ANTI-OBESITY MEDICATION PROTCOLS

TOOLKIT

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MEDICATION PROTOCOLS

1. Liraglutide 3 mg (Saxenda® or Victoza®)
2. Semaglutide 2.4 mg (Ozempic® or Wegovy®)
3. Tirzepatide (Mounjaro®)
4. Phentermine (Adipex®)
5. Phentermine/Topiramate ER (Qsymia®)
6. Lisdexamfetamine (Vyvanse®)
7. Topiramate
8. Setmelanotide (Imcivree®)
9. Metformin (Glucophage®)
10. Orlistat (Xenical®)
11. Naltrexone/bupropion ER (Contrave®)

LIRAGLUTIDE (SAXENDA® OR VICTOZA®) PROTOCOL

Patient Selection

1. FDA-approval:

- **a. Obesity indication (Saxenda®):**
  - i. Youth ≥12 years with body weight above 60 kg (132 lbs) and an initial BMI corresponding to ≥30 kg/m^2 for adults by international cut-offs
  - ii. Adults ≥18 years with BMI ≥30 kg/m^2 or BMI ≥27 kg/m^2 with weight-related comorbidity
- **b. Type 2 diabetes (Victoza®):**
  - i. Pediatric: ≥10 years old
  - ii. Adults: ≥18 years old
- **c. Other Considerations:**
  - i. T2DM
  - ii. Insulin resistance: acanthosis nigricans, elevated fasting blood glucose levels between 100 and 125 mg/dL, or hemoglobin A1c between 5.7 and 6.4%
  - iii. Poor satiety
  - iv. Food cravings
  - v. NAFLD

2. CONTRAINDICATIONS

- **a. Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia (MEN) syndrome type 2**
- **b. Pregnancy and breastfeeding**

3. USE CAUTION

- **a. Thyroid c-cell tumors**
- **b. Pancreatitis**
- **c. Acute gall bladder disease**
- **d. Renal impairment**
- **e. Serious hypoglycemia**
- **f. Suicidal ideation**
- **g. Taking insulin**

4. To Start Liraglutide:

- **a. Check baseline basic metabolic panel to assess kidney function**
- **b. Review warnings with patient and family**
  - i. Nausea, diarrhea, constipation, vomiting, abdominal pain, dyspepsia
  - ii. Headache, dizziness, fatigue
  - iii. Hypoglycemia
- **c. Start liraglutide: 0.6 mg daily subcutaneously for 1 week, then increase by 0.6 mg each week to max dose of 3 mg daily**

5. Follow-up:

- a. See patient every 1-3 months, initially to review side effects, efficacy
- b. Expect BMI stabilization at a minimum

6. Discontinue:

- a. If BMI continues to increase at full dose after 3-4 months or with side effects

LIRAGLUTIDE (SAXENDA® OR VICTOZA®) PATIENT EDUCATION

What is it used for?

Saxenda® (3 mg dose) is a medication that is used to treat obesity in adults and children ages 12 years old and older. It has been approved by the Food and Drug Administration (FDA). The same medication, at a different dose, is also known as Victoza® (1.8 mg dose) and is approved to treat type 2 diabetes.

How does it work?

- Saxenda® and Victoza® work by copying the actions of a hormone called glucagon-like peptide-1 (GLP-1).
- After you eat a meal, insulin (a hormone) is produced. This medication works by increasing the amount of insulin produced. This will lower your blood sugar.
- Saxenda® and Victoza® also stimulate part of the brain that controls appetite (feelings of hunger). It also slows down the rate that food leaves your stomach. You will feel full for a longer period of time. Together, these actions help you feel less hungry.

How should I take this medication?

Saxenda® and Victoza® are taken once a day as an injection — most people either chose to give it either in the morning or in the evening.

- **For Victoza®**
  - **Week 1:** 0.6 mg once a day
  - **Week 2:** 1.2 mg once a day
  - **Final Dose (as tolerated):** 1.8 mg once a day
- **For Saxenda®**
  - **Week 1:** 0.6 mg once a day
  - **Week 2:** 1.2 mg once a day
  - **Week 3:** 1.8 mg once a day
  - **Week 4:** 2.4 mg once a day
  - **Final Dose (as tolerated):** 3.0 mg once a day
- Saxenda® and Victoza® can be injected into your stomach, upper thigh, upper arm, or upper buttock. Use a different place on the body for each injection.
- Make sure to count to 5 very S-L-O-W-L-Y while you are injecting Saxenda® or Victoza®. Your body only needs a very tiny amount of the medication. You will notice only a tiny amount coming out of the needle.
- You should also count to 5 slowly when you are taking out the needle from your skin. By doing this, you are making sure that your body has gotten all the medication.
- If you miss a dose of Saxenda® or Victoza®, skip that dose and take your next dose at the next prescribed time. **Do not take 2 doses of Saxenda® or Victoza® at the same time.**

What are the potential side effects?

The most common side effects include:

- Nausea
- Vomiting (throwing up)
- Decreased appetite
- Indigestion (pain or discomfort in the stomach after eating)
- Constipation (hard to poop or not often enough)

Both Saxenda® and Victoza® may make your stomach feel upset.
If this happens, it may help to:

- Eat smaller meals and eat slower.
  - Eat small meals or snacks throughout the day instead of one large meal.
  - Take about 15 – 20 minutes to eat your meal.
- Eat about half of what you usually eat.
- Add fruits, vegetables, whole grains and lean proteins to meals and snacks.
- Limit foods that are spicy, greasy or fried.
- Limit packaged snacks like cookies, chips, cakes, doughnuts, ice cream.
- Drink water instead of sweet drinks like soda, lemonade, sports drinks.
- Avoid alcohol.
- Take Saxenda® and Victoza® with food to help decrease stomach upset.
- Pay attention to how you are feeling when you eat. When you feel full, stop eating. This will give your stomach time to empty.

Will Saxenda® and Victoza® lower my blood sugar?

There is a small chance you may have some low blood sugar after taking the medication. (Note: If you are also taking insulin, your doctor may recommend adjusting your insulin dose to avoid low blood sugars.)

The signs of low blood sugar are:

- Weakness
- Shaky
- Hungry
- Sweating
- Confusion

****If you notice these signs, please have something to eat or drink and call the doctor.**

Are there any other risks to these medications?

The risk of pancreatitis (inflammation of the pancreas) has been rarely associated with Saxenda® and Victoza®. If you have had pancreatitis in the past, these medications may not be the right medication. Notify the doctor is you have any history of problems with your pancreas.

Symptoms of pancreatitis include:

- Pain in your upper stomach area which may travel to your back and may worsen after eating
- Stomach area may be tender to the touch
- Vomiting, nausea and/or fever

****If you should develop any of these symptoms, stop the Saxenda or Victoza and contact your doctor. They will do a blood test to check for pancreatitis.**

Saxenda® and Victoza® has been associated with thyroid cancer in animal studies.
You should not use Saxenda® and Victoza® if:

1. You have a history of certain types of thyroid cancers or
2. If you have a family history of Multiple Endocrine Neoplasia (MEN) syndrome.

****Notify your doctor if you develop a lump on your neck, hoarseness (unusual change in your voice), difficulty swallowing or breathing.**

How do I store Saxenda®/Victoza®?

Saxenda®/Victoza® can be stored at room temperature, or in the refrigerator, for 30 days after opening. Do not freeze Victoza® or leave the pen in high temperatures above 100 degrees Fahrenheit.

How much Saxenda®/Victoza® do I take?

To reduce the side effects, it is recommended to slowly increase the dose of Saxenda® and Victoza® weekly until you reach your prescribed dose.

SAXENDA®	
First Week	Take 0.6 mg once a day from _____ to _____
Second Week	Take 1.2 mg once a day from _____ to _____
Third Week	Take 1.8 mg once a day from _____ to _____
Fourth Week	Take 2.4 mg once a day from _____ to _____
Fifth Week and on	Take 3.0 mg once a day from _____ to _____ and continuing daily
VICTOZA®	
First Week	Take 0.6 mg once a day from _____ to _____
Second Week	Take 1.2 mg once a day from _____ to _____
Third Week and on	Take 1.8 mg once a day from _____ to _____ and continuing daily

SEMAGLUTIDE (OZEMPIC® OR WEGOVY®) PROTOCOL

Patient Selection

1. FDA-approval:

- **a. Obesity indication (Wegovy®):**
  - i. Youth ≥12 years with BMI ≥95th percentile
  - ii. Adults ≥18 years with BMI ≥30 kg/m^2 or with BMI ≥27 kg/m^2 with weight
- **b. Type 2 diabetes indication:**
  - i. Ozempic®: ≥18 years old
  - ii. Rybelsus® (oral semaglutide): ≥18 years old
- **c. Other Considerations: Consider for patients with:**
  - i. T2DM
  - ii. Insulin resistance: acanthosis nigricans, elevated fasting blood glucose levels between 100 and 125 mg/dL, or hemoglobin A1c between 5.7 and 6.4%
  - iii. Poor satiety
  - iv. Food cravings
  - v. NAFLD

2. CONTRAINDICATIONS

- **a. Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia (MEN) syndrome type 2**
- **b. Pregnancy and breastfeeding**

3. USE CAUTION

- **a. Thyroid c-cell tumors**
- **b. Pancreatitis**
- **c. Acute gall bladder disease**
- **d. Renal impairment**
- **e. Serious hypoglycemia**
- **f. Suicidal ideation**
- **g. Taking insulin**

4. To Start Semaglutide:

- **a. Check baseline basic metabolic panel to assess kidney function**
- **b. Review warnings with patient and family**
  - i. Nausea, diarrhea, constipation, vomiting, abdominal pain, dyspepsia
  - ii. Headache, dizziness, fatigue
  - iii. Hypoglycemia
- **c. Start semaglutide: 0.25 mg subcutaneously subcutaneously weekly x 4, then 0.5mg weekly x 4, then 1mg weekly x 4, then:**
  - i. If using Wegovy®: 1.7mg weekly x 4, then 2.4mg weekly thereafter
  - ii. If using Ozempic®: 2mg weekly thereafter

5. Follow-up:

- a. See patient every 1-3 months, initially to review side effects, efficacy
- b. Expect BMI stabilization at a minimum

6. Discontinue:

- a. If BMI continues to increase at full dose after 3-4 months or with side effects

SEMAGLUTIDE (OZEMPIC® OR WEGOVY®) PATIENT EDUCATION

What is semaglutide used for?

Semaglutide is a medication that is used to treat diabetes and obesity in people 12 years old and older. It has been approved by the Food and Drug Administration (FDA).

How does it work?

Semaglutide works by copying the actions of a hormone called glucagon-like peptide-1 (GLP-1) to help lower appetite (feelings of hunger) and increase metabolism. Metabolism is the chemical reactions in the body's cells that help change food into energy.

The medicine works in three different ways:

1. It works on the part of the brain that makes us feel hungry and it makes us feel a little bit less hungry.
2. It works on the stomach, and it keeps the stomach full for longer, by emptying the stomach more slowly. This makes us feel less hungry because our stomach is actually still full.
3. It works on the pancreas, the organ that makes insulin. It helps the pancreas to secrete a little bit more insulin to help manage blood sugars and use energy faster.

What are the potential side effects?

The person prescribing semaglutide should discuss the side effects with you. We have included a summary of these potential side effects below. Please let us know if there are any additional questions or if you would like to discuss further.

The most common side effects of semaglutide are:

- Stomach upset
- Nausea
- Vomiting (throwing up)
- Decreased appetite
- Indigestion (pain or discomfort in the stomach af eating)
- Constipation (hard to poop or not often enough)

If this happens, it may help to:

- Eat smaller meals and eat slower.
  - Eat about half of what you usually eat
  - Take about 15 – 20 minutes to eat your meal
- Take semaglutide with food to help decrease stomach upset.
- Eat small meals or snacks throughout the day instead of one large meal.
- Add fruits, vegetables, whole grains and lean proteins to meals and snacks.
- Limit foods that are spicy, greasy or fried.
- Limit packaged snacks like cookies, chips, cakes, doughnuts, ice cream.

- Drink water instead of sweet drinks like soda, lemonade, sports drinks.
- Avoid alcohol
- Pay attention to how you are feeling when you eat. When you feel full, stop eating. This will give your stomach time to empty.

Will semaglutide lower my blood sugar?

Although uncommon, blood sugar may be low after taking semaglutide. If you are taking insulin, the medical team may need to change your dose when you start semaglutide. Let the medical team know if you are taking insulin.

Signs of low blood sugar include:

- Feeling lightheaded
- Shaky
- Hungry
- Weak
- Anxious
- Confused
- Sweaty

****If you notice these signs, please have something to eat or drink and give us a call so we can think together about next steps.**

Are there any other risks to this medication?

The risk of pancreatitis (inflammation of the pancreas) has been rarely associated with semaglutide. If you have had pancreatitis in the past, semaglutide may not be the right medication for you. Notify the doctor is you have any history of problems with your pancreas.

Symptoms of pancreatitis include:

- Pain in your upper stomach area which may travel to your back and may be worse after eating
- Stomach area may be tender to the touch
- Vomiting, nausea and/or fever

****If you develop any of these symptoms, stop the semaglutide and contact your doctor. They will do a blood test to check for pancreatitis.**

Semaglutide has been associated with thyroid cancer in animal studies.

You should not use semaglutide if:

1. You have a history of certain types of thyroid cancers or
2. You have a family history of Multiple Endocrine Neoplasia (MEN) syndrome

****Notify your doctor if you develop a lump on your neck, hoarseness (unusual change in your voice), difficulty swallowing or breathing.**

How should I take this medication?

- Semaglutide is taken one time each week
- Semaglutide can be injected into your stomach, upper thigh, upper arm, or upper buttock. Use a different place for each injection.
- Make sure to count to 5 very S-L-O-W-L-Y while you are injecting semaglutide. Your body only needs a very tiny amount of the medication. You will notice only a tiny amount coming out of the needle.
- You should also count to 5 slowly when you are taking out the needle from your skin. By doing this, you are making sure that your body has gotten all the medication.

How much semaglutide do I take?

To reduce the side effects, it is recommended to slowly increase the dose of semaglutide until you reach your goal dose.

- **To start Ozempic®**
  - Give 0.25 mg semaglutide once each week for 4 weeks. **Start:** _____
  - Then, give 0.5 mg semaglutide once each week for 6 weeks. **Start:** _____
  - Then, give 1 mg semaglutide once each week. This is the final dose. Continue until you see the doctor next. **Start:** _____
- **To start Wegovy®**
  - Give 0.25 mg semaglutide once each week for 4 weeks. **Start:** _____
  - Give 0.5 mg semaglutide once each week for 4 weeks. **Start:** _____
  - Give 1 mg semaglutide once each week for 4 weeks. **Start:** _____
  - Give 1.7 mg semaglutide once each week for 4 weeks. **Start:** _____
  - Then, give 2.4 mg semaglutide once each week. This is the final dose. Continue until you see the doctor next. **Start:** _____

How do I store semaglutide (Ozempic® or Wegovy®)?

Semaglutide can be stored at room temperature, or in the refrigerator, for 30 days after opening. Do not freeze semaglutide or leave the pen in high temperatures more than 100 degrees Fahrenheit.

TIRZEPATIDE (MOUNJARO®) PROTOCOL

Patient Selection

1. FDA-approval

- Type 2 diabetes indication for adults >18 years
- Other Considerations: Obesity indication adults > 18 years

2. CONTRAINDICATIONS

- **Personal or family history of medullary thyroid carcinoma in patients with Multiple Endocrine Neoplasia (MEN) syndrome type 2**

3. USE CAUTION

a. **Thyroid c-cell tumors**
b. **Pancreatitis**
c. **Acute gall bladder disease**
d. **Renal impairment**
e. **Serious hypoglycemia**
f. **Suicidal ideation**
g. **Taking insulin**

4. To Start Tirzepatide:

a. **Check baseline basic metabolic panel to assess kidney function**
b. **Review contraindications with patient and family**
    i. Most common side effects: nausea, vomiting, diarrhea, abdominal pain, decreased appetite, constipation, dyspepsia (>5%)
c. **Start tirzepatide: 2.5 mg subcutaneously once weekly x 4 weeks, then 5 mg weekly x 4 weeks, then 7.5 mg weekly x 4, then 10 mg weekly x4, then 12.5 mg weekly x 4, then 15 mg weekly**
d. **Dosing Logistics: single-dose pen for subcutaneous dosing in abdomen, thigh or upper arm. Rotate injection sites with each dose.**

5. Follow-up:

a. See patient every 1-3 months, initially to review side effects, efficacy
b. Check BMP annually to assess kidney function

6. Discontinue:

a. If BMI continues to increase at full dose after 3-4 months of treatment at maximal tolerated dose
b. Side effects

PHENTERMINE (ADIPEX®) PROTOCOL

Patient Selection

1. FDA-approval

a. Not recommended for patients ≤16 years old

b. BMI ≥30 kg/m2 or ≥27 kg/m2 in presence of weight related comorbidities

c. For "short term" use; interpreted by most to be 12 weeks

- **Consider for patients with:**

a. Strong hunger or poor satiety

b. Low energy

2. CONTRAINDICATIONS

a. History of substance abuse

b. History of CVD including arrhythmias, CAD, uncontrolled HTN

c. Hyperthyroidism

d. Glaucoma

e. History or current use of MAOI

f. Agitated state

3. USE CAUTION

a. High blood pressure (obtain cardiac echo and ensure adequate control of HTN before starting phentermine)

b. History of congenital heart disease (consider cardiology consult before starting)

c. Taking SSRIs (fluoxetine/Prozac®, sertraline/Zoloft®, citalopram/Celexa®) or SNRIs (duloxetine/Cymbalta®, venlafaxine/Effexor®, mirtazapine/Remeron®)

d. Taking insulin

e. Renal impairment

f. Taking other psychostimulants

4. To Start Phentermine:

a. Check for heart murmur, BP, HR, creatinine

b. Review warnings with patient and family

i. Cardiovascular

- High blood pressure
- Palpitations
- Tachycardia
- SOB, chest pain, lower extremity edema (primary pulmonary hypertension)

ii. CNS
   - Agitation
   - Restlessness
   - Insomnia
   - Euphoria/dysphoria
   - Tremor
   - Headache
   - Tolerance and possible withdrawal (at least theoretical for withdrawal)

iii. GI
   - Dry mouth
   - Diarrhea
   - Constipation

c. Start phentermine 15mg Q AM

i. Formulations: 8 mg tab, 15 mg cap, 30 mg cap, 37.5 mg tab and cap

ii. Consider starting with 8 mg or ¼ of 37.5 mg tab QAM in younger adolescents (?8-12 yo)

iii. Phentermine is a controlled substance (Class IV); follow local prescribing regulations

iv. FDA-approved for only "short term use" – 12 weeks

d. Document off-label use and consent for treatment in medical record

i. ("We discussed that phentermine is FDA-approved for 'short term' weight loss in youth older than 16. We reviewed the side effects of this medication, and that there are unknown side effects as well. Patient's parent/guardian consents to treatment.")

e. Give family: phentermine patient info and off-label prescribing info

4. Follow-up:

a. Check BP and HR in 2-3 days if patient has hx of HTN. See patient every 1-3 months initially to review BP, HR, exam, side effects, risks/benefits, and off-label use at each visit

b. Dosage should be individualized to obtain adequate response with lowest effective dose. If BMI is not stabilized or if patient develops tolerance, consider: 1) discontinuing phentermine, or 2) increasing dose to 30-37.5 mg QD (or divided), or 3) adding topiramate or other AOM such as GLP1RA

5. Discontinue:

a. If BMI continues to increase

b. Adverse side effects

PHENTERMINE (ADIPEX®)
PATIENT EDUCATION

What is it used for?

Phentermine is used to decrease appetite in people who carry extra weight.

How does it work?

Phentermine is in a class of medications called anorectics. It works by decreasing appetite.

Patients taking phentermine find that they:

- Feel less hunger
- Find it easier to push the plate away
- Have an easier time eating less

For some patients, these feelings are very real and immediate. For other patients, the feelings are less obvious. Like all weight loss medications, phentermine works best when you help it work.

This means:

- Limit tempting high calorie ("junk") food in your house
- Avoid situations or people that may trigger your food cravings
- Eat out only one time or less each week
- Eat your meals at a table with the TV or computer off

How should I take this medication?

Phentermine is usually taken as a single daily dose in the morning. Do not take a larger dose, take it more often, or take it for a longer period than your doctor tells you to.

Is phentermine safe?

Phentermine is FDA-approved for short-term use in adolescents older than 16 years of age. You should not take phentermine if you have uncontrolled high blood pressure, heart disease, hyperthyroidism (overactive thyroid gland), glaucoma, or if you are taking stimulant ADHD medications.

What are the side effects?

Call your doctor right away if you have any of these side effects:

- Increased blood pressure or heart palpitations
- Severe restlessness or dizziness
- Difficulty doing exercises that you have previously been able to do
- Chest pain or shortness of breath
- Swelling of the legs and ankles

If you notice these less serious side effects talk with your doctor:

- Dry mouth
- Diarrhea or constipation
- Trouble sleeping

PHENTERMINE/TOPAMAX® (QSYMIA®) PROTOCOL

Patient Selection

1. FDA-approval

a. Youth ≥12 years old with BMI ≥95th percentile

b. Adults ≥18 years old with BMI ≥30 kg/m^2 or BMI ≥27 kg/m^2 in presence of at least 1 weight-related comorbidity

- **Dosage forms:** 3.75/23 mg, 7.5/46 mg, 11.25/69 mg, 15/92 mg
- **Preferred administration time:** AM. Need to swallow the capsule whole.
- **Consider for patients with:**

a. Strong hunger or poor satiety

b. Binge-eating symptoms

c. Migraine headaches

2. CONTRAINDICATIONS

a. Pregnancy

b. Glaucoma

c. Hyperthyroidism

d. Within 14 days or current use of monoamine oxidase inhibitors

e. History of substance abuse

3. USE CAUTION

a. History of coronary artery disease, arrhythmia, including family history of arrhythmia, stroke, congestive heart failure, uncontrolled hypertension

b. Agitated state, like mania

c. High blood pressure (obtain cardiac echo to assess for baseline end-organ damage and ensure adequate control of blood pressure before starting phentermine)

d. Congenital heart disease (obtain cardiology consultation before starting phentermine)

e. Use of carbonic anhydrase inhibitors (ex: acetazolamide for the treatment of idiopathic intracranial hypertension) as concomitant use with topiramate may increase the risk of metabolic acidosis

f. Use of SSRIs (e.g. fluoxetine, sertraline, citalopram) and SNRIs (e.g. duloxetine, mirtazapine, venlafaxine) may increase risk of serotonin syndrome

g. Use of insulin — with weight loss, dose of insulin may need to be decreased to avoid hypoglycemia

h. Renal impairment, metabolic acidosis (as from ketogenic diet or use of carbonic anhydrase inhibitors)

i. History of kidney stones

j. Depression, suicidal ideation

k. Patients at high risk for pregnancy, do not start Phentermine/Topiramate ER

4. Review contraindications and situations for caution:

a. **Contraindications: Pregnancy, glaucoma, hyperthyroidism, within 14 days or current use of monoamine oxidase inhibitors, history of substance abuse, history of arrhythmia, stroke, heart failure, history of mania**

b. **CAUTION: High blood pressure, congenital heart disease, use of SSRIs, SNRIs, insulin, or valproic acid, renal disease, metabolic acidosis, history of kidney stones, depression, suicidal ideation, high risk for pregnancy**

5. Review side effects and warnings:

a. **Most common: paresthesia, dizziness, dysgeusia, insomnia, constipation, arthralgia, depression**

b. **Most serious: teratogenic, cleft lip/palate in fetus; counsel on avoiding pregnancy while taking Qsymia®**

c. **Full list:**

i. Cardiovascular: hypertension, tachycardia, palpitations, pulmonary hypertension (presenting with shortness of breath, lower extremity edema and chest pain)

ii. Neurologic: agitation, restlessness, insomnia, anxiety, euphoria/dysphoria, tremor, headache, paresthesia, dizziness, dysgeusia, cognitive impairment (impairment of concentration/attention or memory, word-finding difficulties), potential seizure with abrupt discontinuation (especially relevant for patients with history of seizures, including febrile seizures)

iii. Gastrointestinal: dry mouth, diarrhea, constipation; encourage hydration

iv. Fetal toxicity: may cause cleft lip with or without cleft palate; discuss avoidance of pregnancy

v. Eye: acute onset of decreased visual acuity and/or ocular pain may suggest glaucoma

vi. Worsening depression or suicidal thoughts or behavior (but no more often than any other psychotropic medication)

vii. Metabolic acidosis, elevation of creatinine, nephrolithiasis; encourage hydration

viii. Hypoglycemia in patients taking insulin or insulin secretagogues; decrease insulin dose by 10%, counsel on symptoms of hypoglycemia, monitor BG closely

ix. Oligohydrosis and hyperthermia; encourage hydration especially in hot weather

6. Check for heart murmur, BP, HR, creatinine, bicarbonate, pregnancy test, height for pediatric patient

7. Prescribe phentermine/topiramate ER:

- Phentermine/topiramate ER 3.75mg/23mg capsule Q AM x 14 days,
- Phentermine/topiramate ER 7.5mg/46mg Q AM

Phentermine is a controlled substance (Class IV); follow local prescribing regulation

8. Patient follow-up:

a. Check BP and HR in 3-5 days if patient has elevated blood pressure at baseline

b. See patient monthly x 3 initially

c. Review BP, HR, cardiac exam, height, side effects, pregnancy risk at each visit

d. If patient is tolerating phentermine/topiramate ER 7.5mg/46mg and desired weight loss not achieved, increase to 11.25mg/69mg x 14 days, then 15mg/92mg

e. Dosage should be individualized to obtain desired response with the lowest effective dose. The minimum desired response is BMI stabilization in patients whose BMI had been trending upward before starting phentermine/topiramate ER

f. May experience irregular bleeding or spotting if also on OCPs d/t interference with metabolism, do not discontinue OCPs.

g. If BMI is not stabilized or does not decrease by ≥5% in 3 months, consider:

   i. Increasing dose

   ii. Adding a second AOM such as a GLP1RA

   iii. If patient has side effects, such as high blood pressure or neurological symptoms, consider decreasing dose

9. Discontinue:

a. If BMI continues to increase at full dose after 3-4 months or with side effects

b. Need to taper down prior to discontinuation.

LISDEXAMFETAMINE (VYVANSE®) PROTOCOL

Patient Selection

1. FDA-approval

a. Youth ≥6 years old for attention deficit hyperactivity disorder (ADHD)

b. Adults ≥18 years old for binge eating disorder (BED)

c. Other Considerations:
Consider for patients with:

i. With ADHD

ii. Impulsivity or impulsive eating

iii. Binge eating behaviors

- **Dosage forms:**

a. Capsules: 10, 20, 30, 40, 50, 60, 70 mg, capsules can be opened and sprinkled onto food

b. Chewable tablets: 10, 20, 30, 40, 50, 60 mg

2. CONTRAINDICATIONS

a. Use of MAO inhibitors within 14 days

b. Taking phentermine?

3. USE CAUTION

a. High blood pressure (obtain cardiac echo and ensure adequate control of HTN before starting)

b. History of congenital heart disease or pacemaker (cardiology consult before starting)

c. Anxiety

4. To Start Lisdexamfetamine:

a. Check BP and HR, CV exam, height, pregnancy test

b. Review side effects with patient and family

i. anxiety

ii. loss of appetite

iii. nausea

iv. diarrhea

v. trouble sleeping

vi. dizziness

vii. upper stomach pain

viii. dry mouth

ix. vomiting

x. irritability

xi. growth suppression

c. Start lisdexamfetamine 30 mg Q AM; if patient does not have diagnosed ADHD, consider using diagnostic code of "impulsive"

5. Patient follow-up:

a. See patient monthly x 3, at least to start

b. Increase by 10 mg increments every 1-2 months

c. For adolescents with BED: start at 30 mg Q AM x 1 week, then increase to 50 mg Q AM. May increase to 70mg Q AM as needed to decrease frequency of binge eating.

d. In growing youth, monitor height

e. Consider adding topiramate for patients whose weight loss has reached a plateau

6. Discontinue:

a. If unable to tolerate

b. If BMI continues to increase

TOPIRAMATE
PATIENT EDUCATION

What is it used for?

Topiramate helps patients feel full more quickly and feel less hungry. It may also help patients binge eat less often. Topiramate may help you stick to a healthy diet, though used alone, it will not cause weight loss.

Although topiramate is **not currently approved by the FDA for weight loss**, it is used commonly in weight management clinics for this purpose.

Topiramate may help you:

- Feel less interest in eating in between meals
- Think less about food and eating
- Find it easier to push the plate away
- Find giving up pop/soda easier
- Have an easier time eating less

For some patients, topiramate works right away. They feel and think quite differently about food. Other patients don't feel much of a change but find, in fact, that they have lost weight! Like all weight loss medications, topiramate works best when you help it work.

This means:

- Have less tempting high calorie ("junk") food around the house
- Have lower-calorie food (fruits, vegetables, low-fat meats and dairy) for snacks
- Eat out only one time or less each week
- Eat your meals at a table with the TV or computer off

How does it work?

Topiramate is a medication that was originally developed to treat seizures in children and migraine headaches in adults. It affects chemical messengers in the brain, but the exact way it works to decrease weight is unknown.

How should I take this medication?

Start with 25 mg (1 tab) daily for a week. Increase to 50 mg (2 tabs) daily for the next week. At the third week, take 3 tabs (75 mg) daily. Stay at 3 tabs until you are seen again.

Is topiramate safe?

Most people tolerate topiramate with no problems. Please tell your doctor if you have a history of kidney stones, if you are taking phenytoin or birth control pills, or if you are pregnant. Topiramate is harmful in pregnancy. Topiramate can decrease your ability to tolerate hot weather. Be sure to drink plenty of water to prevent dehydration and kidney stones.

What are the side effects?

Call your doctor right away if you have any of these side effects:

- Change in mood, especially thoughts of suicide
- Rash
- Pain in your flanks (side and back) or groin

If you notice these less serious side effects, talk with your doctor:

- Numbness or tingling in hands and feet
- Nausea
- Mental fogginess, trouble concentrating, memory problems
- Diarrhea

ONE OF THE DANGERS OF TOPIRAMATE IS THE POSSIBILITY OF BIRTH DEFECTS

If you get pregnant when you are taking topiramate, there is the risk that your baby will be born with a cleft lip or palate. If you are taking topiramate and are of childbearing age, you must use a reliable form of birth control or refrain from sexual intercourse.

IMPORTANT NOTE: Topiramate may decrease the effectiveness of birth control pills.

TOPIRAMATE PROTOCOL

Patient Selection

1. FDA-approval

a. ≥ 2 years old for seizures

b. ≥ 12 years old for migraine prophylaxis

c. Other Considerations:
Consider for patients with:

i. Poor satiety

ii. Food cravings

iii. Symptoms of binge eating disorder

iv. Weight gain due to atypical antipsychotic medication (eg aripiprazole/Abilify®, olanzapine/Zyprexa®, ziprasidone/Geodon®, risperidone/Risperdal®) AND do not have insulin resistance/prediabetes

v. Migraine headaches

vi. Night eating

vii. Seizures (discuss with neurologist: valproic acid+topiramate may increase risk of hyperammonemia)

viii. Mood swings who could benefit from mood stabilizer

3. CONTRAINDICATIONS – none

4. USE CAUTION

i. Kidney stones

ii. Glaucoma

iii. High risk for pregnancy due to fetal toxicity (and because topiramate may render oral contraceptives less effective)

iv. Metabolic acidosis — especially if on acetazolamide (as for pseudotumor cerebri) or with kidney disease or diabetes

v. Active suicidal ideation

vi. Poor cognitive function and academic struggles

5. To Start Topiramate:

1. **Check baseline basic metabolic panel to assess for metabolic acidosis and kidney function**
2. **Check baseline urine pregnancy test in females**
3. **Review warnings with patient and family**
   a. **Paresthesia – most common**
   b. **Fatigue**
   c. **Cognitive dysfunction – especially short-term memory loss and word-finding difficulty at doses above 100 mg QD**

d. **Teratogenic potential**
e. **Symptoms of kidney stones**
f. **Oligohydrosis and hyperthermia, especially in summer months — encourage good hydration**
g. **Itching**
h. **Mood changes**
i. **Acute myopia**

6. **Start topiramate:** 25 mg Q AM for week 1, 50 mg Q AM for week 2, then 75 mg Q AM for week 3 and thereafter; consider dosing at night if patient is fatigued at baseline or develops fatigue

7. **Include discussion of off-label use of topiramate and consent for treatment in documentation** ("We discussed that topiramate is not FDA approved for the indication of weight loss, but that it has been shown to help reduce weight in well-controlled clinical studies. We reviewed the side effects of this medication, and that there are unknown side effects as well. Patient's parent/guardian consents to treatment.")

8. **Give family topiramate patient info and off-label prescribing info**

9. **Follow-up**
   a. See patient every 1-3 months initially
      i. Recheck electrolytes at 6 months to monitor bicarbonate and regularly thereafter
      ii. Review side effects, risks/benefits, and off-label use
   b. Expect BMI stabilization at a minimum; may need to split dose or increase dose (up to 75-200 mg BID?) if patient not responding; consider adding phentermine if BMI stabilizes but not yet decreasing

10. **Discontinue**
    a. If BMI continues to increase at full dose (75-100 mg BID) after 3-4 months or with side effects
    b. To stop topiramate, wean off slowly. Abrupt discontinuation may precipitate seizures

SETMELANOTIDE (IMCIVREE®) PROTOCOL

Patient Selection

1. FDA-approval

a. ≥6 years old with genetic variants interpreted as pathogenic, likely pathogenic, or variant of uncertain significance (VUS) in the following genes:

i. POMC (propiomelanocortin)

ii. PCSK-1 (proprotein convertase subtilisin/kexin type 1

iii. LEPR (leptin receptor)

b. ≥6 years old with Bardet-Biedl syndrome

2. CONTRAINDICATIONS – none

3. USE CAUTION

a. Renal disease

4. To Start Setmelanotide:

1. Ensure patient has an eligible genetic mutations or syndromes
2. Complete "Imcivree Start" form available on-line. Copy of patient's genetic test results will need to be submitted with form, except for BBS.
3. Contact specialty pharmacy to ensure supply of medication is available
4. Check basic metabolic panel to ensure adequate kidney function.
5. Perform a complete skin exam, paying attention to nevi.
6. **Review contraindications and side effects with patient and family:**

   Most common side effects: Injection site reactions, darkening of skin (≈ 60- 70%), nausea, vomiting, diarrhea, abdominal pain, headache, back pain, depression (≈ 25%), erections that happen without any sexual activity in males (≈ 25%)
7. **Start setmelanotide:**

   a. **6 - <12 years old:**

   – 1 mg subcutaneously QD x 2 weeks, then

   – 2 mg subcutaneously QD x 2 weeks, then

   – 3 mg subcutaneously QD thereafter

   b. **≥12 years old:**

   – 2 mg subcutaneously QD x 2 weeks, then

   – 3 mg subcutaneously QD thereafter
8. **Dosing Logistics:**

   Vial and syringe administration. To minimize injection site reactions, provide instruction to remove excess medication such as droplets from outside syringe

5. Follow-up

a. If dose escalation is not tolerated, decrease by 1 mg daily and re-assess after 1 week

b. Check patient monthly x 3, at least, to start

- Review side effects
- Target dose is 3 mg daily
- If BMI is not stabilized or does not decrease by ≥5% in 3-4 months, consider adding a second AOM such as phentermine, topiramate or a GLP1RA

c. Check BMP annually to assess kidney function

d. Periodic complete skin examinations to follow up on existing nevi and evaluate for new skin lesions

6. Discontinue

a. If BMI continues to increase after 3-4 months of treatment at maximal tolerated dose.

b. If unable to tolerate

METFORMIN (GLUCOPHAGE®) PROTOCOL

Patient Selection

1. FDA-approval

a. ≥10 years old with type 2 diabetes

   i. Studied in children ≥ 6 years old with obesity

b. Other considerations:
Consider for patients:

   i. Taking second-generation atypical antipsychotics (in order of most to least obesogenic: olanzapine/Zyprexa®, quetiapine/Seroquel®, risperidone/Risperdal®, ziprasidone/Geodon®, aripiprazole/Abilify®)

   ii. Polycystic ovary syndrome

   iii. Pre-diabetes [HbA1c 5.7-6.4 or IFG (100-125) or IGT (2 hour-OGTT 140-199)]

   iv. Type 2 diabetes

2. CONTRAINDICATIONS

a. Metabolic acidosis, including DKA

3. USE CAUTION

a. Renal or liver disease

4. To Start Metformin:

a. Check basic metabolic panel, ALT, and HbA1c

b. If suspect type 1 DM, check auto-antibodies (glutamic acid decarboxylase, IA-2 antibody, insulin antibody, islet cell antibody IgG, zinc transporter antibody)

c. Review side effects with patient and family

   – GI symptoms are most common — diarrhea, nausea, vomiting, flatulence

   – Rare cobalamin (B12) deficiency

d. Start metformin XR 500 mg QD with dinner for week 1, then increase to 1000 mg XR with dinner (if <10 yo, consider starting at 250 mg QD).

e. Suggest daily multivitamin containing B12 vitamin

5. Follow-up:

a. Consider increasing to 2,000 mg XR with dinner as tolerated, especially if also taking atypical antipsychotics

b. Monitor HbA1c every 3-6 months, basic metabolic panel and CBC annually

c. Hold metformin during an illness with vomiting or diarrhea. Also, stop at time of IV contrast for CT studies and resume 48 hours after the procedure

6. Discontinue:

a. If unable to tolerate

b. If BMI continues to increase and no improvement in HbA1c

ORLISTAT (XENICAL®) PROTOCOL

Patient Selection

1. FDA-approval

a. Youth ≥12 years old with BMI ≥95th percentile

b. Adults with BMI ≥30 kg/m^2 or ≥27 kg/m^2 with weight-related comorbidities

c. Other considerations:
Consider for patients:

i. Want a medication that is not systemically absorbed or without central activity

ii. Prefer to purchase medication over-the-counter

2. CONTRAINDICATIONS

a. Chronic malabsorption

b. Cholestasis

3. USE CAUTION in the following patients:

a. Taking levothyroxine

b. Taking cyclosporine

c. Taking seizure medications

d. Liver disease

e. Renal impairment

4. To Start Orlistat:

a. Check baseline AST, ALT, liver function tests, creatinine

b. Start orlistat 120 mg TID with meals

i. Skip dose if skipping meals

ii. Take daily multivitamin with fat-soluble vitamins and beta-carotene 2 hours before or after orlistat dose

c. Consider over-the-counter formulation if insurance does not cover Xenical

i. OTC dose is 60 mg TID with meals (close to 80% as effective as prescription strength)

d. Review side effects

i. Most common are GI: 50% of all GI side effects lasted for less than 1 week and majority for no more than 4 weeks

ii. Hepatic dysfunction: jaundice, pruritus, anorexia, dark urine, light-colored stools

iii. Oxalate nephrolithiasis or nephropathy: painful or frequent urination, blood in urine, severe flank, back or groin pain, swelling of legs

iv. Cholelithiasis: nausea, vomiting, RUQ pain

5. Discontinue:

a. If unable to tolerate

b. If serious side effect is suspected

b. If BMI continues to increase after 3 months of treatment

BUPROPRION/NALTREXONE ER (CONTRAVE®) PROTOCOL

Patient Selection

1. FDA-approval

a. Adults ≥18 years old with BMI ≥30 kg/m2 or BMI ≥27 kg/m2 in presence of at least 1 weight-related comorbidity

- **Dosage forms:** 8/90 mg extended release tablet
- **Preferred administration time:** Morning and evening. Need to swallow the tablet whole. Should not take with high-fat meal

c. Other considerations:
Consider for patients:

i. Strong hunger

ii. depression

2. CONTRAINDICATIONS

a. Uncontrolled hypertension

b. Seizure disorder or history of seizures

c. Anorexia or bulimia

d. Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs

e. Use of other buproprion-containing agents

f. Within 14 days or current use of monoamine oxidase inhibitors

g. Known allergy to any of the ingredients in Contrave®

3. USE CAUTION in the following patients:

a. Substance abuse

b. Glaucoma

c. High blood pressure

d. Use of insulin — with weight loss, dose of insulin may need to be decreased to avoid hypoglycemia

i. Hepatic or renal impairment (dose adjustments recommended)

ii. Depression, suicidal ideation

iii. Patients at high risk for pregnancy

4. To Start Buproprion/Naltrexone ER:

a. Review contraindications and situations for caution

b. Review side effects and warnings

– Suicidal thoughts and behaviors

– Cardiovascular: hypertension, tachycardia, palpitations,

- Neuropsychiatric: seizure, headache, depression, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania,
- Allergic Reactions
- Hepatotoxicity
- Increased serum creatinine
- Gastrointestinal: nausea, vomiting, dry mouth, diarrhea, constipation; encourage hydration
- Eyes: angle closure glaucoma. acute onset of decreased visual acuity and/or ocular pain may suggest glaucoma
- Hypoglycemia in patients taking insulin or insulin secretagogues; decrease insulin dose by 10%, counsel on symptoms of hypoglycemia, monitor BG closely

c. Check for heart murmur, BP, HR, creatinine, liver function, pregnancy test

BUPROPRION/NALTREXONE ER : DOSING RECOMMENDATIONS		
Week	**Morning Dose**	**Evening Dose**
Starting: Week 1	1 tablet	None
Week 2	1 tablet	1 tablet
Week 3	2 tablets	1 tablet
Week 4 Onward	2 tablets	2 tablets

5. Follow-up

a. Check BP and HR in 3-5 days if patient has elevated blood pressure at baseline
b. See patient monthly x 3 initially
c. Review BP, HR, cardiac exam, side effects, pregnancy risk at each visit
d. If BMI is not stabilized or does not decrease by ≥5% in 3 months, consider adding a second AOM such as a GLP1RA
e. If patient has side effects, such as high blood pressure or neurological symptoms, consider decreasing dose

6. Discontinue

a. If BMI continues to increase at full dose after 3-4 months or with side effects

BUPROPRION/NALTREXONE ER (CONTRAVE®) PATIENT EDUCATION

What is it used for?

Contrave® is used to decrease appetite in people who carry extra weight

How does it work?

Contrave® is a prescription medicine which contains two medicines (naltrexone and bupropion). How it works is not fully known, but with a reduced-calorie diet it has been shown to help patients lose weight.

How should I take this medication?

Contrave® is started as one pill in the morning and increased weekly to a dosage of two pills twice a day. Contrave® should not be taken with a high-fat meal. Tablets should be swallowed whole.

HOW TO TAKE CONTRAVE®		
Week	**Morning Dose**	**Evening Dose**
Starting: Week 1	1 tablet	None
Week 2	1 tablet	1 tablet
Week 3	2 tablets	1 tablet
Week 4 Onward	2 tablets	2 tablets

Is Contrave® safe?

Contrave® is FDA-approved for in adults (>18 years of age). You should not take Contrave® if you have uncontrolled high blood pressure, seizures, have or have had an eating disorder (anorexia or bulimia) or are dependent on opioid pain medications. Contrave® should not be taken while pregnant or breastfeeding.

You should not take Contrave® if you are taking or have recently taken other certain medications: buproprion (Wellbutrin® or Aplenzin®), monoamine oxidase inhibitors (MAOIs), or sedatives.

You should avoid alcohol while taking Contrave®.

What are the side effects?

Call your doctor right away if you have any of these side effects:

- Suicidal thoughts
- Seizures
- Depressed or manic mood
- High blood pressure or heart rate
- Chest pain or shortness of breath
- Yellowing of the eyes or darker urine
- Eye pain or change in vision

If you notice these less serious side effects, talk with your doctor:

- Nausea
- Constipation
- Dizziness
- Vomiting
- Trouble sleeping
- Headache
- Dry mouth

UNDERSTANDING OFF-LABEL USE OF DRUGS AND MEDICAL DEVICES
PATIENT EDUCATION

What does "off-label" mean?

The Food and Drug Administration (FDA) approves all drugs and medical devices before they can be sold to the public. Each drug or device is approved for a specific use or purpose. But often, it can be used to treat other conditions as well.

When doctors prescribe something for a purpose not approved by the FDA, it is called "off-label" use.

How are drugs and devices used off-label?

Off-label use can take several forms:

- A drug may be used to treat a disease not listed on the package insert. For example, a doctor may prescribe an anti-depressant to treat headaches.
- A doctor may give you a different dose from that listed on the package insert.
- A device approved for one kind of surgery may be used in another. For example, surgeons may use a device to stabilize a patient's spine, even though it was approved for use in the leg bones.

How common is off-label use?

Off-label use is very common, and it seems to be growing. In some cases, it is the standard treatment for a given condition. It also plays a large role in advancing drug therapy and medical care.

Studies have shown that many patients have received at least one drug off-label. And for some drugs, off-label use accounts for most of the sales.

How risky is off-label use?

There is no direct link between off-label use and medical risk. Risk depends on:

- How different the off-label use is from the standard treatment of your condition.
- Evidence to support the off-label use.

When off-label use has been well-studied and is accepted practice, there is no increased risk. In such cases, not offering off-label use to patients may be improper.

Will my doctor tell me if I'm using a drug or device off-label?

Doctors do not routinely mention off-label use. It is so common that in many cases it does not warrant a discussion. If you have questions or concerns about off-label use, be sure to ask your doctor.

WEIGHT LOSS MEDICATIONS TABLE

MEDICATIONS GENERIC (BRAND)	OBESITY APPROVAL STATUS	WT LOSS MECH(S) OF ACTION	MODE OF ADMIN + DOSING	ADULT WT LOSS EFFICACY (BMI)	PEDS WT LOSS EFFICACY (BMI)	EFFECTS ON CO-MORBIDITY + RISK FACTORS	SIDE EFFECTS	CONTRA-INDICATIONS	COST	PATIENT SELECTION
Liraglutide (Saxenda® or Victoza®)	YES ≥12yo	GLP-1 RA Central effect on hypothalamus and reward centers; slows gastric motility	Subcutaneously 3 mg once daily	5%	5% in 1yr	None significant	Increased heart rate; nausea; vomiting; diarrhea; hypoglycemia; constipation; headache; dyspepsia; fatigue; dizziness; abdominal pain	Pregnancy; personal or family history of MTC or MEN 2	$$$	T2DM, difficulty sustaining feeling of fullness after eating, food cravings, NAFLD
Semaglutide (Ozempic® or Wegovy®)	YES ≥12yo	GLP-1 RA Central effect on hypothalamus and reward centers; slows gastric motility	Subcutaneously 2.4 mg once weekly	15%	17% in 1yr	Adults: Reduces HbA1c, total cholesterol, LDL, TG and ALT. Improves QOL	Increased heart rate; nausea; vomiting; diarrhea; hypoglycemia; constipation; headache; dyspepsia; fatigue; dizziness; abdominal pain	Pregnancy; personal or family history of MTC or MEN 2	$$$	T2DM, difficulty sustaining feeling of fullness after eating, food cravings, NAFLD
Tirzepitide (Mounjaro®)	NO ≥18yo for T2DM	Dual GLP-1 and GIP receptor agonist	Subcutaneously 15 mg once weekly	17.8%	No data	Improves quality of life, blood pressure, lipids, fasting insulin	Increased heart rate; nausea; vomiting; diarrhea; hypoglycemia; constipation; headache; dyspepsia; fatigue; dizziness; abdominal pain	Pregnancy; personal or family history of MTC or MEN 2	$$$	T2DM
Metformin (Glucophage®)	NO	Activation of AMP-activated protein kinase	Oral: up to 1,000 mg twice daily	Limited data	3% in 6-12 months	Adults: Reduces incidence of T2DM; Pediatrics: modestly reduces glucose, insulin, and HOMA-IR	Nausea; vomiting; diarrhea/ loose stools; reduced vitamin B12	Metabolic acidosis	$	Good for PCOS, pre- diabetes, diabetes, weight gain from atypical antipsychotic
Phentermine (Adipex®)	YES ≥16yo for short-term use (12 wk)	Norepinephrine reuptake inhibition	Oral: up to 37.5 mg once daily in the morning	No RCTs; 3- 4% in 26-28 wks	No RCTs; 4% in 6 mos	Limited data	Increased heart rate and blood pressure; palpitations; ischemic events; primary pulmonary hypertension; valvular disease; restlessness; insomnia; potential abuse/dependence; ability to engage in potentially hazardous tasks	History of CVD or drug use; MAOI use; hyperthyroidism; glaucoma; agitated states; pregnancy; nursing; hypersensitivity to sympathomimetic amines	$	Good for strong hunger, low energy
Phentermine + Topiramate ER (Qsymia®)	YES ≥12yo	Norepinephrine reuptake inhibition; modulation of GABA	Oral Mid-dose: (phentermine 7.5mg/topiramate ER 46mg) High-dose: (phentermine 15mg/topiramate ER 92mg) Once daily in the morning	7% for mid-dose and 9% for high-dose in 1 year	5% for mid-dose and 7% for high-dose in 1 year	Pediatrics: Improved TG and HDL; no effect on QOL	Paresthesia; dizziness; dysgeusia; insomnia; constipation; dry mouth	Pregnancy; MAOI use; hyperthyroidism; glaucoma; hypersensitivity to sympathomimetic amines	$$	–

WEIGHT LOSS MEDICATIONS TABLE *(continued)*

MEDICATIONS GENERIC (BRAND)	OBESITY APPROVAL STATUS	WT LOSS MECH(S) OF ACTION	MODE OF ADMIN + DOSING	ADULT WT LOSS EFFICACY (BMI)	PEDS WT LOSS EFFICACY (BMI)	EFFECTS ON CO-MORBIDITY + RISK FACTORS	SIDE EFFECTS	CONTRA-INDICATIONS	COST	PATIENT SELECTION
Lisdexamphetamine (Vyvanse®)	NO ≥6yo for ADHD; ≥18yo for BED	Dopamine>> norepinephrine reuptake inhibitor	Oral: ADHD up to 70mg/d BED 50-70mg/d	No data	No data	No data	Anxiety, irritability, insomnia, dry mouth	–	$$	ADHD, BED
Topiramate (Topiramax®)	NO 2yo for seizures; ≥ 12yo for migraine prophylaxis	Modulation of GABA	Oral: up to 200 mg twice daily (obesity dosing varies widely); XR formulation	5-8% for doses ranging from 96mg to 256mg	Limited data	Adults: Reduces blood pressure and glucose; pediatric data limited	Paresthesia; difficulty with concentration and memory; depression; language problems; psychomotor slowing	Acute myopia; secondary angle closure glaucoma; suicidal ideation; metabolic acidosis	$	Good for poor satiation and satiety, binge eating, cravings, weight gain from atypical antipsychotic, seizures, migraines, mood lability
Naltrexone + Bupropion ER (Contrave®)	YES ≥18yo	Opioid receptor antagonism; dopamine and norepinephrine reuptake inhibition	Oral: 16 mg/ 180 mg, twice daily	5%	No data	Adults: Reduces glucose, insulin, HOMA-IR, and CRP; improves lipids; no pediatric data	Nausea; vomiting; diarrhea; constipation; headache, dizziness; insomnia; dry mouth; increased heart rate and blood pressure; worsening depression or suicidal ideation in youth	Uncontrolled hypertension; seizure disorders; anorexia; bulimia; MAOI use; pregnancy	$$	Depression, food cravings
Orlistat + Xenical (OTC as Alli®)	YES ≥12yo	Gastric/pancreatic lipase inhibition	Oral: 120 mg, three times daily with meals (OTC 60 mg three times daily has 80% effect)	3%	2.5% in 1yr	Adults: Reduces LDL and incidence of T2DM; Pediatrics: No cardiometabolic improvements; limited data	Oily spotting; flatus with discharge; fecal urgency; fatty/ oily stool; decreased absorption of fat- soluble vitamins	Chronic malabsorption or cholestasis	$$$	Constipation, not centrally acting, elevated LDL
Setmelanotide (Imcivree®)	YES ≥6yo POMC, PCSK1, and LEPR mutations; BBS	Melanocortin-4 receptor agonist, analog of alpha-melanocyte stimulating hormone (MSH)	Subcutaneous 3 mg once daily	Body weight reduction: POMC/PCSK1 26% LEPR 13% BBS 6.5% (for participants > 12 years of age)		Limited data	Hyperpigmentation nausea, headache, diarrhea, abdominal pain, vomiting, depression, and spontaneous penile erections	–	$$$$	Monogenic or syndromic obesity

GLP1RA – glucagon-like peptide 1 receptor agonist; GIP – glucose-dependent insulinotropic polypeptide; CNS – central nervous system; HbA1c – hemoglobin A1c; CRP – C reactive protein; PAI-1- plasminogen activator inhibitor-1; DM – diabetes mellitus; MTC – medullary thyroid carcinoma; MEN 2 – multiple endocrine neoplasia type 2; QOL – quality of life; NASH – non-alcoholic steatohepatitis; PCOS – polycystic ovarian syndrome; MAOI – monoamine oxidase inhibitor; BED – binge-eating disorder; CVD – cardiovascular disease; OTC – over-the-counter; POMC – proopiomelanocortin; PCSK1 – proprotein convertase 1; LEPR – leptin receptor; BBS – Bardet Biedl syndrome

ANTI-OBESITY MEDICATION PROTCOLS

TOOLKIT

Adapted by the Obesity special interest group from the original protocol developed by Claudia Fox, MD, of University of Minnesota's Center for Pediatric Obesity Medicine.

PES

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