The Art & Science of Prescribing Anti-Obesity Medications:
A Case Based Approach

Amy Ingersoll, PA-C, MMS
<table>
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<th><strong>Objectives</strong></th>
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<td><strong>Discuss</strong></td>
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<td><strong>Review</strong></td>
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Obesity is a chronic, progressive, relapsing disease that requires a comprehensive, long-term approach.
Obesity is treatable

Treating obesity improves outcomes

• Prevents further complications
• Many complications improve or resolve
Obesity Treatment Goals

- Prevent further weight gain / induce weight loss
- Prevent complications
- Improve complications & co-morbidities
- Improve quality of life
Use of Pillars

You may utilize all of the comprehensive treatment pillars to treat one patient, or maybe only a few.
Pharmacotherapy goals

- Treat the disease of obesity
- Facilitate healthy eating behavior
- Slow the progression of weight gain & regain
- Improve weight, health, quality of life

Even a 5-10% weight reduction improves weight-related complications.
Who is Eligible?

• FDA Eligibility criteria
  • BMI ≥30
  • BMI ≥ 27 with complication such as T2DM, HTN, Dyslipidemia, OSA...
Anti-Obesity Medicines Today

**Phentermine**  
(Adipex-p, Suprenza, Lomaira)*

**Orlistat**  
(Xenical, Alli)

**Lorcaserin**  
(Belviq, Belviq XR)*

**Phentermine-topiramate ER**  
(Qsymia)*

**Naltrexone-bupropion**  
(Contrave)

**Liraglutide**  
(Saxenda)

*scheduled medication

BOLDED- FDA Approved for long term use
Italicized: FDA Approved for short term use
## Short-term Medications

<table>
<thead>
<tr>
<th>Phentermine*</th>
<th>Diethylpropion*</th>
<th>Phendametrazine*</th>
</tr>
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<tbody>
<tr>
<td>Schedule IV</td>
<td>Schedule IV</td>
<td>Schedule III</td>
</tr>
<tr>
<td>Endocrine Society indicates that specialists have used it long-term with no negative consequences</td>
<td>norepinephrine-releasing agent</td>
<td>Sympathomimetic</td>
</tr>
<tr>
<td>Component of phentermine / topiramate ER (Qysimia)</td>
<td>25 mg one hour before meals</td>
<td></td>
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<tr>
<td></td>
<td>75 mg controlled-release</td>
<td></td>
</tr>
<tr>
<td></td>
<td>35 mg every 8-12 hours</td>
<td></td>
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<tr>
<td></td>
<td>105 mg extended release</td>
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</table>

These meds were approved for short-term use before we understood that obesity is a chronic disease. At this point, nobody will pay for the study.

*scheduled medication
Mechanisms of Action

- **Sympathomimetic Amines**: Works in hypothalamus to suppress *cravings & hunger*

- **Orlistat**: Decreases absorption of fat

- **Lorcaserin**: Works on POMC neurons in hypothalamus to *decrease food intake and increase satiety*

- **Phentermine / Topiramate ER**: Works in hypothalamus to *suppress cravings & hunger* and promote *satiety*

- **Naltrexone HCL/bupropion HCL extended release**: Targets appetite regulation and reward system in the brain to *decrease hunger & food cravings*

- **Liraglutide 3mg**: Targets GLP-1 receptors in the brain to *decrease hunger & increase satiety*
<table>
<thead>
<tr>
<th>Drug</th>
<th>Description</th>
<th>Main Side Effects</th>
<th>Illustrative Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phentermine</td>
<td>Phentermine was approved in 1959, and is the oldest available approved anti-obesity drug. It is a DEA Schedule IV stimulant agent approved for short-term use (12 weeks). Some patients may lose about 5% of body weight.</td>
<td>Side effects include headache, high blood pressure, rapid or irregular heart rate, overstimulation, tremor, and insomnia. Should not use with overactive thyroid or uncontrolled high blood pressure or seizure disorder. Contraindicated in patients with history of cardiovascular disease, within 14 days of monoamine oxidase inhibitors, glaucoma, agitated states, drug abuse.</td>
<td>Monoamine oxidase inhibitors, sympathomimetics, antidepressants, alcohol, adrenergic neuron blocking drugs, and some anesthetic agents</td>
</tr>
<tr>
<td>Orlistat</td>
<td>Orlistat impairs digestion of dietary fat. Lower doses are approved over-the-counter. Some patients may lose about 5% of body weight.</td>
<td>Side effects include oily discharge with flatus from the rectum, especially after fatty foods. (May help with constipation.) May promote gallstones and kidney stones. Will need to take a multivitamin daily. Contraindicated in chronic malabsorption syndrome and cholestasis.</td>
<td>Cyclosporine, hormone contraceptives, seizure medications, thyroid hormones, warfarin</td>
</tr>
<tr>
<td>Lorcaserin</td>
<td>Lorcaserin is a DEA Schedule IV agent that improves the sense of fullness. Some patients may lose 5 – 10% of body weight.</td>
<td>Lorcaserin is a generally well-tolerated drug, with headache, dizziness, fatigue, nausea, dry mouth, and constipation occurring more frequently compared to placebo. Warnings and Precautions include serotonin syndrome, heart failure, psychiatric disorders, and priapism.</td>
<td>Serotonergic (SSRI's, SNRI's, MAO inhibitors) or anti-dopaminergic medications, St John's wort, triptans, bupropion, dextromethorphan, CYP 2D6 substrates</td>
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<td>Drug</td>
<td>Description</td>
<td>Main Side Effects</td>
<td>Some Drug Interactions</td>
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<td>-----------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>Liraglutide 3mg</td>
<td>Liraglutide is an injectable drug, that in lower doses (1.8 mg per day), is also used to lower blood sugar. Some patients may lose 5 – 10% of body weight with the higher dose of the liraglutide 3.0 mg per day, which is the dose approved for treatment of obesity.</td>
<td>Adverse reactions include nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue dizziness, abdominal pain, increase lipase, and renal insufficiency. Contraindicated with personal family history of medullary thyroid cancer or Type 2 Multiple Endocrine Neoplasia syndrome. Discontinue with suspected pancreatitis, gall bladder disease, or suicidal behavior and ideation.</td>
<td>May slow gastric emptying, which may impact absorption of concomitantly administered oral medication.</td>
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<td>Naltrexone / bupropion</td>
<td>This is a combination of naltrexone (opioid antagonist used for addictions) and bupropion (used for depression and smoking cessation). Some patients may lose 5 - 10% of body weight.</td>
<td>Naltrexone / bupropion can cause nausea, constipation, diarrhea, and headache. The bupropion component is an antidepressant, and antidepressants can increase the risk of suicide thinking in children, adolescents, and young adults; monitor for suicidal thoughts and behaviors. Should not be used in patients with uncontrolled high blood pressure, seizure disorders, or drug/alcohol withdrawal.</td>
<td>Opioid pain medications, anti-seizure medications, MAO inhibitors, and possible drug interactions with other drugs.</td>
</tr>
<tr>
<td>Phentermine / topiramate</td>
<td>This is a combination of phentermine (anti-obesity drug) and topiramate (used to treat seizures and migraine headaches). This DEA Schedule IV drug is approved as a weight management pharmacotherapy. Some patients may lose 5 – 10% of body weight.</td>
<td>Phentermine / topiramate can cause tingling or numb feelings to extremities, abnormal taste, insomnia, constipation, and dry mouth. Should not be used in patients with glaucoma, uncontrolled high blood pressure, heart disease, or hyperthyroidism. Topiramate can cause birth defects. Therefore, phentermine / topiramate should not be started until a pregnancy test is negative, unless the woman is using acceptable contraception, and pregnancy tests should be done monthly during use.</td>
<td>Monoamine oxidase inhibitors. May alter oral contraceptive blood levels.</td>
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-3.1 We suggest against the off-label use of medications approved for other disease states for the sole purpose of producing weight loss. A trial of such therapy can be attempted in the context of research and by healthcare providers with expertise in weight management dealing with a well-informed patient.

## Resources for AOM Knowledge:

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<td>- Weight Effects of Common Medications</td>
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<td>- Online Store @ <a href="https://obesitymedicine.org/">https://obesitymedicine.org/</a></td>
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Meet Lucy

• 36 y.o. female, she has struggled with weight her entire life. She reports she struggles mainly with cravings.

• **SH:**
  • Married with two children, ages 6 and 8
  • Lawyer in a busy litigation firm

• **FH:**
  • Family hx of obesity and T2DM

• **Current Meds**
  • *Metformin* ER 2000 mg daily
  • *Liraglutide* 1.8 mg daily
  • IUD

• **PMH:**
  • T2DM x 1 year
  • Hypertriglyceridemia
  • NAFLD
  • Mild knee OA
Lucy’s Weight & Labs

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<th>Weight</th>
<th>Weight Change</th>
<th>% Loss</th>
<th>BP</th>
<th>A1c</th>
<th>Fast Glu</th>
<th>Trig</th>
<th>HDL-C</th>
<th>LDL-C</th>
<th>Chol</th>
<th>Vitamin D</th>
</tr>
</thead>
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<tr>
<td>Initial</td>
<td>182 (BMI: 34.4)</td>
<td>--</td>
<td>--</td>
<td>128/82</td>
<td>6.4</td>
<td>132</td>
<td>215</td>
<td>45</td>
<td>112</td>
<td>193</td>
<td>44</td>
</tr>
</tbody>
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LFTs mildly elevated d/t NAFLD

Kidney function WNL

TSH: 1.8
Obesity staging systems

• Determine the extent of the disease
• Determine quality of life and functional ability
• Determine how aggressive treatment should be

Edmonton Obesity Staging System (EOSS)
• Designates five obesity stages (0-4)
Edmonton obesity staging system

**Stage 0**
- No obesity related risk factors

**Stage 1**
- Obesity-related preclinical risk factors
  - Prediabetes pre-HTN, minor aches, distress & impairment of daily function

**Stage 2**
- Established complications & co-morbidities
  - T2DM, HTN, OSA, Osteoarthritis, GERD, knee, hip, pain, fatigue, depression, eating disorders

**Stage 3**
- Significant health impairment
  - Diabetes complications, MI, heart failure, incapacitating osteoarthritis

**Stage 4**
- Severe health impairment
  - End-stage disease & disability
Lucy’s Diagnosis

1. Class 1, Stage 2 Obesity
2. T2DM, well-controlled
3. NAFLD
4. Mild knee OA
5. Hypertriglyceridemia
The 7 Step AOM Prescribing Guide

Step 1: Determining if patient is a candidate for pharmacotherapy

Step 2: Consider complications, co-morbidities, symptoms, or other conditions that would benefit from a particular medication(s)

Step 3: Screen for contraindications

Step 4: Screen for medication interactions

Step 5: Discuss options with patients

Step 6: Choose & initiate medication

Step 7: Monitor response
Applying the 7 Step Process with Lucy
Step 1: Determining if patient is a candidate for pharmacotherapy

Lucy has a BMI of 34, so she is a candidate for pharmacotherapy.
Step 2: Consider complications, co-morbidities, symptoms, or other conditions that would benefit from a particular medication(s)

Co-Morbid Conditions

- T2DM
- Hypertriglyceridemia
- NAFLD

-Liraglutide and Locaserin have been noted to lower HbA1c.

Determine prior AOM history & experience

- Lucy has no past AOM history.
- She reports CRAVINGS.
- In looking at med options:
  - 1- Liraglutide 3mg
    - decrease hunger & increase satiety.
    - Increased BMI reduction with 3mg dose of Liraglutide vs 1.8mg dose.
  - 2- Naltrexone HCL/bupropion HCL extended release
    - target cravings/emotional eating.
  - 3- Phentermine
    - decrease cravings, reduce hunger
    - Schedule IV
Step 3: Screen for contraindications

- All AOMs
  - Not pregnant—IUD in place.

- Naltrexone HCL/Bupropion HCL extended release
  - She is on no narcotics
  - She has no history of seizures

- Liraglutide 3mg
  - She has no personal or family medullary thyroid cancer or MENS2
  - She has no hx pancreatitis
  - Currently on Liraglutide 1.8mg

- Phentermine:
  - Her BP well controlled
  - She has no unstable CVD
Step 4: Screen for medication interactions

- Metformin ER 2,000 mg daily
- Liraglutide 1.8
- IUD-Mirena

- She is on no narcotics (Contrave)
- If Liraglutide 3mg (Saxenda) is utilized, this would replace the Liraglutide 1.8mg (Victoza).

- No other medication interactions noted.
Wants help with cravings

Already doing an injection

Is willing to add an additional medication

Is willing to take a pill BID

Is willing to tolerate possible nausea

Is willing to risk insomnia, dry mouth, jitteriness

Is willing to investigate AOM coverage

Is willing to spend up to $100 per month on additional medication

Step 5:
Discuss options with patient to determine patient preference, patient’s comfort with route of administration, medication timing, patient’s willingness to tolerate possible adverse effects, cost, and insurance coverage
Shared Decision Making

- Is used when there is more than one path forward
- Requires the patient & clinician to be active partners
- Requires both parties to take responsibility
- Patients are more likely to be compliant when they participate in decisions

Patients are more knowledgeable

Patients have a better experience with clinicians

Improved treatment adherence

Lowered patient anxiety

Potentially less costly

Care is aligned with patient values

Making Shared Decisions About AOMs with Lucy

Step 6: Choose & initiate medication

Given the options of Saxenda, Contrave, and phentermine, patient is most interested in Contrave.

Craving suppression
Has insurance coverage for AOMs,
If no coverage, cash $99 per 120 tablets
If she didn’t want to spend, we could: prescribe generics.

Start with 1 tablet in am with food x 1 wk.
Instructed to contact clinician if not tolerating.

Increase to 1 tablet BID if previous dose well tolerated and any SE have resolved

Provide written titration schedule in addition to pharmacy

Contrave Clinical Pearl:
1- Label instructs to titrate by week; the art is to do it based on patient’s response.
2- Not all patients will need full dose to have positive response. If patient feels in control with their eating behavior and BMI improving, less is more.
3- Take with food to minimize nausea.
4- Clinically have found it is best for patients with emotional eating/cravings.
Step 7: Monitor response

RTC in two weeks

- Tolerated well the first week, with some nausea the first few days that resolved.
- Same nausea pattern when increased to 1 tablet BID, it is decreasing, but hasn’t resolved. No vomiting.
- No weight loss, but feels more in control
- BP in range
- BS stable
- IUD in place
- Instructed to continue current dose until nausea resolves
- 4-7 days after nausea resolves increase to 1 in am and 2 in pm

Frequent monitoring is associated with improved outcomes
Step 7: Monitor Response

RTC 2 weeks later

She continues 1 tablet BID, but nausea hasn’t resolved.

Decision is made to discontinue due to side effects, despite slight reduction in cravings and feeling more in control

- Weight is stable, feels more in control
- BP in range
- BS stable
- IUD in place

After discussion, decision is made to d/c Victoza and start Saxenda via titration schedule for greater BMI reduction.

Review BMI reduction differences between Liraglutide 1.8mg vs Liragludide 3mg.

Once nausea has resolved for one week, increase liraglutide to 2.4 mg and follow titration schedule
Increase liraglutide to 3.0 mg

- Manage hunger
- Increase satiety
- Induce weight loss

Determine insurance coverage & complete pre-authorization

Increase by 0.6 mg increments q 1-2 weeks

Monitor blood glucose carefully *

*LIf patient is on concomitate T2DM medications such as insulin, sulfonylureas or other insulin secretagogues.
Step 7: Monitor Response

RTC 3 weeks later

Increased liraglutide to 2.4 mg 2 weeks ago, tolerated well

Increased to 3.0 dose one week later, tolerating well

- Increased weight control
- Increased satiety resulting in improved adherence to eating plan
- BP in range
- IUD in place
- BS improving

Liraglutide 3mg Pearls

- May need to decrease dose to find a place where she is tolerating and has efficacy (not package insert)
- Micro-clicks (off label)- 10 “micro clicks” between each dosing
  - can increase 2 micro-clicks q 2 days until hunger controlled and to minimize GI side effects.
Step 7: Monitor Response

RTC 4 weeks

Tolerating 3.0 mg liraglutide well

<table>
<thead>
<tr>
<th>Continued weight control</th>
<th>Continued satiety and mostly adhering to eating plan</th>
<th>BP in range</th>
<th>IUD in place</th>
<th>BS stable</th>
</tr>
</thead>
</table>

Continue frequent follow-ups/monitoring until medications are stable, co-morbid conditions are stable, and all pillars of disease state management have been implemented.
Step 7: Monitor Response

RTC 8 weeks later

Tolerating 3.0 mg liraglutide well
- Weight loss,
- BP in range
- BS stable
- IUD in place
- Due for f/u labs (3 months since previous)

Continued satiety, but snacking in evening due to cravings

Shared Decision Making:
- Add Phentermine

Recommend check of CMP at 2-3 months after start of medication.
Phentermine

Dosing: 8-37.5 mg PO q am

Phentermine (Lomaira) 8mg
Phentermine 15/30mg Capsule
Phentermine 37.5 mg Capsule/Tablet

DEA Schedule: IV

FDA approved for short-term use, but frequently prescribed off label for long-term use.

No withdrawl sx—no addiction (say potential, but hasn’t occurred)
Long Term Use of Phentermine

Obesity is a chronic, progressive disease state that intermittent/short term therapy is not medically appropriate.

Currently Qsymia is FDA approved for chronic management of obesity with phentermine 15mg component.

There currently is minimal evidence of any serious long-term side effects when phentermine is used alone for weight control.

Long-term Prescribing of Phentermine - Endocrine Society Clinical Practice Guideline.

“The question then is whether or not it is reasonable to prescribe phentermine off-label long term. In making this decision with a patient, direction and guidance provided by State Medical Boards and local laws always take precedence.”

“Given the wide clinical prescribing of phentermine for more than 20 years and the lack of evidence of serious side effects, even in the absence of long-term controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term as long as the patient:

- Has no evidence of serious CVD
- Does not have serious psychiatric disease or a history of substance abuse
- Has been informed about weight loss medications that are FDA approved for long-term use and told that these have been documented to be safe and effective whereas phentermine has not
- Does not demonstrate a clinically significant increase in pulse or BP when taking phentermine
- Demonstrates a significant weight loss while using the medication

These aspects of care should be documented in the patient’s medical record, and the off-label nature of the prescribing should be documented at each visit. Medication should be started at 7.5 or 15 mg/d initially and only increased if the patient is not achieving clinically significant weight loss. Patients should be followed at least monthly during dose escalation and then at least every 3 months when on a stable dose.”
Step 7: Monitor Response

Targeting late afternoon / eve cravings

Start Lomaira 8 mg at 9 am on a Friday to determine response:
- Monitor: onset, duration, side effects (particularly insomnia)
- Rx for Lomaira 8mg TID PRN, #90/0 refills
- Patient instructed to take once a day and handout with instructions given

Gradually shift time to later by 1 hour q 1-3 days until determine that latest time that gives evening coverage without disrupting sleep
Step 7: Monitor Response

RTC in 2 weeks due to new med start

Now taking Lomaira 8 mg at 4 pm

Continues 3.0 mg Liraglutide

Good evening craving suppression which has eliminated evening snacking
Continuation & Discontinuing

If hasn’t achieved 5% weight loss at 3 months, Endocrine Society recommends discontinuing and considering another medication.

If no clinical improvements after 12-16 weeks, increase dose or switch to another med.

If favorable response and no safety issues, continue medication.
Chronic Nature of Obesity

Things To Consider

- Improvement of other conditions
- Weight reduction and maintenance (preventing weight gain)
- Our initial goals
- The guidelines haven’t caught up with obesity as a chronic disease and the goals of treatment beyond weight reduction
Meet Lucy

• 36 y.o. female, she now feels more in control with her eating behaviors, healthier, and happier than ever before.

• She has improved to a low carb nutrition style and increased daily movement.

• She is able to keep up with her kids better and states she feels healthier than she has in a long time. She no longer has any knee pain.

• Current Meds
  • Metformin ER 2000 mg daily
  • Liraglutide 3 mg daily
  • Lomaira 8mg once daily
  • IUD

• PMH:
  • T2DM x 1 year
  • Hypertriglyceridemia
  • NAFLD
  • Mild knee OA
  • Class I, Stage II Obesity
## Lucy’s Weight & Labs

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<th>Follow Up</th>
<th>Weight Change</th>
<th>% Loss</th>
<th>BP</th>
<th>A1c</th>
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<th>HDL-C</th>
<th>LDL-C</th>
<th>Chol</th>
<th>Vitamin D</th>
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<tr>
<td></td>
<td><strong>164</strong> (BMI: 31.0)</td>
<td>18 lbs</td>
<td>10%</td>
<td>115/72 (improved)</td>
<td>5.3% (decreased from 6.4%)</td>
<td>88 (improved from 132)</td>
<td>72</td>
<td>47</td>
<td>110</td>
<td>182</td>
</tr>
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- LFTs normalized
- Kidney function WNL
- TSH: 1.8
Lucy’s Diagnosis

1. Class 1, Stage 2 Obesity, improved
2. T2DM, well-controlled, improved
3. NAFLD, improved
4. Mild knee OA, improved
5. Hypertriglyceridemia, resolved.
PAs in Obesity Medicine At a Glance....

AAPA SIG Group

PAs in Obesity Medicine
https://www.facebook.com/groups/PAsinObesityMedicine/

AAPA Obesity Leadership Edge

7 free online modules

In progress: Primary Care Obesity Management Certificate Program

OMA NP/PA Certificate of Advanced Education

https://obesitymedicine.org/cme/np-pa-certificate-obesity-medicine/
Local Resource:

Arizona Obesity Organization

Treat or Refer

- Mission:
  - Premier group of obesity medicine specialists for the state of Arizona providing a comprehensive resource for the latest in the disease state and management of obesity

- Vision:
  - Every patient affected by pre-obesity and obesity will receive evidence-based treatment and coverage for their care

Coming Soon: arizonaobesity.org
Thank you!

Amy Ingersoll, PA-C, MMS

aingersoll@orthoarizona.org
Where to find an Obesity Medicine Clinician

- Confirm does not utilize HcG
- Physicians: ABOM Certified
- PAs/NPs- Advance Certificate of Obesity Management

- [https://obesitymedicine.org/find-obesity-treatment/](https://obesitymedicine.org/find-obesity-treatment/)
- [https://obesitycareproviders.com/](https://obesitycareproviders.com/)
References

• *The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 5, 1 May 2015, Pages 2135–2136, https://doi.org/10.1210/jc.2015-1782*


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