

Patient Name: _____ Form Completed By: _____ Date: _____

Pre-Pharmacological Treatment Interventions

These steps should be completed prior to pharmacological treatment:	YES	NO
1. Does the patient have significant weight loss? (> 5% in past 30 days or > 10% in past 180 days)	<input type="checkbox"/>	<input type="checkbox"/>
2. Has the patient been evaluated for depression?	<input type="checkbox"/>	<input type="checkbox"/>
3. Has an antidepressant been added (such as Remeron® (mirtazapine)?)	<input type="checkbox"/>	<input type="checkbox"/>
4. Have other possible causes been evaluated? (Swallowing disorders, taste/sensory changes, ill-fitting dentures, missing teeth, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
5. Have <i>non-pharmacological</i> interventions been tried? (Favorite foods, ethnic food preferences, assistance, food served at proper temp, Comfortable surroundings at mealtime, verbal cueing, house supplements, snacks, high calorie foods, etc)	<input type="checkbox"/>	<input type="checkbox"/>
6. Have additional interventions been tried? (Multivitamins, medical nutrition supplements, protein added to meals, Pre-albumin testing)	<input type="checkbox"/>	<input type="checkbox"/>
7. Has the weight loss persisted despite intervention attempts?	<input type="checkbox"/>	<input type="checkbox"/>
Pre-treatment steps completed?	<input type="checkbox"/>	<input type="checkbox"/>

Current medication order to treat Involuntary Weight Loss

- DRONABINOL** _____
- MEGESTROL** _____
- MIRTAZAPINE** _____
- OTHER** _____

Treatment Guidelines	YES	NO
1. If a weight gain/appetite stimulant was initiated, was weight monitored weekly for 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
Week 1: Date: _____ Weight: _____		
Week 2: Date: _____ Weight: _____		
Week 3: Date: _____ Weight: _____		
Week 4: Date: _____ Weight: _____		
2. Physician follow-up for discontinuation of medication after evaluation of effectiveness in 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>

Provide additional intervention details below (as needed):

Remove this page and attach intervention/progress notes (as needed).

Additional clinical considerations for these medication therapies are included on the following page.

Signature: _____

Clinical Considerations: 2, 4, 8➤ **Dronabinol (Marinol®)**

- **FDA-approved Indication: Anorexia in patients with AIDS**
 - Initial (capsules): 2.5 mg twice daily (1 h before lunch and dinner); if intolerable, may reduce to 2.5 mg once daily (1 h before dinner or at bedtime to reduce risk of CNS symptoms, particularly in elderly); may increase dose gradually based on response/tolerability (**max: 20 mg/day** [in divided doses])
 - Initial (oral solution): 2.1 mg twice daily (1 h before lunch and dinner); if tolerated/further therapeutic effect is needed, may gradually increase to 2.1 mg 1 h before lunch and 4.2 mg 1 h before dinner, and (if needed) to 4.2 mg twice daily (1 h before lunch and dinner) (**max: 16.8 mg/day** [in 2 divided doses])
 - If unable to tolerate 2.1 mg twice daily, consider 2.1 mg once daily (1 h before dinner or at bedtime) to lower risk of central nervous system (CNS) effects
- **Off-label Use: Cancer-related anorexia**
 - Initial (capsules): 2.5 mg by mouth twice daily (1 h before lunch and dinner)
- Dronabinol has demonstrated efficacy in improving appetite in patients with AIDS, however, less so when compared to megestrol in patients with advanced cancer.
- **Dronabinol is ranked as Acceptable with Caution by the PharMerica P&T committee** due to unfavorable side effect profile.
 - **Dronabinol can be associated with profound CNS side effects.**⁵
 - When CNS side effects do occur, they usually resolve in 1 to 3 days and do not require dose reduction.²
 - Adverse effects (>10%) include: abdominal pain, dizziness, drowsiness, dysphoria, emotional lability, euphoria, impaired cognition, nausea, paranoia, and vomiting.
- **Current Beers Criteria List does not reference dronabinol.**

➤ **Megestrol (Megace EC)**

- **FDA-approved Indication: Anorexia, cachexia, or unexplained significant weight loss in patients with AIDS**
 - Initial (oral): 625 mg daily (of 125 mg/mL suspension) OR 800 mg daily (of 40 mg/mL suspension); daily doses of 400 to 800 mg
- **Off-label Use: Cancer-related cachexia**
 - 200 to 600 mg/day; treatment length depends on goals and risks/benefits
 - 160 to 800 mg/day doses have been effective at increasing weight, with higher doses (>160 mg) associated with more weight gain
- **Megestrol is ranked as Acceptable with Caution by the PharMerica P&T committee** as it has *not* been shown effective in producing significant weight gain *in the elderly*.
- Potential side effects include: edema, hypogonadism, hyperglycemia, adrenal suppression, and deep vein thrombosis.
 - For the latter reason, megestrol acetate should not be used in immobile persons.
- **Megestrol has been associated with an increase in all-cause mortality without increasing weight gain in elderly nursing home residents.**⁵
- **Current Beers Criteria List strongly recommends avoiding megestrol** due to minimal effect on weight and increased risk of thrombotic events/possibility of death in the elderly.¹

➤ **Mirtazapine (Remeron®)**

- **No FDA-approved or off-label indications/dose recommendations for weight gain**
- **FDA-approved: Major depressive disorder**
- Mirtazapine is **associated with weight gain**, and it may be a **reasonable option for elderly adults with depression and weight loss**.
 - Onset of significant weight gain has been seen after 1 week of therapy.
- **Mirtazapine is ranked as Acceptable by the PharMerica P&T committee**
- Potential side effects include: appetite stimulation, constipation, drowsiness, dizziness, hypercholesterolemia, weight gain, xerostomia.
- **Black Box Warning:** increased the risk of suicidal thoughts and behaviors.
- **Current Beers Criteria strongly recommends using with caution** as it may exacerbate or cause SIADH or hyponatremia.¹

Other Drugs used to Treat Involuntary Weight Loss➤ **Cyproheptadine**

- **Off-label Use: Decreased appetite secondary to chronic disease**
 - Initial (oral): 2 mg 4 times/day for one week, then 4 mg 4 times/day
- **Discontinue** if weight gain or appetite stimulation does not occur within first few weeks.
- Research has shown that cyproheptadine may improve appetite, but it does not seem to improve weight gain in patients with advanced cancer.⁶
- **Cyproheptadine is ranked Non-Acceptable by the PharMerica P&T Committee due to unfavorable side effect profile in the elderly.**
- Potential side effects include: blurred vision, confusion, dizziness, drowsiness, constipation, agranulocytosis, nausea, vomiting.
- **Current Beers List Criteria strongly recommends avoiding cyproheptadine due to anticholinergic effects and reduced clearance in the elderly.**¹

Reference:

- 1) American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694. <https://pubmed.ncbi.nlm.nih.gov/30693946/>.
- 2) Clinical Pharmacology Database. <https://www.clinicalkey.com/pharmacology/login>. [subscription required]. Accessed February 10, 2022.
- 3) Dickerson L: Retrospective Review and Intervention in the use of Megesterol Acetate in residents of Skilled Nursing Facilities in South Carolina. The Consultant Pharmacist Dec 2002; 17(12): 1040-44
- 4) Lexicomp. <https://online.lexi.com/lco/action/login>. [subscription required]. Accessed February 10, 2022.
- 5) Ritchie C, Yukawa M. Geriatric nutrition: Nutritional issues in older adults. UpToDate [subscription required]. <https://www.uptodate.com/login>. Updated August 9, 2021. Accessed February 9, 2022.
- 6) Unintentional Weight Loss in Older Adults. DynaMed [subscription required]. <https://www.dynamed.com>. Accessed February 9, 2022.
- 7) Yeh SS: Improvement in quality of life measures and stimulation of weight gain after treatment with Megesterol Acetate oral suspension in geriatric cachexia: results of a double-blind, placebo controlled study. J Am Geriatr Soc 2000; 48:485-92
- 8) Yeh et al: Pharmacologic Treatment of Geriatric Cachexia: Evidence and Safety in Perspective. JAMDA DOI:101016/J.JAMDA.2007.05.001

This resource highlights important clinical considerations sourced from products' FDA labels, primary research articles, and tertiary drug information references.

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