in extreme circumstances, e.g., patients unable to achieve weight loss goals required for life-saving surgery who would reasonably achieve goals for surgery with support of a WMM.

1b: Patients for whom high-quality, peer reviewed, published evidence suggests short-term mortality benefit with a WMM for a specific cohort with overweight or obesity. The evidence must come from well-designed, randomized controlled trials (RCT), providing level 1A evidence and published in peer-reviewed journals. At the time of publication, Tier 1b describes a population aligned with the SELECT Study, is applicable to semaglutide only, and cardiovascular disease is defined as prior myocardial infarction; prior ischemic or hemorrhagic stroke; or symptomatic PAD with an ankle-brachial index <0.85, peripheral arterial revascularization procedure or amputation due to atherosclerotic disease. This tier's indications and applicable WMMs are expected to expand with emerging evidence.

**Tier 2: Patients likely to experience short-term benefit from weight reduction based on the presence of weight-related conditions.**
Patients with evidence of disease associated with excess weight. Clinicians should consider how directly the condition correlates with excess weight, likelihood of short-term harm if WMM therapy is delayed, and how amenable the condition(s) will be to treatment with a WMM. These tiers include populations for whom RCT data suggest short-term benefit (e.g., patients with obesity and heart failure with preserved ejection fraction (HFpEF) with or without diabetes). Also included are populations experiencing or at short-term risk for end organ damage or incapacitating disability due to excess weight.

In the absence of RCT data, Tier 2 hierarchy is based on the number of weight-related comorbid conditions and is further stratified by BMI classification. The number of comorbidities and BMI are selected as surrogate indicators of weight-related disease severity with the intent to identify persons most likely to be harmed by treatment delay. These are imperfect surrogates and have limitations as evidence continues to emerge to inform obesity management. To that end, persons with fewer than the listed number of weight-related conditions, but experiencing advanced disease, may benefit from treatment sooner and should be considered for early treatment.

Examples of weight-related conditions include (but are not limited to) hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, and metabolic dysfunction-associated steatotic liver disease (MASLD).

Examples of advanced disease associated with weight-related conditions include severe obstructive sleep apnea documented by sleep study, incapacitating osteoarthritis of a weight-bearing joint (housebound, non-ambulatory, registered disability), and metabolic dysfunction-associated steatohepatitis (MASH) with objective evidence of fibrosis (e.g., Stage >=F2), obesity hypoventilation syndrome, inability to work due to weight). Consideration should also be given to patients experiencing a treatment delay for a severe weight-related condition due to excess weight who could reasonably achieve goals for treatment with support of a WMM (e.g., unable to achieve weight loss goals required for surgery).

**Tier 3: Patients with elevated BMI suggesting an increased risk for weight-related conditions, but without a diagnosed weight-related condition.**

This is the lowest tier in the hierarchy as it includes persons at risk for weight-related conditions but who do not exhibit evidence of weight-related disease. As stated, during periods of scarce resources, the recommended approach is to first treat persons believed to be at greatest risk for harm if treatment were delayed. However, as resources permit, clinical evaluation and treatment, if indicated, is strongly recommended for persons in Tier 3. The minimum BMI for Tier 3 is 30 $kg/m^2$ consistent with VA PBM Criteria for Use and FDA prescribing labels for WMM.

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| **Tier 1**<br>Patients who may be most harmed by delaying treatment | **a.** | Patients with a **life-threatening weight-related condition** or experiencing treatment delay for a life-threatening condition due to excess weight for whom treatment delay would likely increase mortality risk within the next year | | |
| | **b.** | Patients without diabetes who are **> 45yrs old with established cardiovascular disease** | **AND** | i. BMI ≥ 40 $kg/m^2$ |
| | | | | ii. BMI 35–39.9 $kg/m^2$ |
| | | | | iii. BMI 30–34.9 $kg/m^2$ |
| | | | | iv. BMI 27–29.9 $kg/m^2$ |
| **Tier 2**<br>Patients likely to experience short-term benefit from weight reduction based on the presence of weight-related conditions | **a.** | Patients with at **least three weight-related conditions**<br>**OR**<br>**Heart Failure with Preserved Ejection Fraction (HFpEF)** | **AND** | i. BMI ≥ 40 $kg/m^2$ |
| | | | | ii. BMI 35–39.9 $kg/m^2$ |
| | | | | iii. BMI 30–34.9 $kg/m^2$ |
| | | | | iv. BMI 27–29.9 $kg/m^2$ |
| | **b.** | Patients with at least **two weight-related conditions** | **AND** | i. BMI ≥ 40 $kg/m^2$ |
| | | | | ii. BMI 35–39.9 $kg/m^2$ |
| | | | | iii. BMI 30–34.9 $kg/m^2$ |
| | | | | iv. BMI 27–29.9 $kg/m^2$ |
| | **c.** | Patients with at least **one weight-related condition** | **AND** | i. BMI ≥ 40 $kg/m^2$ |
| | | | | ii. BMI 35–39.9 $kg/m^2$ |
| | | | | iii. BMI 30–34.9 $kg/m^2$ |
| | | | | iv. BMI 27–29.9 $kg/m^2$ |
| **Tier 3**<br>Patients with elevated BMI, suggesting an increased risk for weight-related conditions, but without a diagnosed weight-related condition | | | | i. BMI ≥ 40 $kg/m^2$ |
| | | | | ii. BMI 35–39.9 $kg/m^2$ |
| | | | | iii. BMI 30–34.9 $kg/m^2$ |