WEIGHT LOSS/MANAGEMENT

IS IT JUST ANOTHER

PIPE DREAM?

THE OBESITY MEDICINE ASSOCIATION'S DEFINITION OF OBESITY

- "Obesity is defined as a chronic, relapsing, multi-factorial, neurobehavioral disease, wherein an increase in body fat promotes adipose tissue dysfunction and abnormal fat mass physical forces, resulting in adverse metabolic, biomechanical, and psychosocial health consequences."

Obesity Algorithm @2017-2018 Obesity Medicine Association

OBJECTIVES:

Determine which patients will benefit from weight loss medications.

Review medications qualities that associate with patient needs.

Prescriptions for Weight Reduction

Indiana Code 35-48-3-11 states that only a physician licensed under IC 25-22.5, a physician assistant licensed under IC 25-27.5, or an advanced practice nurse licensed under IC 25-23 with prescriptive authority may treat a patient with a Schedule III or Schedule IV controlled substance for the purpose of weight reduction or to control obesity.

A physician licensed under IC 25-22.5, a physician assistant licensed under IC 25-27.5, or an advanced practice nurse licensed under IC 25-23 with prescriptive authority may not prescribe, dispense, administer, supply, sell, or give any amphetamine, sympathomimetic amine drug, or compound designated as a Schedule III or Schedule IV controlled substance under IC 35-48-2-8 and IC 35-48-2-10 for a patient for purposes of weight reduction or to control obesity, unless the physician, physician assistant, or advanced practice nurse does the following:

Prescribing Weight Loss Drugs continued:

1.Determines through review of the physician's records of prior treatment of the patient or the records of prior treatment of the patient provided by a previous treating physician or weight loss program, that the physician's patient has made a reasonable effort to lose weight in a treatment program using a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without using controlled substances and that the previous treatment has been ineffective for the physician's patient.

2.Obtains a thorough history and performs a thorough physical examination of the physician's patient before initiating a treatment plan using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity.

WEIGHT LOSS DRUGS

Xenical (orlistat)

Belviq (locaserin)

Qsymia

Contrave

Saxenda

WEIGHT LOSS DRUGS: XENICAL

- **Xenical (orlistat)** also called Alli over the counter. blocks some of the fat that you eat, keeping it from being absorbed by your body.

WEIGHT LOSS MEDICATIONS: BELVIQ/BELVIQ XR

- BELVIQ/BELVIQ XR is a serotonin 2C receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obese) (1) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes)
- The most common side effects of BELVIQ include: headache, dizziness, fatigue, nausea, dry mouth, constipation, cough, low blood sugar (hypoglycemia) in patients with diabetes , back pain
- Inform patients of the possibility of serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions with the combined use of BELVIQ/BELVIQ XR with other serotonergic drugs, including selective serotonin-norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), triptans, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs]), dietary supplements such as St. John's Wort and tryptophan, tramadol, or antipsychotics or other dopamine antagonists.
- May cause drowsiness, s/s valvular heart disease, worsening of suicidal thoughts, may cause erections greater than 4 hours in men--- direct to the ER, pregnancy and breast feeding.

WEIGHT LOSS MEDICATIONS: BELVIQ

- In the BELVIQ placebo-controlled clinical database of trials of at least one year in duration, of 6888 patients (3451 BELVIQ vs. 3437 placebo; age range 18-66 years, 79.3% women, 66.6% Caucasians, 19.2% Blacks, 11.8% Hispanics, 2.4% other, 7.4% type 2 diabetics), a total of 1969 patients were exposed to BELVIQ 10 mg twice daily for 1 year and 426 patients were exposed for 2 years.
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- In clinical trials of at least one year in duration, 8.6% of patients treated with BELVIQ prematurely discontinued treatment due to adverse reactions, compared with 6.7% of placebo-treated patients. The most common adverse reactions leading to discontinuation more often among BELVIQ treated patients than placebo were headache (1.3% vs. 0.8%), depression (0.9% vs. 0.5%), and dizziness (0.7% vs. 0.2%).

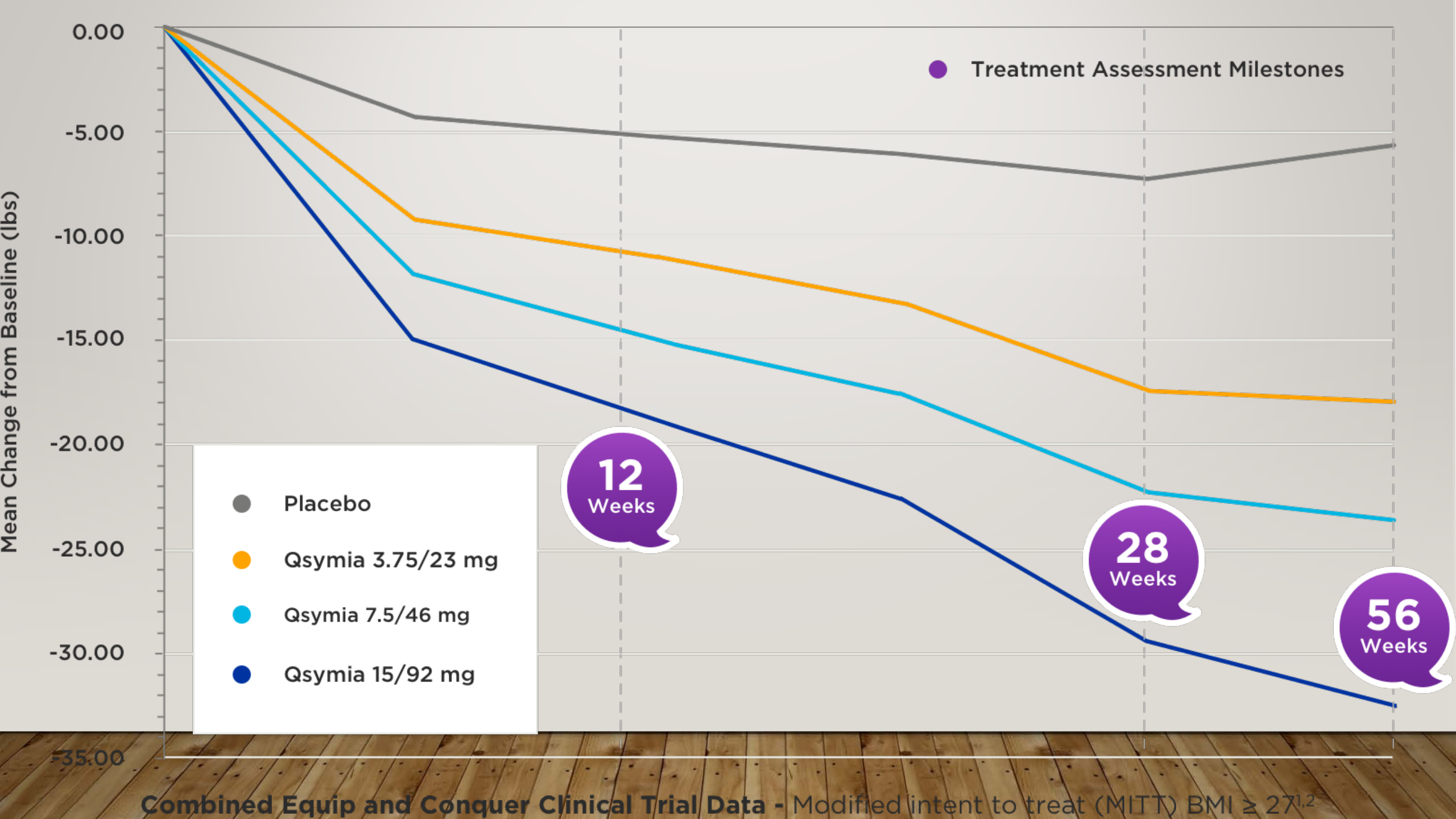
WEIGHT LOSS MEDICATIONS: BELVIQ/BELVIQ XR

- Weight Loss at 1 Year in Studies 1 and 2 Combined
- BELVIQ N=3098 Placebo N=3038
- Weight (kg) Baseline mean 100.4 Placebo 100.2
- % of Patients losing greater than or equal to 5% body weight 47% Placebo 22.6
- Difference from placebo (95% CI) 24.5** (22.2, 26.8)
- % of Patients losing greater than or equal to 10% body weight 22.4 Placebo 8.7

https://www.belviq.com/hcp/resources-and-supportia/File

WEIGHT LOSS MEDICATIONS: QSYMIA

- Qsymia contains a combination of phentermine and topiramate in an extended-release capsule. Phentermine is an appetite suppressant similar to an amphetamine. Topiramate is a seizure medication, also called an anticonvulsant. Qsymia is used together with diet and exercise to treat obesity.



Combined Equip and Conquer Clinical Trial Data - Modified intent to treat (MITT) BMI ≥ 27[1,2]

WEIGHT LOSS MEDICATIONS: QSYMIA

- **LIMITATIONS OF USE:**
- The effect of Qsymia on cardiovascular morbidity and mortality has not been established
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established

- Contraindications: pregnancy, glaucoma, hyperthyroidism, within 14 days of MAOI.
- Adverse events: increased heart rate, increased suicidal thoughts. Mood disorders like anxiety, depression or insomnia, potential for cognitive dysfunction. Metabolic acidosis, increased serum creatinine. Hypoglycemia in insulin dependent DM or those on insulin secretagogues.
- Most common adverse events: paresthesia, dizziness, insomnia, constipation, and dry mouth.

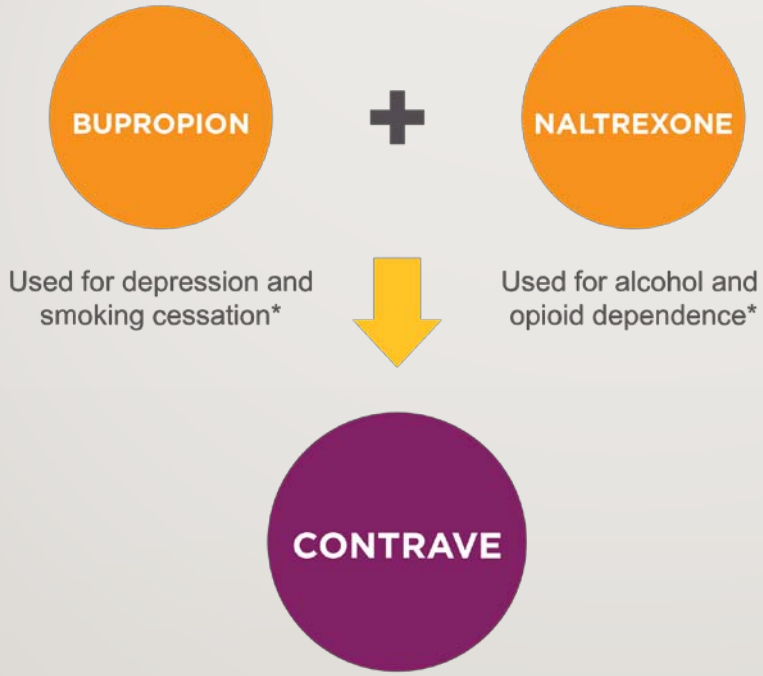
https://qsymia.com

WEIGHT LOSS MEDICATIONS: CONTRAVE

- CONTRAVE is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia).

CONTRAVE® is believed to work on 2 areas of the brain,
the hypothalamus (hunger center) and the mesolimbic reward system.

The components of CONTRAVE are believed to work together synergistically to help your patients lose weight[1]



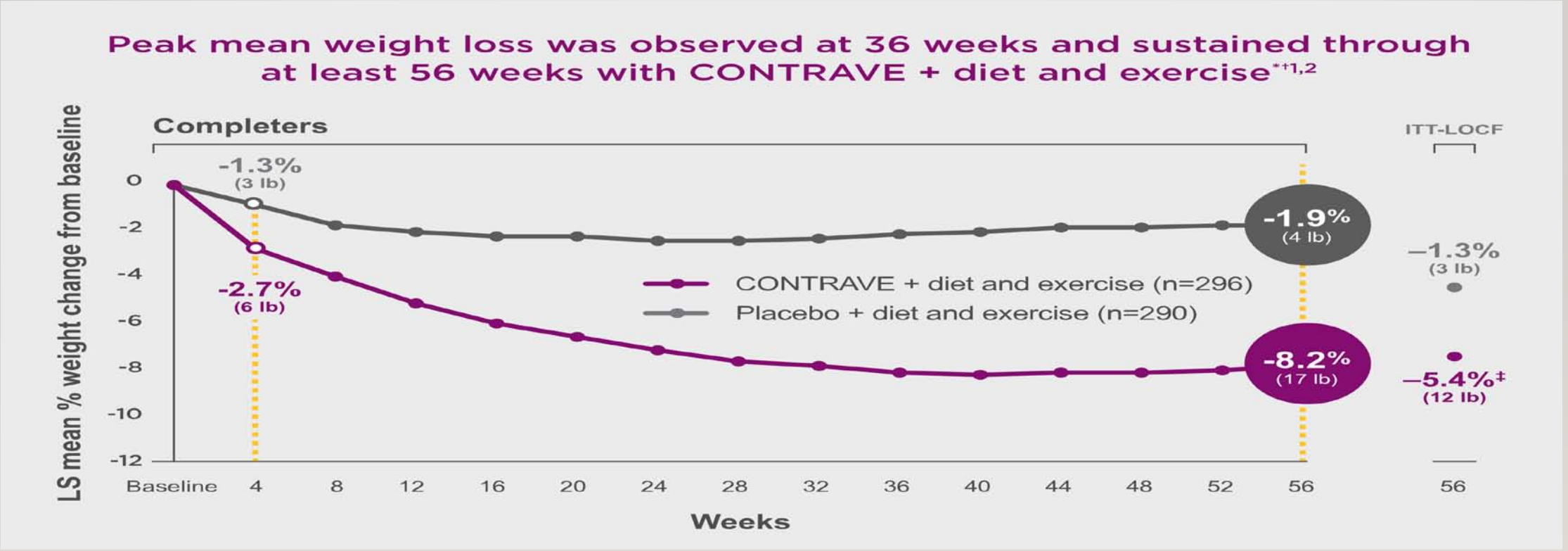
- **Bupropion**—Stimulates POMC cells (hypothalamus cells that reduce hunger are POMC)
- **Naltrexone**—Blocks the autoinhibitory loop on POMC cells

*CONTRAVE is not approved for smoking cessation, to treat depression or other mental illnesses, or to treat alcohol or opioid dependence.

COR-I Study

Patients lost 4 times more weight on average when CONTRAVE® was part of their diet and exercise approach

CONTRAVE + diet and exercise produced statistically significant mean weight loss as early as 4 weeks[1,2]



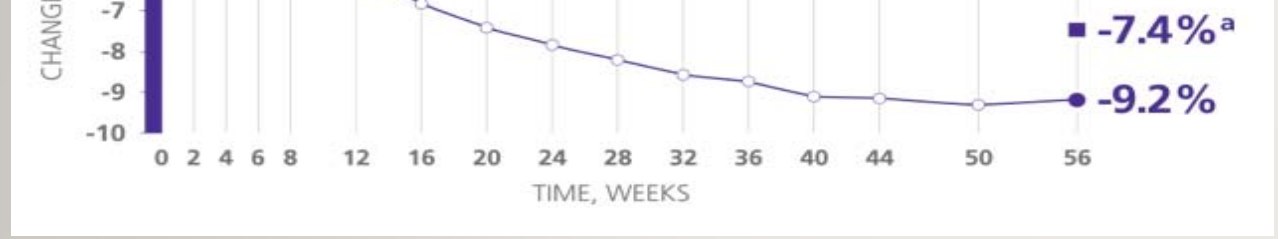
WEIGHT LOSS MEDICATIONS: CONTRAVE

- Contraindications: uncontrolled HTN, pregnancy, seizure disorder or history of seizures, chronic opioid use, not within 14 days of MAOIs.
- Adverse Events: anaphylactic reaction, Steven-Johnson Syndrome, Suicidal ideations/thoughts, mania activation, hypoglycemia with antidiabetic meds,
- Most common adverse reactions include: nausea , constipation, headache, vomiting, dizziness, insomnia, dry mouth, and diarrhea.
- https://contravehcp.com/

WEIGHT LOSS MEDICATIONS: SAXENDA (LIRAGLUTIDE)

- For chronic weight management in adult patients with a BMI ≥30 kg/m^2, or ≥27 kg/m^2 with one or more weight-related comorbidities, as an adjunct to a reduced-calorie diet and increased physical activity.
- Saxenda slows gastric emptying and can delay absorption of medications.

- Contraindicated in patients with a personal or family history of Medullary Thyroid Carcinoma and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Pregnancy, hypersensitivity reaction.
- Warning: hypoglycemia risk with DM medications, heart rate increase, renal impairment, suicide ideation, and hypersensitivity reaction.
- Most common adverse events: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase



Saxenda® + diet and physical activity
ITT-MI week 56 (n=2,487)
Completers (n=1,812)

Placebo + diet + physical activity
ITT-MI week 56 (n=1,244)
Completers (n=822)

[a]Difference from placebo was statistically significant. ITT-M, intention to treat with multiple imputations.[1]

21-lb mean weight loss

achieved by patients on Saxenda® who completed the study[3]

https://www.saxendapro.com/

Mean baseline body weight was 233.9 lb and mean baseline BMI was 38.3 kg/m^2

Measuring circumference correctly is simple to learn and important to know

Saxenda® reduced waist circumference by 3.2 inches vs 1.6 inches with placebo.[1]

Mean waist circumference at baseline was 45.3 inches for patients treated with Saxenda® (n=2,487) and 45.1 inches for patients taking placebo (n=1,244)[1]

Click below to expand

Study 1 (1-year)[1,5]

- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with a BMI of ≥30, or ≥27 with 1 or more weight-related comorbidities (N=3,731) were randomized to receive once-daily Saxenda® (n=2,487) or placebo (n=1,244) in conjunction
- Patients underwent a 4-week dose-escalation period followed by 52 weeks on the full dose
- The primary end points were mean percent weight change, percentage of patients achieving ≥5% of baseline weight loss, and per centage of patients achieving >10% of baseline weight los
- Secondary end points included changes in waist circumference, blood pressure, and lipids
- Mean baseline body weight was 233.9 lb and mean BMI was 38.3 kg/m^2
- Patients with type 2 diabetes were excluded from participating

https://www.saxendapro.com/

References

Bays HE, Seger JC, Primack C, McCarthy W, Long J, Schmidt SL, Daniel S, Wendt J, Horn DB, Westman EC: Obesity Algorithm 2017, presented by the American Society of Bariatric Physicians. 2016 - 2017. www.obesityalgorithm.org (Accessed = January 2, 2017)

ttps://www.in.gov/pla/3024.htm

https://www.belviq.com/hcp/resources-and-support

https://qsymia.com

https://contravehcp.com/

https://www.saxendapro.com/