Update on Anti-Obesity Medications (AOM’s)

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MCT2D Program Co-Director

May 2022
Objectives

- Compare and contrast anti-obesity medications.
- Appreciate prior authorization criteria.
- Apply selection of a medication to a case.
Adiposity-Based Chronic Disease
“Diabesity”

30-50% of new cases of diabetes are due to obesity

85% of people with diabetes have overweight or obesity
Treat Diabetes or Obesity First?

**Old Treatment Paradigm**
*Treat Weight *LAST*

<table>
<thead>
<tr>
<th>Dyslipidemia</th>
<th>HTN</th>
<th>IGT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meds</td>
<td></td>
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</tr>
</tbody>
</table>

Note: Garvey 2016; Apovian 2016

**New Treatment Paradigm**
*Treat Weight *FIRST*

<table>
<thead>
<tr>
<th>Overweight/Obesity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor</td>
</tr>
<tr>
<td>Diet</td>
</tr>
<tr>
<td>Exercise</td>
</tr>
<tr>
<td>Meds</td>
</tr>
</tbody>
</table>

**Dyslipidemia**

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Lipid panels Lipoproteins subsets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↓ Total fat</td>
</tr>
<tr>
<td>Meds</td>
<td>Statins Fibrates Resins Niacin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Blood Pressure Ambulatory Blood Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↓ Sodium</td>
</tr>
<tr>
<td>Meds</td>
<td>Central acting Renal effective Peripherally acting diuretics Thiazide diuretics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Blood sugar Glycosylated hemoglobin distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↓ Sugar</td>
</tr>
<tr>
<td>Meds</td>
<td>Insulin Sulfonyleureas Glidizones Absorption agents</td>
</tr>
</tbody>
</table>

**Overweight/Obesity**

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Weight and BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Any diet patient will adhere to</td>
</tr>
<tr>
<td>Exercise</td>
<td>150 minutes of moderate-intensity aerobic activity/wk and muscle-strengthening activities on &gt; 2 days/wk</td>
</tr>
<tr>
<td>Meds</td>
<td>Orlistat, phentermine, phentermine/topiramate, lorcaserin</td>
</tr>
</tbody>
</table>

**Dyslipidemia**

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Lipid panels Lipoproteins subsets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↓ Sat + trans fat</td>
</tr>
<tr>
<td>Meds</td>
<td>Statins Fibrates</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Blood Pressure Ambulatory Blood Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↓ DASH Diet</td>
</tr>
<tr>
<td>Meds</td>
<td>ACE Inhibitors ARBs Thiazide diuretics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Blood sugar Glycosylated hemoglobin distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>↑ Fiber</td>
</tr>
<tr>
<td>Meds</td>
<td>Metformin Exenatide Liraglutide</td>
</tr>
</tbody>
</table>

Garvey 2016; Apovian 2016
# FDA Approved Anti-Obesity Medications

<table>
<thead>
<tr>
<th>Agents</th>
<th>Mechanism</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phentermine</td>
<td>Sympathomimetic</td>
<td>Appetite regulation</td>
</tr>
<tr>
<td>Phentermine + Topiramate ER</td>
<td>Sympathomimetic + anticonvulsant (GABA receptor modulation, carbonic anhydrase inhibition, glutamate antagonism)</td>
<td>Appetite regulation</td>
</tr>
<tr>
<td>(Qsymia)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naltrexone + bupropion SR</td>
<td>Opioid receptor antagonist + Dopamine / norepinephrine reuptake inhibitor</td>
<td>Appetite regulation</td>
</tr>
<tr>
<td>(Contrave)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liraglutide (Saxenda)</td>
<td>GLP-1 receptor agonist</td>
<td>Appetite regulation</td>
</tr>
<tr>
<td>Semaglutide (Wegovy)</td>
<td>GLP-1 receptor agonist</td>
<td>Appetite regulation</td>
</tr>
<tr>
<td>Orlistate (Xenical or Alli)</td>
<td>Pancreatic lipase inhibition</td>
<td>Reduce fat absorption</td>
</tr>
</tbody>
</table>
## Anti-Obesity Medications

### FDA Approved
- Phentermine
- Diethylpropion
- Phendimetrazine
- Benzphetamine
- Orlistat
- Phentermine/Topiramate
- Naltrexone/Bupropion
- Liraglutide
- Semaglutide

### Off Label Use
- Metformin
- SGLT2I’s
- Pramlintide
- Topiramate
- Zonisamide
- Bupropion
- Naltrexone

### Future pipeline…
- Tirzepatide (GLP-1/GIP dual agonist)
- Cagrilintide (amylin analog)
- Cagrilintide+ semaglutide
- Bimagrumab (monoclonal Ab)
How do Anti-Obesity Medications Work?

- Bupropion / Naltrexone
- Liraglutide
- Semaglutide
- Topiramate
- Phentermine
Case 1: L.J.

45-year-old female with T2D A1C 11.1

- PMH: CAD, PCI 2019, BMI 45, asthma
- Labs: A1C 11.1, GFR >90, microalbumin (-)
- Had COVID-19 with 50-pound weight gain
- Lost 50 lbs with Weight Watchers
- “I started feeling hungry all the time.”

Height 5’3”  Weight 260 lb
L.J.'s Medications

- Metformin 1000 mg PO BID
- Glipizide XR 15 mg QD
- Albuterol prn
- ASA 81 po QD
- Atorvastatin 40 po QD
- Fluticasone prn
- Lisinopril 20 mg QD
- Metoprolol XL 50 mg QD
Which medications are obesogenic?

- Metformin 1000 mg PO BID
- Glipizide XR 15 mg QD
- Albuterol prn
- ASA 81 po QD
- Atorvastatin 40 po QD
- Fluticasone prn
- Lisinopril 20 mg QD
- Metoprolol XL 50 mg QD

- Sulfonylureas ~ 2-3 kg
- Metoprolol ~ 1kg

Domecq 2015, Messerli 2007
L.J.'s Weight History

- Pregnancy
- Night shifts
- Sedentary
- Processed food
- Poor sleep
- HTN, CAD, T2D
- Obesogenic rx
  - metoprolol
  - glipizide
- Weight Watchers
Which AOM would you choose for L.J.?

"Hungry Brain"  
Phentermine-Topiramate

"Emotional Brain"  
Bupropion-Naltrexone

"Hungry Gut"  
GLP-1-RA  
Liraglutide  
Semaglutide

"Slow Burn"  
Phentermine

Acosta 2021; icons from Noun project.
Semaglutide 2.4 mg

MOA: increases satiety, decreases gastric emptying.

Dose: start at 0.25 mg SQ weekly, titrate monthly to 2.4 mg SQ weekly

CI’s: PMH or FH medullary thyroid cancer, MEN II syndrome, pregnancy or lactation

AE’s: commonly, nausea headache, GERD, constipation rarely, pancreatitis, gallstones, renal impairment, hypoglycemia

Counsel: eat slow, smaller portions, tx nausea, constipation
Obesity Outcomes:
Semaglutide 2.4 mg v. 1.0 mg

5-15% weight loss improves T2D
## GLP-1 Receptor Agonists

<table>
<thead>
<tr>
<th>Liraglutide (Saxenda)</th>
<th>Semaglutide (Wegovy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 0.6 mg SQ daily X1wk</td>
<td>• 0.25 mg SQ daily X4wk</td>
</tr>
<tr>
<td>• 1.2 mg SQ daily X1wk</td>
<td>• 0.5 mg SQ daily X4wk</td>
</tr>
<tr>
<td>• 1.8 mg SQ daily X1wk</td>
<td>• 1.0 mg SQ daily X4wk</td>
</tr>
<tr>
<td>• 2.4 mg SQ daily X1wk</td>
<td>• 1.7 mg SQ daily X4wk</td>
</tr>
<tr>
<td>• 3.0 mg SQ daily</td>
<td>• 2.4 mg SQ daily X4wk</td>
</tr>
</tbody>
</table>

✔ Similar safety and precautions to GLP-1RA prescribed for Type 2 Diabetes
✔ Can titrate dose slower depending on adverse effects and efficacy
GLP-1-RA Prescribing Considerations

- Consider Liraglutide 3.0 mg or Semaglutide 2.4 mg if insufficient weight loss with Liraglutide 1.8 mg or Semaglutide 1.0 mg.
- Semaglutide 2.0 FDA approved for diabetes available soon.
- Supply chain issues with Semaglutide 2.4 mg, use Liraglutide 3.0 mg for new start if needed.

Frias 2021; Jain 2021
Switching between GLP-1-RAs

Decision to switch GLP-1RA

- Discontinue current GLP-1RA
- Counsel patient regarding differences between agents

Switch from QD/BID including oral semaglutide QD

Switch to any GLP-1RA (BID, QD, QW)
First dose administered the following day after discontinuation

Switch from QW

Switch to any GLP-1RA (BID, QD, QW)
First dose administered 7 days after discontinuation*

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<table>
<thead>
<tr>
<th>Agent</th>
<th>Frequency</th>
<th>Equivalent Dose†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide</td>
<td>QW</td>
<td>2 mg</td>
</tr>
<tr>
<td>Dulaglutide</td>
<td>QW</td>
<td>0.75 mg</td>
</tr>
<tr>
<td>Semaglutide</td>
<td>QW</td>
<td>0.25 mg</td>
</tr>
<tr>
<td>Liraglutide</td>
<td>QD</td>
<td>0.6 mg</td>
</tr>
<tr>
<td>Lixisenatide</td>
<td>QD</td>
<td>10 μg</td>
</tr>
<tr>
<td>Oral semaglutide</td>
<td>QD</td>
<td>3 mg</td>
</tr>
<tr>
<td>Exenatide</td>
<td>BID</td>
<td>5 μg</td>
</tr>
</tbody>
</table>
Case 1: L.J.

- **Nutrition**: Appropriate portions, plate-planning
- **Activity**: Short brisk walks BID, resistance QW
- **Behavior**: SMART goal for activity
- **Meds**: Stopped glipizide, metoprolol
- **Meds**: Started semaglutide, titrate to 2.4 mg

- “Less hungry,” better satiety, smaller portions
- Lost 15% body weight, experienced comorbidity improvement in T2D, HTN, asthma
Case 2: M.D.

67-year-old male with T2D, A1C 6.8, BMI 45

- Retinopathy, neuropathy, CKD3
- PMH: HTN, HL, chronic low back pain, DPN
- Labs: A1C 10.0, Creat 1.7, GFR 47
- Recommended to lose weight to treat low back pain by orthopedic surgery consultant.

“I quit alcohol and I’m working hard on cigarettes. Now it’s sweets. I opened a sleeve of Oreos the other day and ate the whole thing.”
M.D.’s Medications

- Empagliflozin 25 mg po QD
- Metformin XR 1000 mg po BID
- Valsartan-HCTZ 320-25 mg po QD
- Rosuvastatin 5mg po QD
- Paroxetine 30 mg po QD
- Gabapentin 300 mg po TID
Which medications are obesogenic?

- Empagliflozin 25 mg po QD
- Metformin XR 1000 mg po BID
- Valsartan-HCTZ 320-25 mg po QD
- Rosuvastatin 5mg po QD
- Paroxetine 30 mg po QD
- Gabapentin 300 mg po TID

- Paroxetine
- Gabapentin ~ 2.2 kg
Which AOM would you choose for M.D.?

“Hungry Brain”
Phentermine-Topiramate

“Emotional Brain”
Bupropion-Naltrexone

“Hungry Gut”
GLP-1-RA
Liraglutide
Semaglutide

“Slow Burn”
Phentermine
Bupropion-Naltrexone (8/90 mg)

MOA: DA/NE reuptake inhibitor + opioid antagonist

Dose: titrate from 1 tab po QAM to 2 tabs PO BID by 1 tab per week, max dose 1 tab BID with CYP2B6 inhibitors (eg clopidogrel)

CI’s: Uncontrolled HTN; seizure, bulimia or anorexia nervosa; abrupt DC of alcohol, BDZP, barbiturate, antiepileptic; chronic opioid use; MAOI use within 14 days; pregnancy.

AE’s: black box - suicidal thoughts / neuropsychiatric reaction; nausea, headache, insomnia, dizziness

Counsel: avoid opioid use. Monitor BP and pulse.

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/200063s000lbl.pdf
Bupropion / Naltrexone (Contrave)

<table>
<thead>
<tr>
<th>Week</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>One tab PO QAM</td>
</tr>
<tr>
<td>2</td>
<td>One tab PO BID</td>
</tr>
<tr>
<td>3</td>
<td>Two tab PO QAM, one tab PO QPM</td>
</tr>
<tr>
<td>4</td>
<td>Two tabs PO BID</td>
</tr>
</tbody>
</table>

- Do not take with high fat meals to avoid increasing systemic levels of bupropion and naltrexone.

- Caution with acute hepatitis / liver failure. Reduce dose to one tablet BID with CYP2B6 inhibitors (ticlopidine, clopidogrel)

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/200063s000lbl.pdf
Bupropion-Naltrexone (8/90 mg)

Relative Contraindications: mood changes (bupropion)
  • Risk of worsening depression, anxiety, suicidal ideation, mania activation, monitor symptoms

BP and heart rate elevation
  • Monitor pulse and BP. Caution with controlled HTN and ASCVD.

Hepatotoxicity (naltrexone)
  • Monitor symptoms of hepatitis, DC if elevated LFT or acute liver disease.

Hypoglycemia
  • Monitor and adjust insulin & secretagogues

Angle closure glaucoma
  • Monitor symptoms.

Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/200063s000lbl.pdf
Treat Obesity to Reduce A1C

Hollander 2013: Effects of naltrexone SR / bupropion SR on body weight and glycemic parameters (T2D + overweight / obesity)
Case 2: M.D.

**Nutrition:** choose lower carb snacks with protein

**Activity:** local fitness center “MyFitRx”

**Behavior:** CBT worksheet for emotional eating, scheduled future appt with therapist

**Meds:** tapered paroxetine, gabapentin

**Meds:** started bupropion-naltrexon, titrated dose

“I’m in control of what I’m eating.”

Lost 10% body weight, cancelled back procedure, stopped smoking, DPN stable
Case 3: C.M.

52-year-old F with preDM, A1C 6.1, BMI 42
- PMH: anxiety, depression, insomnia, chronic GERD, IBS, NAFLD, nephrolithiasis

“I’m miserable all the time. I can only eat bland carbs or I get bloated and I don’t have any energy to exercise. I get home from work and I just sit around.”
C.M.’s Medications

- Escitalopram 10 mg po QD
- Omeprazole 20 mg po QAM
- Hydroxyzine 100 mg po QHS

Allergy/intolerance

- Semaglutide SQ – abdominal pain
- Metformin – severe diarrhea

Jørgensen 2007
C.M.’s Weight History

COVID-19 Pandemic
Anxiety worse, Hydroxyzine

Dx DPN, IBS
Which AOM would you choose for C.M.?

"Hungry Brain"  
Phentermine-Topiramate

"Emotional Brain"  
Bupropion-Naltrexone

"Hungry Gut"  
GLP-1-RA  
Liraglutide  
Semaglutide

"Slow Burn"  
Phentermine

Acosta 2021; icons from Noun project.
Phentermine-Topiramate CR

**MOA:** sympathomimetic + anticonvulsant (GABA receptor modulation, carbonic anhydrase inhibition, glutamate antagonism)

**Dose:** start at 3.75/23 mg QD, maximum 15/92 mg QD, if CrCl<50 mL/min max 7.54/46; if Child-Pugh 7-9, max 7.5-46

**CI’s:** pregnancy or lactation, glaucoma, uncontrolled hyperthyroidism, recent MAOI use within 14 days, allergy

**RCI’s:** tachycardia, depressed/suicidal thoughts, sleep disturbance, attention / memory disturbance, **metabolic acidosis**

**Counsel:** **REMS**, AE’s – paresthesia, dizziness, dysgeusia, insomnia, constipation, dry mouth
# Phentermine / Topiramate CR (Qsymia)

<table>
<thead>
<tr>
<th>Pill</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.75/23 mg</td>
<td>One tab PO QAM X14 days</td>
</tr>
<tr>
<td>7.5/46 mg</td>
<td>One tab PO QAM X3 months</td>
</tr>
<tr>
<td></td>
<td>If &lt; 3% weight loss, consider DC or increase dose as follows:</td>
</tr>
<tr>
<td>11.25/69 mg</td>
<td>One tab PO QAM X14 days</td>
</tr>
<tr>
<td>15/92 mg</td>
<td>One tab PO QAM X3 months</td>
</tr>
<tr>
<td></td>
<td>If &lt;5% weight loss, consider DC</td>
</tr>
<tr>
<td></td>
<td>Taper: one pill every other day X1 week then stop.</td>
</tr>
</tbody>
</table>

Topiramate: risk of oral cleft defect

**HIGHLY EFFECTIVE Methods to use alone**
- IUD
  - copper
  - levonorgestrel
- Implant (levonorgestrel)
- Tubal sterilization
- Partner vasectomy

**ACCEPTABLE Methods to use alone**

**Methods to use together**

**One of these:**
- Hormonal contraception
  - estrogen/progestin
    - oral
    - transdermal
    - vaginal ring
  - progestin only
    - oral
    - injection

**And one of these:**
- Barrier method
  - diaphragm + spermicide
  - cervical cap + spermicide
  - male condom
  +/- spermicide

**ACCEPTABLE Methods to use together**

**One of these:**
- diaphragm + spermicide
- cervical cap + spermicide

**And one of these:**
- Barrier method
  - male condom
  +/- spermicide

✔ Mfr. recommends pregnancy test prior to use and monthly
Phentermine / Topiramate CR (Qsymia)

- CDC US Medical Eligibility Criteria for Contraception
  - Topiramate is a CYP3A4 inducer and *may* reduce effectiveness of CHC and POP.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sub-Condition</th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
<th>Implant</th>
<th>DMPA</th>
<th>POP</th>
<th>CHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity</td>
<td>a) Body mass index (BMI) ≥30 kg/m²</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>b) Menarche to &lt;18 years and BMI ≥ 30 kg/m²</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Anticonvulsant therapy</td>
<td>a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3*</td>
</tr>
<tr>
<td></td>
<td>b) Lamotrigine</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3*</td>
</tr>
</tbody>
</table>

**Key:**

1. No restriction (method can be used)
2. Advantages generally outweigh theoretical or proven risks
3. Theoretical or proven risks usually outweigh the advantages
4. Unacceptable health risk (method not to be used)

Source: CDC US Medical Eligibility Criteria
Phentermine / Topiramate CR (Qsymia)

- Relative Contraindications: Qsymia increases heart rate.
  - Monitor heart rate. Do not use if recent MI or stroke, serious arrhythmia, or congestive heart failure. Caution with controlled ASCVD or HTN.

<table>
<thead>
<tr>
<th></th>
<th>Placebo N=1561 n (%)</th>
<th>Qsymia 3.75 mg/23 mg N=240 n (%)</th>
<th>Qsymia 7.5 mg/46 mg N=498 n (%)</th>
<th>Qsymia 15 mg/92 mg N=1580 n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than 5 bpm</td>
<td>1021 (65.4)</td>
<td>168 (70.0)</td>
<td>372 (74.7)</td>
<td>1228 (77.7)</td>
</tr>
<tr>
<td>Greater than 10 bpm</td>
<td>657 (42.1)</td>
<td>120 (50.0)</td>
<td>251 (50.4)</td>
<td>887 (56.1)</td>
</tr>
<tr>
<td>Greater than 15 bpm</td>
<td>410 (26.3)</td>
<td>79 (32.9)</td>
<td>165 (33.1)</td>
<td>590 (37.3)</td>
</tr>
<tr>
<td>Greater than 20 bpm</td>
<td>186 (11.9)</td>
<td>36 (15.0)</td>
<td>67 (13.5)</td>
<td>309 (19.6)</td>
</tr>
</tbody>
</table>

Patients with elevations in heart rate in clinical studies of up to one year.
Source: https://qsymia.com/patient/include/media/pdf/prescribing-information.pdf
Phentermine / Topiramate CR (Qsymia)

Relative Contraindications:
Metabolic acidosis (topiramate):

• Hyperchloremic, non-anion-gap metabolic acidosis and hypokalemia
• Caution if renal & lung disease, diarrhea, status epilepticus, surgery, keto diet
• Caution use with carbonic anhydrase inhibitors (Zonisamide, Acetazolamide)
• Stay hydrated
• Check electrolytes at one month
• Monitor symptoms, nephrolithiasis

Glaucoma

• Topiramate associated with secondary angle closure glaucoma
• Typically in 1st month of treatment
• Monitor for blurry vision and eye pain and stop drug if present.

Source: https://qsymia.com/patient/include/media/pdf/prescribing-information.pdf
Phentermine / Topiramate CR (Qsymia)

Relative Contraindications:

Elevated creatinine
• Decreased GFR peaks at 4-8 weeks, monitor labs

Hypoglycemia
• Monitor and adjust insulin & secretagogues

Hypotension
• Monitor and adjust anti-hypertensive medications

CNS depression
• Avoid alcohol use
Case 3: C.M.

52-year-old F with preDM, A1C 6.1, BMI 42
- PMH: anxiety, depression, insomnia, chronic GERD, IBS, NAFLD, nephrolithiasis

“I had another kidney stone and the emergency room doctor stopped my medication.”
Phentermine

**MOA:** Inhibits Na2+-dependent NE transporter, reduces NE uptake
Inhibits serotonin and dopamine reuptake

**Dose:** 15-37.5 mg QD (*alt* 18.75 Qd or BID), or 8mg TID

**CI’s:** Active CV disease, uncontrolled HTN, cardiac arrhythmias, hyperthyroidism, glaucoma

**AE’s:** Dry mouth, constipation, insomnia, palpitations, HA, irritability

**Counsel:** Schedule IV controlled substances, monitor BP. Avoid with EtOH. Heavy machinery warning.
Phentermine Myths and Facts

No evidence of addiction, withdrawal

No established relationship related to cardiac valvulopathy or pulmonary hypertension

No studies on people with cardiovascular disease, but among those studied:

- HR “short-term … group had no significant change in HR at 6, 12, or 24 months”
- HR “medium-term [biggest change was] at 6 months and was 1.6 (95% CI: 1.0-2.2) bpm “
- SBP “stable at 6 and 12 months, but at 24 months, it had increased by 1.8 (0.5-3.2) mmHg”

Do know your state prescribing laws for short term or long-term use.
Phentermine: Long Term Outcomes

Figure 3 Estimated percent weight loss at 6 months and 1 and 2 years after phentermine initiation among responders; results from multivariable linear models. Models include only phentermine responders, patients who had lost ≥3% body weight by 3 months after initiating medication. Estimates at each time point are from separate multivariable linear models, and n (%) by group over follow-up is presented in Table 2. Note that because real clinical follow-up does not occur at exact 6-month intervals, weights were drawn from an acceptable time window of outpatient visits around each time point of interest, as outlined in Methods. Estimates for the referent group (on-label continuous) were based on the y-intercept of multivariable models in the case in which all covariates are set to referent. Estimates for comparison groups were generated by summing the intercept weight loss and the additional change in weight by group at each time point. Error bars represent 95% CI for each estimate.
Case 3: C.M.

Nutrition: plate planning with protein every meal and non-inflammatory vegetables / complex carbs referral to GI / IBS specific nutritionist

Activity: add pilates three days a week, brisk walk after work

Behavior: SMART goal sheet for activity

Meds: tapered hydroxyzine

Meds: continued phentermine

"I have a lot more energy, and now that I’m moving I feel better."

Lost 7% body weight, bloating improved.
Initiating Anti-Obesity Medications

1. Start at lowest dose
2. 2-4 week follow-up
   - Well tolerated?
     - Titrate dose
   - Adverse effects?
     - DC or reduce dose
3. 3 month follow-up
   - 3-5% weight loss
     - Continue dose
   - <3-5% weight loss
     - Titrate dose
     - < 3-5% wt loss @ max dose
     - DC and switch meds
# Weight Loss and Impact on ABCD’s

<table>
<thead>
<tr>
<th>% weight loss</th>
<th>ABCD</th>
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<tr>
<td>5-≥10%</td>
<td>Male hypogonadism, SUI</td>
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<tr>
<td>5-≥15%</td>
<td>T2D, HLD, HTN, PCOS, NAFLD</td>
</tr>
<tr>
<td>7-8%</td>
<td>Asthma / reactive airway disease</td>
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<tr>
<td>7-11%</td>
<td>OSA</td>
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<tr>
<td>10%</td>
<td>PreDM, metabolic syndrome, female infertility</td>
</tr>
<tr>
<td>≥10%</td>
<td>Osteoarthritis, GERD</td>
</tr>
<tr>
<td>10-40%</td>
<td>Steatohepatitis</td>
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</table>

Increase intensity of intervention
Barriers to Prescribing AOM’s

- Lack of training in medical school and residency
- Lack of knowledge
  - Evidence-based obesity guidelines (AACE/AHA/TOS, Endocrine Society, Obesity Medicine Association)
- Lack of time and competing priorities in office visits
- Overemphasis on general advice / under-emphasis on intensive behavioral / nutrition / pharmacotherapy
- Obesity bias
- Lack of insurance coverage and high copays for medications
- Lack of “obesity specialist” for referral and treatment (eg endocrinologist, multi-disciplinary team)
### Michigan Medicaid Formulary

<table>
<thead>
<tr>
<th>Anorexiant Combinations</th>
<th>Qsymia 3.75mg-23mg, 7.5mg-46mg, 11.25mg-69mg, 15mg-92mg Capsule</th>
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<td>Anorexiant</td>
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<table>
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<tr>
<th>Anti-Obesity - Fat Absorption Decreasing Agents</th>
<th>XENICAL 120 MG CAPSULE</th>
<th>*PDL-P AGE PA</th>
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<tbody>
<tr>
<td>Anti-Obesity - Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists</td>
<td>SAXENDA 18 MG/3 ML PEN</td>
<td>*PDL-P AGE PA</td>
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<td>WEGOVY 0.25 MG/0.5 ML PEN</td>
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<td>WEGOVY 1 MG/0.5 ML PEN</td>
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<td>WEGOVY 1.7 MG/0.75 ML PEN</td>
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</tr>
<tr>
<td></td>
<td>WEGOVY 2.4 MG/0.75 ML PEN</td>
<td>*PDL-P AGE PA</td>
</tr>
</tbody>
</table>

| Anti-Obesity - Opioid Antag/Norepinephrine & Dopamine Reuptake Inhibit | CONTRAVE ER 8-90 MG TABLET | *PDL-P AGE PA |
Prior Authorization Criteria

Medicaid Health Plan Pharmacy Benefit

This webpage is designed to provide easy access for members and providers looking for information on the drugs and supplies covered by Michigan Medicaid Health Plans.

All plans must at a minimum cover the drugs listed on the Medicaid Health Plan Common Formulary.

History of Formulary Changes:
- Pre-Single PDL Changes (before October 1, 2020)
- Post-Single PDL Changes (after October 1, 2020)

General Formulary Information

FOR PROVIDERS AND PRESCRIBERS ONLY

<table>
<thead>
<tr>
<th>Prior Authorization (PA)</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Prior Authorization criteria for drugs indicated on the Medicaid Health Plan Common Formulary as requiring PA is below:</td>
<td>The Step Therapy criteria for drugs indicated on the Medicaid Health Plan Common Formulary as requiring ST is below:</td>
</tr>
<tr>
<td><strong>Drug PA Criteria</strong></td>
<td><strong>Step Therapy Criteria</strong></td>
</tr>
<tr>
<td>A standard prior authorization form, FIS 2288, was created by the Michigan Department of Insurance and Financial Services (DIFS) to simplify the process of requesting prior authorization for prescription drugs. This form or a prior authorization used by a health plan may be used.</td>
<td></td>
</tr>
</tbody>
</table>

https://www.michigan.gov/mdhhs/0,5885,7-339-71547_4860-380454--,00.html
Prior Authorization Criteria

MHP Common Formulary Prior Authorization Criteria

**ANTIOBESITY AGENTS**

**Drug Class:** Anti-Obesity Agents

**Preferred Agents:** Clinical Prior Authorization below

- **Pancreatic Lipase Inhibitors:**
  - Xenical (orlistat)

- **GLP-1 Agonists:**
  - Saxenda (liraglutide)
  - Wegovy (semaglutide)

- **Combination Products:**
  - Qsymia (phentermine/topiramate); C-IV
  - Contrave (bupropion/naltrexone)

- **Noradrenergic Sympathomimetic Agents:**
  - benzphetamine (only available as generic); C-III
  - diethylpropion (only available as generic); C-IV
  - Adipex-P (phentermine); C-IV
  - Lomaira (phentermine); C-IV
  - phentermine; C-IV
  - phenidimetrazine (only available as generic); C-III

**Clinical Prior Authorization**

**Initial**

- Patient must have a body mass index (BMI) ≥ 30 kg/m²; OR
- Patient must have a body mass index (BMI) ≥ 27 kg/m² but <30 kg/m² and at least one of the following risk factors:
  - Hypertension, coronary artery disease, diabetes, dyslipidemia, or sleep apnea; AND
  - Patient age ≥ 12 years (Xenical, Saxenda); OR
  - Patient age ≥ 18 years (Wegovy, Qsymia, Contrave, benzphetamine, diethylpropion, phentermine, phenidimetrazine); AND
- Prescriber attests to patient's absence of any contraindications to use of the requested product; AND
- Prescriber attests that the patient is not pregnant or lactating; AND
- Prescriber attests that at least one previously documented weight reduction attempt in the past year; AND
- Prescriber attests medication therapy is part of a total treatment plan including a calorie and fat restricted diet and exercise regimen.

**MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.**

**Renewal**

- Prescriber attests that patient has achieved a weight loss of ≥ 5% of weight at time of last prior authorization;
- Length of approval for both initial and renewal: 6 months

☐ **Duration of Approval:** 6 months

Standard Prior Authorization Form

Michigan Prior Authorization Request Form for Prescription Drugs

(Prescribers Submit This Form to the Patient's Health Plan)

A) Reason for Request
☐ Initial Authorization Request ☐ Renewal Request ☐ DAW

B) Patient Demographics
Is patient hospitalized? ☐ Yes ☐ No

Patient Name: ___________________________ DOB: ___________________________

Patient Health Plan ID: ___________________________

☐ Male ☐ Female

C) Pharmacy Insurance Plan
☐ Priority Blue Cross Blue Shield of Michigan ☐ HAP

☐ Total Health Care ☐ Blue Care Network ☐ HealthPlex of Michigan ☐ Meridian Health Plan

D) Prescriber Information
Prescriber Name: ___________________________ Specialty: ___________________________

DEA (required for controlled substance requests only): ___________________________

Contact Name: ___________________________ Contact Phone: ___________________________

Health Plan Provider ID (if accessible): ___________________________

E) Pharmacy Information (optional)
Pharmacy Name: ___________________________ Pharmacy Telephone: ___________________________

F) Requested Prescription Drug Information
Drug Name: ___________________________ Strength: ___________________________

Dosing Schedule: ___________________________ Duration: ___________________________

Diagnosis (specific) with ICD#: ___________________________

Place of infusion / injection (if applicable): ___________________________

Facility Provider ID (if NPI): ___________________________

Has the patient already started the medication? ☐ Yes ☐ No If so, when? ___________________________

G) Rationale for Prior Authorization (e.g., information such as history of present illness, past medical history, current medications, etc.; you may also attach chart notes to support your request if you believe they will assist with the review process)

H) Failed/Contraindicated Therapies

Drug Name: ___________________________ Strength: ___________________________

Dosing Schedule: ___________________________ Duration: ___________________________

Adverse Event/Specific Failure: ___________________________

I) Other Pertinent Information (Optional - to be filled out if other information is necessary such as relevant diagnostic labs, measures of response to treatment, etc.) Please refer to plan's website for additional information that may be necessary for review. Please note that sending this form with insufficient clinical information may result in extended review period or adverse determination.

I represent to the best of my knowledge and belief that the information provided is true, complete and fully disclosed. A person may be committing insurance fraud if false or deceptive information with the intent to defraud is provided.

Physician's Name: ___________________________

Physician's Signature: ___________________________

Date: ___________________________

PA 216 of 1996 (as amended) requires the use of a standard prior authorization form by prescribers when a patient's health plan requires prior authorization for prescription drug benefits.

*For Health Plan Use Only*

Request Date: ___________________________  ☐ LB: ___________________________

Approved By: ___________________________ ☐ Denied By: ___________________________

Effective Date: ___________________________ Reason for Denial: ___________________________

Additional Comments: ___________________________

Why did my prior authorization get rejected?

- Does the patient have a BMI of ≥27 and at least one approved co-comorbidity if BMI <30? (HTN, CAD, DM, HLD, OSA)
- Did I attest that the patient had tried a prior weight loss attempt?
- Did I provide documentation of a calorie and fat restricted diet and planned exercise regimen?
Why did my prior authorization get rejected?

Authorization note template:

I evaluated @name@, a @age@ year old adult for an anti obesity medication.

@vs@

(BMI≥30) Starting weight was *** and starting BMI was ***
(BMI 27-29.9) Starting weight was *** and starting BMI was *** with the following comorbidity: *** hypertension, CAD, diabetes, hyperlipidemia, sleep apnea

I attest that:

✔ there are no contraindications to the medication I have prescribed.
✔ the patient is not pregnant or lactating.
✔ the patient has at least one previously documented weight reduction attempt in the last year. Details include ***.
✔ the patient is engaging in a calorie and fat restricted diet and exercise regimen. Details include: ***

I recommended that the patient engage in the Diabetes Prevention Program and/or Diabetes Education Program.
What about repeat prior authorizations?

• Provide initial attestation information and also:
  • I evaluated @name@ who was prescribed the medication *** on **/**/**. After six months @name@ has experienced a weight change of *** lb, for a percent weight change of **%.
Considerations

If there is a long delay to meet with a nutritionist or other health professional to prescribe a calorie-restricted eating plan, you may want to wait to prescribe AOM until that visit so that your patient maximizes their likelihood of 5% weight loss during Medicaid’s 6 month initial authorization period.
SB 247: Prior Authorization

All insurers must have

• Standard electronic PA request process
• Base PA requirements on peer reviewed clinical review criteria
• Requires a licensed physician to review appeal prior to affirming an appeal denial

https://www.msms.org/
SB 247: Prior Authorization

By June 1 2023

• Must act on urgent PA within 72 hours
• Must act on standard PA within 9 calendar days

Must adopt a performance-based PA program

Quality Improvement To-Do List

1. **Aim:** to increase the utilization of anti-obesity medications for people with obesity on Medicaid who are eligible and would benefit from them.

2. **PDSA:**
   - **Plan:** meet with your staff person who assists with prior authorization, review criteria and develop workflow.
   - **Do:** try prescribing for one patient.
   - **See:** where are any barriers to authorization?
   - **Act:** address barriers and continue prescribing when appropriate.
Figure 2: Primary outcomes and remission of type 2 diabetes in relation to weight loss at 12 and at 24 months
Regression models adjusted for practice list size, study centre, and a random effect for practice. (A) First coprimary outcome, achievement of at least 15 kg weight loss, by randomised group. (B) Second coprimary outcome, remission of type 2 diabetes (HbA$_1c$ <48 mmol/mol [6.5%] and off antidiabetes drugs since baseline), by randomised group. (C) Remission of type 2 diabetes in relation to weight loss achieved (both randomised groups combined).
ADA Standards on Obesity

- Short term VCLD may be used with medical supervision
- AOM’s are effective as adjunct to lifestyle change.
- Reducing overall carbohydrates is beneficial for glycemia. Emphasize high fiber, minimally processed vegetables, fruits and whole grains.
Weight loss of ≥10% early in the Type 2 diabetes disease trajectory was associated with a doubling of the likelihood of remission at 5 years. This was achieved without intensive lifestyle interventions or extreme calorie restrictions. Greater attention should be paid to enabling people to achieve weight loss following diagnosis of Type 2 diabetes.
Resources: Coming Soon

Medication one-page guide
Insurance coverage grid
<table>
<thead>
<tr>
<th>Medication Coverage By Payer in Michigan</th>
<th>Anti-Obesity Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRIVATE PLANS</strong></td>
<td><strong>PUBLIC PLANS</strong></td>
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<td>BCBM/BCN</td>
<td>HAP</td>
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<tr>
<td>Phentermine High Dose</td>
<td>Priority Health 90%</td>
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<tr>
<td>Oral - Daily/With Meals</td>
<td>Medicare</td>
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<tr>
<td>Preferred</td>
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<td>Phentermine 8 Low Dose</td>
<td>Medicaid</td>
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<td>Lomaira</td>
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<td>Preferred</td>
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<td>Injectable - Weekly</td>
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<td>Not preferred</td>
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</table>

Estimated cost generated from medicare.gov tool, with Medicare Part D, Washtenaw County selected.

Download this coverage table:
https://michmed.org/Mx2M3

Based on Q1-2022 Payer Policies. Subject to Change
See an error? Let us know at ccteam@mct2d.org
Last Updated: 2022-April 29
<table>
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<tr>
<th>Medication</th>
<th>Aetna</th>
<th>BCBSM/BCN</th>
<th>HAP</th>
<th>Humana</th>
<th>Priority Health</th>
<th>United</th>
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</tbody>
</table>

Download this coverage table: [https://michmed.org/Mx2M3](https://michmed.org/Mx2M3)
Questions?
What resources do you want / need to enhance your care of patients with T2D and obesity?
References


Extra Slides
OFF LABEL: Phentermine and Topiramate

Phentermine 15 mg capsules
Phentermine 37.5 mg tablets
one-half tablet (18.75 mg)

Topiramate 25 mg, 50 mg
Topiramate ER 50 mg

Start Phentermine 15 or 18.75 mg PO QAM
Add Topiramate 25 mg PO QHS X 2 weeks

Continue Phentermine 15/18.75 mg PO QAM
Increase Topiramate to 25 mg PO BID
OR
Switch to Topiramate ER 50 mg QD

Continue Phentermine 15/18.75 mg PO QAM
Increase Topiramate to 50 mg PO BID
OR
Switch to Topiramate ER 100 mg QD

Winkelman 2020
OFF LABEL: Bupropion and Naltrexone

Bupropion SR 150 mg tablets
Bupropion XL 150/300 mg tablets
Naltrexone 50 mg tablets

Start bupropion SR 150 mg QD for 2 weeks
Increase bupropion SR 150 mg BID
OR
Start bupropion XL 150 QD for 4 weeks
Increase bupropion XL to 300 mg QD

Then add on:
Naltrexone 12.5 mg (1/4 tab) QD for 2 weeks
Increase to 12.5 mg (1/4 tab) BID for 2 weeks
Increase to 25 mg BID r 50 mg QD if tolerated

Contrave 8/90mg tab ~ Naltrexone 12.5 mg + 150mg Bupropion 150 mg tab
The Body Defends a Weight Set Point

Behavior drives physiology

Physiology drives behavior
Selecting Anti-Obesity Medications

- **Safety** – contraindications and precautions
- **Tolerability** - side effect profile
- **Efficacy**
- **Preferences** – out of pocket cost and regimen
- **Dual benefits** – double benefit for a co-occurring disorder or risk factor.
Stepped Treatment Recommendations for Obesity

[Image: Obesity Treatment Pyramid]

1. **Multicomponent/Intensive Behavioral Intervention**
   - 2-5% goal weight loss

2. **Prescriptive Nutritional Intervention**
   - 5-10% goal weight loss
   - Examples: meal replacements, intermittent fasting, specific diet

3. **Pharmacotherapy**
   - 5-20% goal weight loss

4. **Endoscopic Procedures**
   - 10-20% goal weight loss

5. **Surgery**
   - 20-40% goal weight loss

**Increasing health risks, increasing adiposity**

- BMI > 40
- BMI > 35 with comorbidity

- BMI > 30
- BMI > 27 with comorbidity

Tucker 2021