# *Pediatric Obesity: Considerations in the Care of Muscular Dystrophy*

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# Conflict of Interest Disclosure

**I have served as a site Principal Investigator and currently as a Co-Investigator for Novo Nordisk**

**I will be discussing off-label use of medications**

# Objectives

1. Learn about pediatric obesity: prevalence, trends, and causes

2. Understand the interplay between obesity and muscular dystrophy

3. Learn about treatment options for pediatric obesity
    a. Weight Management Clinics
    b. Lifestyle Modifications
    c. Anti-Obesity Medications
    d. Metabolic/Bariatric Surgery

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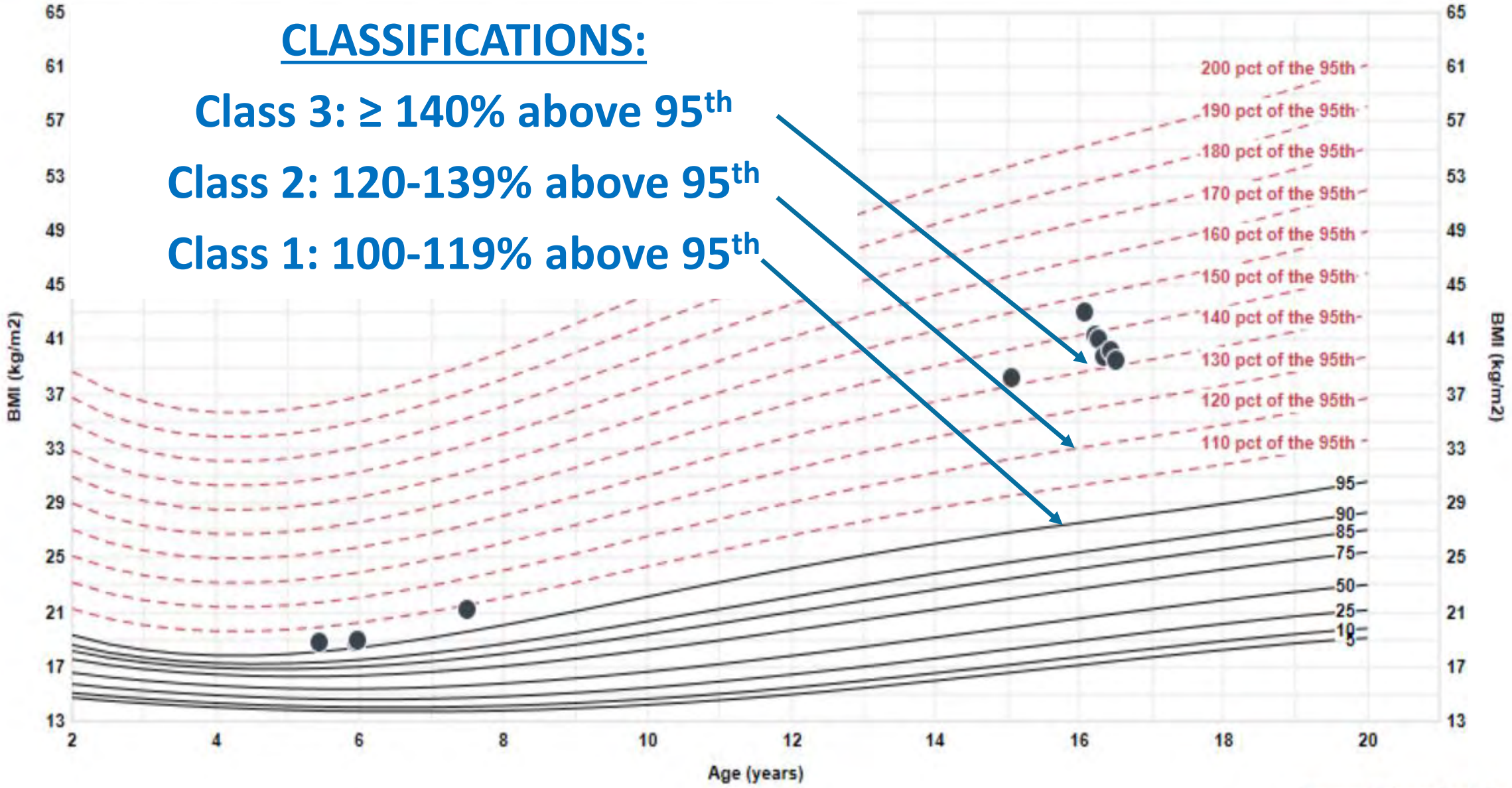
# Pediatric Obesity Definitions

## CLASSIFICATIONS:

**Class 3: ≥ 140% above 95th**

**Class 2: 120-139% above 95th**

**Class 1: 100-119% above 95th**



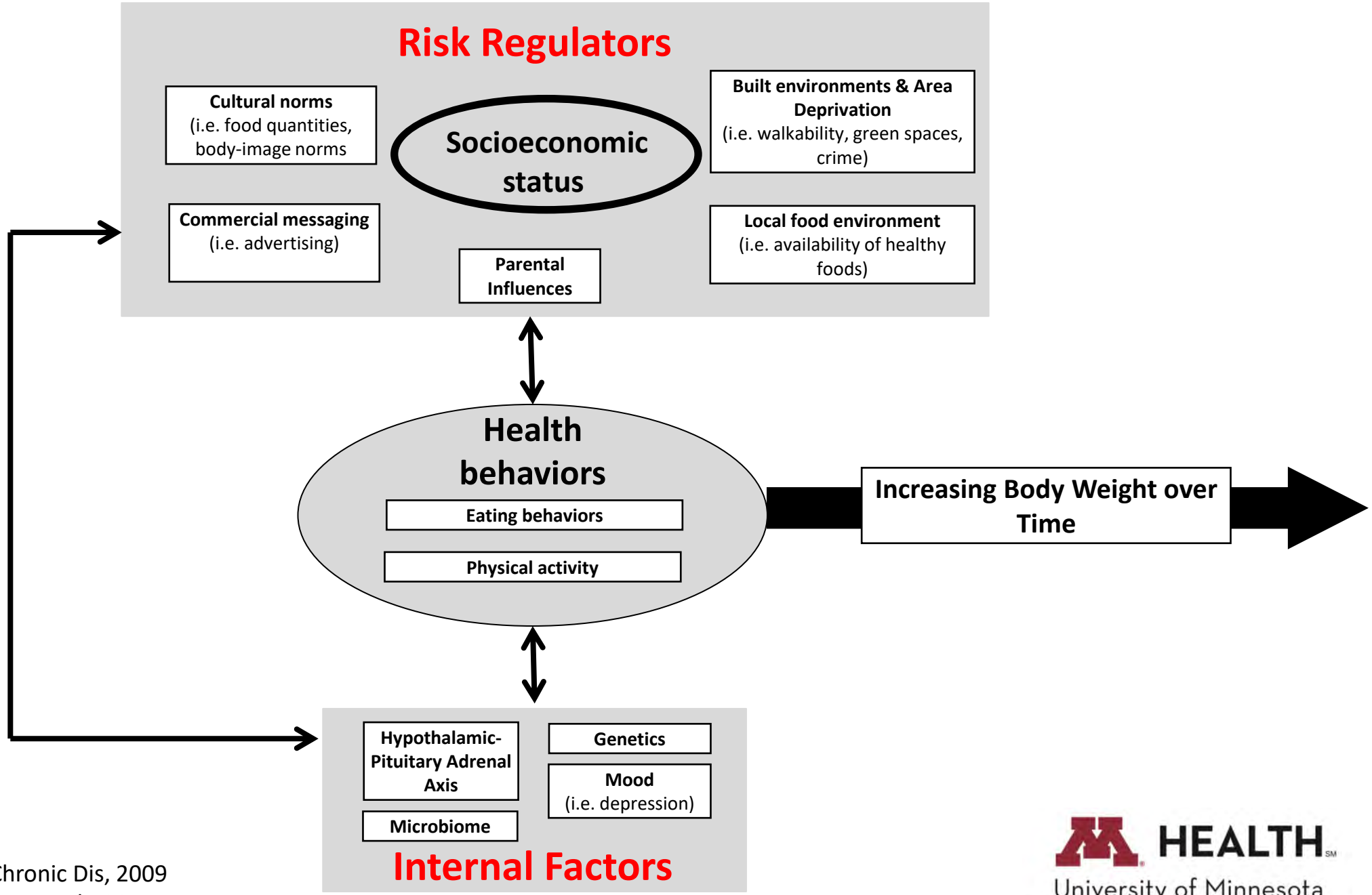

Source: University of Colorado

# Prevalence and Trends

- **Nearly 1 in 5 children and adolescents in the U.S. have obesity**[1]

- **Class 2/3 (Severe) Pediatric Obesity:**
  - *Fastest growing obesity category*
  - 4 - 5 million children/adolescents in U.S. (older estimates, likely higher)[2]
  - Greatest risk for developing obesity-related health consequences
  - Lifestyle modifications alone generally **ineffective** in this population[3]

[1] Ogden et al, JAMA 2018
[2] Freedman et al, J Pediatr, 2007
[3] Danielsson et al, Arch Pediatr Adol Med, 2012




Huang et al, Prev Chronic Dis, 2009
Bomberg et al, J Comp Path, 2017

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Ryder, University of Minnesota, 2018

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# Increased Obesity Susceptibility

- **Higher susceptibility to developing obesity**
  - Prevalence reportedly as high as 50-70%[1-2]
  - Body Mass Index (BMI) typically higher in both steroid-treated/untreated children
  - BMI already begins to increase before losing ambulation[3]

- **Obesity risk further increased due to disease-specific factors**[4]
  - Steroid use (as applicable)
  - Decreased mobility
  - Reduced resting and total energy expenditure (limited options for activity)
  - Increased time and financial pressures

[1] Martigne et al, Br J Nutr, 2011
[2] Davidson et al, Eur J Clin Nutr, 2014
[3] Houwen-van Opstal et al, Neuromusc Disord, 2022
[4] Weber et al, Pediatr, 2018

# Complications to Specifically Consider in Muscular Dystrophy

- **Reduced mobility and physical function with increased falls and fractures**[1-2]

- **Higher metabolic complications (also associated with steroid use)**[3-4]
  - Metabolic syndrome (i.e., high blood pressure; abnormal cholesterol levels)
  - Insulin resistance
  - Liver enlargement, fatty liver disease, fibrosis

- **Worsened lung function and sleep**[5]

[1] Weber et al, Pediatr, 2018
[2] Billich et al, Nutrients, 2022
[3] Rodriguez-Cruz et al, Act Neurol Scand, 2016
[4] Naume et al, Acta Pediatr, 2023
[5] Chew et al, Resp Med, 2016

# Importance of Preventing/Managing Obesity in Muscular Dystrophy

- **Foster mobility and ease of transfer**[1]
- **Reduce sleep-disordered breathing**[1]
- **Reduce complications from obesity** (i.e., diabetes, high cholesterol)[1]
- **Improve quality of life**[2]

[1] Weber et al, Pediatr, 2018
[2] Jeronimo et al, Nutr, 2016

# Obesity Prevention Strategies

- **Introduce at key time points[1]:**
  1. Diagnosis
  2. Time of steroid initiation (as applicable)
  3. Time of loss of mobility
  4. Any increased in weight or BMI z-score of ≥ 0.5

- **Should include[1]:**
  1. Facilitating healthy home food environment in consultation with dietician
  2. Counseling on sleep hygiene, screen time
  3. Psychosocial assessments for both patients and caregivers
  4. Approaches to physical activity

*Pediatric Weight Management Referral (?)*

Weber et al, Obesity (Silver Spring), 2018

# Previous Interventions in Muscular Dystrophy

- **Overall few studies in prevention and management**
- **Family-based behavioral interventions have shown modest short-term BMI reduction**[1-2]
- **Only few small previous medication studies:**
  - *Metformin*[3]: Randomized controlled trial; average 2 kg weight loss at 6 months (n=42)
  - *Topiramate*[4]: Report of 2 patients
  - *Omega-3 fatty acids*[5]: Randomized controlled trial; improved insulin resistance at 6 months (n=28)
- **No current evidence-based management guidelines for individuals with muscular dystrophy or children with physical/developmental disabilities**[6]
  - Pediatric guidelines adapted

[1] Vincent et al, Disabil Rehabil Assist Technol, 2015
[2] Barton, Pediatr, 2010
[3] Casteels et al, Pediatr Diab, 2010
[4] Carter et al, Muscle Nerve, 2005
[5] Rodriguez-Cruz et al, Clin Nut, 2019
[6] Weber et al, Pediatr, 2018

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# Pediatric Weight Management Clinics

Pediatrics

**LOCATIONS:**

1. Riverside Campus (University)
2. Maple Grove
3. Woodbury
4. Burnsville

## Healthy You: Pediatric Weight Management Program

Find a Provider

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# Weight Management Visit

- **Annual and symptom-based screening for conditions associated with obesity**
  - Diabetes, high blood pressure/cholesterol, sleep apnea, non-alcoholic fatty liver disease, depression
- **Identify contributing factors**
  - Sleep disorders, disordered eating, socioeconomic issues
  - Medications associated with weight gain (e.g., steroids, insulin)
- **Screening for secondary causes of obesity (as indicated)**
  - Genetic causes: Leptin deficiency, etc.
  - Neurologic causes: Brain injury/irradiation
  - Endocrine causes: Hypothyroidism, growth hormone deficiency, Cushing disease
- **Develop treatment plan**
  - Intensive, age-appropriate, culturally sensitive, family centered

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# Weight Management Visit

1. **Food Goals**

2. **Activity Goals**

**ALL MADE WITH SHARED DECISION MAKING**

3. **Medications**

4. **Others**
   - Labs
   - Referrals: Sleep Study, Psychology, Physical/Occupational Therapy, etc.

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# Lifestyle Modifications:

## *The Background for All Treatments*

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# Lifestyle Modifications: Dietary Principles

- Decrease fast foods, added table sugar, high-fructose corn syrup
- Decrease high-fat, high-sodium,  or processed foods
- Reduce saturated dietary fat intake (>2 years)
- Consume whole fruit rather than fruit juices
- Eliminate sugar-sweetened beverages
- Educate on Portion control
- Follow USDA intake of dietary fiber, fruits, and vegetables
- Timely, regular meals; avoid constant “grazing”
- Recognize eating cues (boredom, stress, loneliness, or screen time)
- Encourage single portion packaging and improved food labeling for easier use by consumers
  - Ungraded good practice statement

Styne et al, JCEM, 2017

Tropicana

100% Orange Juice

**Nutrition Facts**

Serving Size 1 Bottle (450mL)
Servings Per Container

| Amount Per Serving | |
|---|---|
| **Calories** 220 | |
| | **% Daily Value*** |
| **Total Fat** 0g | 0% |
| **Sodium** 30mg | 1% |
| **Potassium** 840mg | 24% |
| **Total Carbohydrates** 51g | 17% |
| Sugars 45g | |
| **Protein** 3g Not a significant source of protein | |

| | |
|---|---|
| Vitamin C 180% | * Calcium 4% |
| Thiamin 20% | * Niacin 4% |
| Vitamin B6 8% | * Folate 30% |
| Magnesium 10% | |

Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, vitamin A and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

Coca-Cola

**Nutrition Facts**

Serving Size 1 bottle
Servings Per Container 1

| Amount Per Serving | |
|---|---|
| **Calories** 240 | |
| | **% Daily Value*** |
| **Total Fat** 0g | **0%** |
| **Sodium** 75mg | **3%** |
| **Total Carbohydrate** 65g | **22%** |
| Sugars 65g | |
| **Protein** 0g | |

Not a significant source of fat calories, saturated fat, trans fat, cholesterol, fiber, vitamin A, vitamin C, calcium and iron.

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

**20 oz Tropicana:**
290 calories
59 gm sugar

**20 oz Coke:**
240 calories
65 gm sugar

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# Lifestyle Modifications: Exercise Principles

- **Goal 60 minutes of moderate to vigorous physical activity daily**
  - Does not need to be accomplished in 1 session
- **Provide written prescription to engage in physical activity**
  - "Dose" describing duration, intensity, frequency
- **Limit non-academic screen time (<2 hours per day)**
- **<u>Importance of shared decision making!!</u>**

Diabetes Clinical Practice Guidelines, Pediatr, 2013

# FDA-Approved Anti-Obesity Medications (YOUTH)

| Medication | Year Approved | Duration Approved | Age | Weight Loss Relative to Baseline Weight, Medication versus Placebo | |
|---|---|---|---|---|---|
| | | | | kg | % BMI |
| **Phentermine** | 1959 | ≤ 3 months | ≥ 16 y/o | -3.2 (6 mo) | -4.1 (6 mo) |
| **Orlistat** | 2003 | Chronic | ≥ 12 y/o | +0.5 vs +3.1 (1 yr) | -0.55 vs +0.31 (1 yr) |
| **Ligalutide 3.0 mg** (Saxenda) | 2021 | Chronic | ≥ 12 y/o | -2.6 vs 2.3 (1 yr) | -1.4 vs 0.19 (1 yr) |
| **Phentermine/Topiramate** (Qsymia) | 2022 | Chronic | ≥ 12 y/o | Mid Dose: -5.5 vs +6.6 (1 yr)<br>High Dose: -9.2 vs +6.6 (1 yr) | Mid Dose: -4.8 vs 3.3 (1 yr)<br>High Dose: -7.1 vs 3.3 (1 yr) |
| **Semaglutide 2.4 mg** (Mounjaro) | 2022 | Chronic | ≥ 12 y/o | -15.3 vs +2.4 (68 wk) | -16.1 vs +0.6 (68 wk) |

[1]Styne et al, JCEM, 2017

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[1]Styne et al, JCEM, 2017

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# Anti-Obesity Medications: In Trials (YOUTH)

| Medication | Mechanism of Action | Ages | From Studies |
|---|---|---|---|
| **Liraglutide 3.0 mg** (Saxenda) | GLP-1 receptor agonist | 6 to <12 years old | Weight loss (adults, 1 year):<br>3.0 mg: -8.0%<br>Placebo: - 2.6% |
| **Semaglutide 2.4 mg** (Wegovy) | GLP-1 receptor agonist | 6 to <18 years old | Weight loss (adolescents, 1 year):<br>2.4 mg: -16.1%<br>Placebo: +0.6% |
| **Tirzepatide** (Mounjaro) | Dual GLP-1/GIP receptor agonist | 12 to <18 years old | Weight loss (adults, 72 weeks):<br>5 mg dose: -15%<br>10 mg dose: -19.5%<br>15 mg dose: -20.9%<br>Placebo: -3.1% |

GLP-1 = glucagon-like peptide-1; GIP = gastric inhibitory peptide

# Other Anti-Obesity Medications: in the Pipeline

| Medication | Mechanism of Action | Ages | From Studies |
|---|---|---|---|
| **Semaglutide 50 mg** (oral) | GLP1 agonist | Adults (in trials) | Weight loss (adults with obesity) (68 week):<br>50 mg: -15.1%<br>Placebo: -2.4% |
| **Danuglipron** (oral) | GLP1 agonist | Adults (in trials) | Weight loss (adults with diabetes) (16 week):<br>Highest dose: -4.6%<br>Placebo: - 0.4% |
| **Retatrutide** | GIP/GLP-1/Glucagon receptor tri-agonist | Adults (in trials) | Weight loss (adults with obesity) (48 week):<br>Highest dose): -24.2%<br>Placebo: - 2.1% |

GLP-1 = glucagon-like peptide-1; GIP = gastric inhibitory peptide

# FDA-Approved Anti-Obesity Medications (ADULTS)

| Medication | Approved | MOA | Trial | Weight Loss Relative to Baseline Weight, Drug versus Placebo | |
|---|---|---|---|---|---|
| | | | | kg | % |
| **Orlistat** | 1999 | GI Lipase Inhibitor | XENDOS | -5.8 vs -3.0 (4 yr) | Not reported |
| **Phentermine/Topiramate** (Qsymia) | 2012 | Sympathomimetic amine with anorectic effect/unknown | CONQUER | -10.2 vs -1.4 (1 yr) | -9.8 vs -1.2 (1 yr) |
| | | | EQUIP | Not reported | -10.9 vs -1.6 (1 yr) |
| | | | SEQUEL | Not reported | -10.5 vs -1.8 (2 yr) |
| **Naltrexone/Bupropion** (Contrave) | 2014 | Opioid receptor agonist/antidepressant | COR-I | -6.1 vs -1.4 (1 yr) | -6.1 vs -1.3 (1 yr) |
| | | | COR-II | -6.2 vs -1.3 (1 yr) | -6.4 vs -1.2 (1 yr) |
| | | | COR-BMOD | Not reported | -9.3 vs -5.1 (1 yr) |
| | | | COR-Diabetes | Not reported | -5.0 vs -1.8 (1 yr) |
| **Liraglutide 3.0 mg** (Saxenda) | 2014 | GLP-1 receptor agonist | SCALE Obesity/Pre-DM | -8.4 vs -2.8 (1 yr) | -8.0 vs -2.6 (1 yr) |
| | | | SCALE Diabetes | -6.4 vs -2.2 (1 yr) | -6.0 vs -2.0 (1 yr) |
| | | | SCALE Maintenance | -6.0 vs -0.1 (1 yr) | -6.2 vs -0.2 (1 yr) |
| **Semaglutide 2.4 mg** (Wegovy) | 2021 | GLP-1 receptor agonist | STEP 3 | -16.8 vs -6.2 (1 yr) | -16.0 vs -5.7 (1 yr) |

# Possible Anti-Obesity Medication Options

- **Orlistat**
- **Phentermine**
- **Topiramate** (Topamax)
- **Phenterine + Topiramate XR** (as Qsymia or separately)
- **GLP-1 Agonists**
  - Liraglutide (Victoza, Saxenda)
  - Exenatide (Byetta, Bydureon)
  - Semaglutide (Wegovy, Ozempic)
  - Others
- **Metformin**
- **Naltrexone**
- **Naltrexone + Bupropion** (as Contrave or separately)
- **Tirzepatide** (Mounjaro)
- **Lisdexamfetamine** (Vyvanse)
  - Or other ADHD stimulants

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# Medication Selection: Factors to Consider

1. Mechanism of action
2. Side effect profile and contraindications
3. Patient eating phenotype
4. Patient co-morbidities
5. Cost/access
6. Patient/family preference

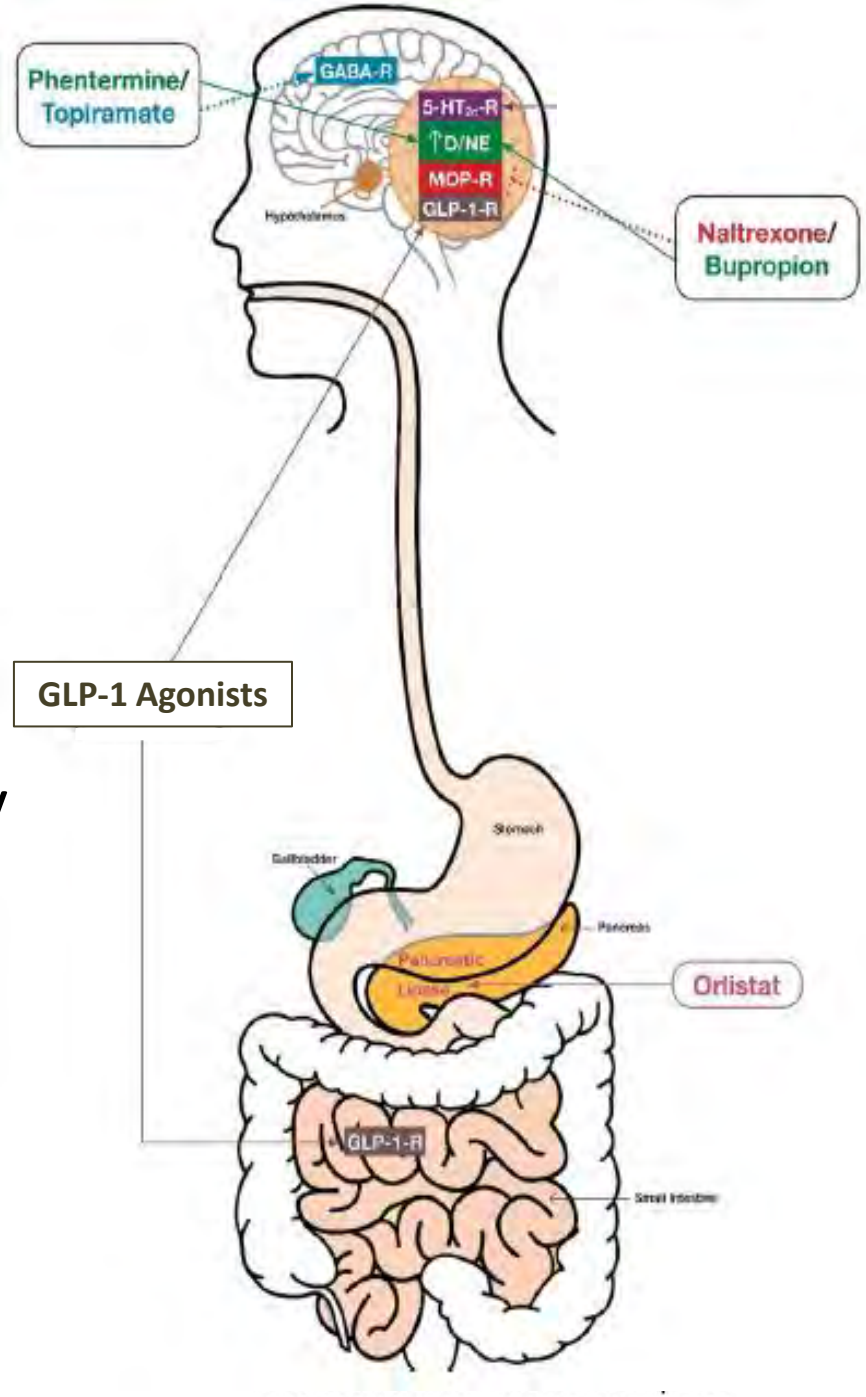
# Mechanisms of Action

**Orlistat:** Gastrointestinal lipase inhibitor

**Phentermine/Topiramate:** Reduces appetite/ mechanism unknown

**Naltrexone/Bupropion:** Opioid receptor blocker/ mechanism unknown

**GLP-1 Agonists:** Improves fullness

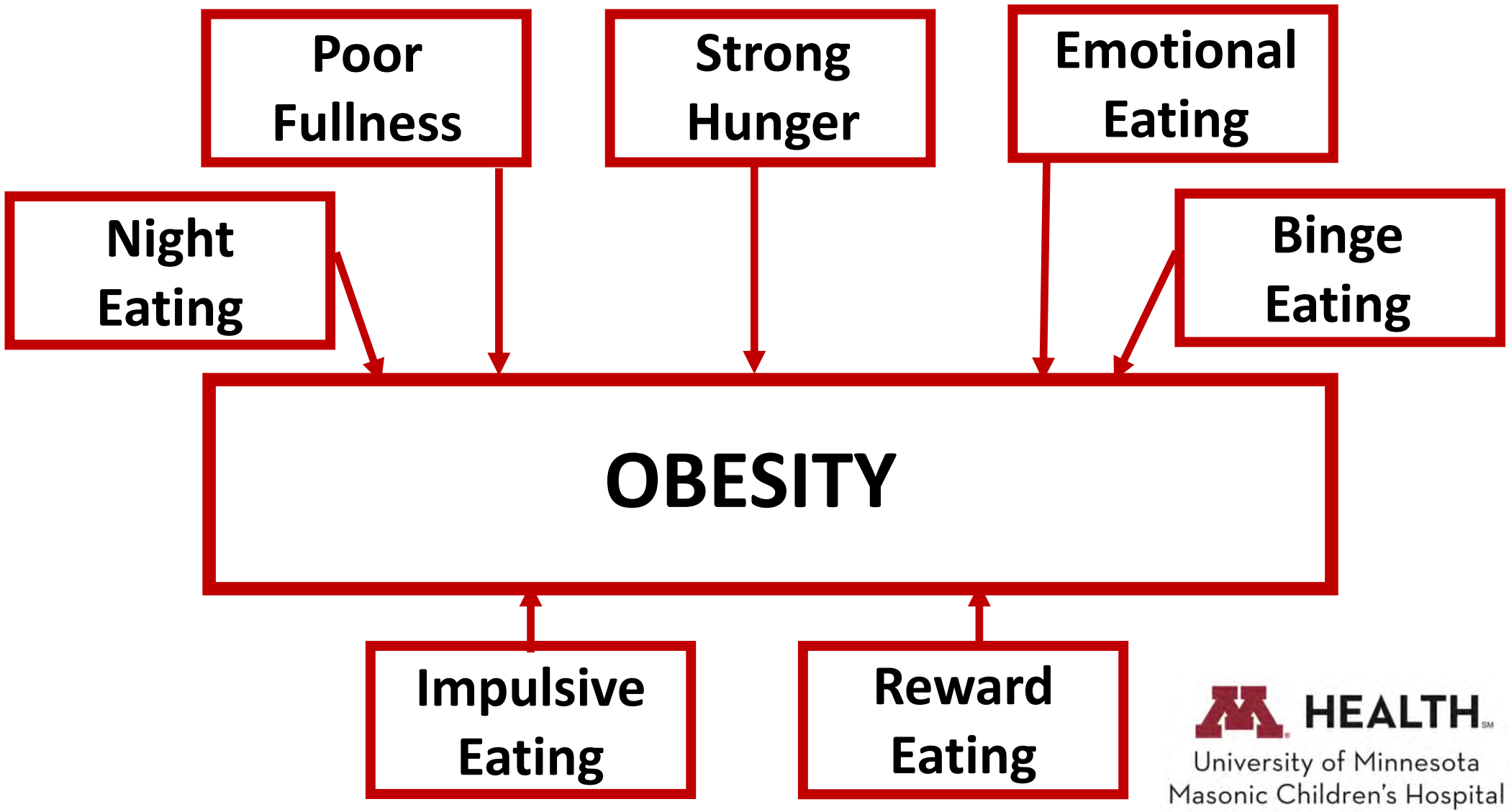


# Side Effect Profiles and Contraindications*

| Medication | Side Effects | Contraindications |
|---|---|---|
| **Orlistat** | Upset stomach, decreased fat-soluble vitamin absorption | Chronic malabsorption, gallbladder disease |
| **Phentermine** | Restlessness, insomnia, short-term increased blood pressure/heart rate, theoretical potential abuse/dependence | Cardiovascular disease, hyperthyroidism, uncontrolled blood pressure, glaucoma, agitated states, seizures, drug abuse |
| **Topiramate** | Tingling/numbness, concentration/memory impairment, birth defects (cleft lip/palate) | Calcium oxalate kidney stones, secondary angle closure glaucoma |
| **Naltrexone** | Upset stomach, elevated liver enzymes | Opioid dependence, current use of opiates, liver failure |
| **Bupropion** | Increased heart rate, agitation, dry mouth, insomnia, headaches, tremor, upset stomach | Seizure disorder, MAOI use |
| **GLP-1 Agonists** | Upset stomach, increased heart rate, headache, low blood sugar (rare), pancreatitis, gallstones | History of pancreatitis, personal/family history of MTC or MEN 2 syndrome |
| **Metformin** | Upset stomach, reduced vitamin B12 level | History of lactic acidosis (none reported in pediatric trials), kidney failure |

*Not exhaustive

# Proposed Eating Phenotypes

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# Patient Comorbidities

| COMORBIDITIES | CONSIDERATIONS |
|---|---|
| **Type 2 Diabetes** | GLP-1 agonists; once daily insulin before adding combination or pre-mixed insulin |
| **Type 2 Diabetes + High Blood Pressure** | ACE inhibitors/angiotensin receptor blockers or calcium channel blockers before β-blockers |
| **Depression/Psychiatric** | Shared decision making; naltrexone/bupropion |
| **Atypical Antipsychotics** | Metformin, topiramate, GLP-1 agonists |

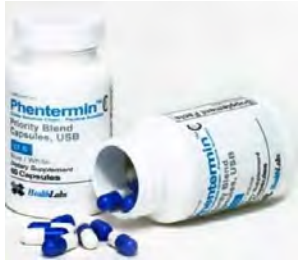
Adult Practice Guidelines, JCEM, 2015
Saunders et al., Med Clin N Am, 2018

# Cost/Access

- Many insurances require prior authorization and will **not** approve off-label use
- Out of pocket costs can be expensive (i.e., GLP-1 agonists ~$1000-1500/month)

# To Defray Costs

- Manufacturer website for coupons/discounts
- Shop pharmacies (e.g., GoodRx)
- Split pills if able
- Prescribe components separately

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# Patient/Family Preference

- **Importance of discussing benefits and risks**
- **Status as non FDA-approved** (as appropriate)
- **<u>Shared decision making!!</u>**
  - Obesity is a chronic disease

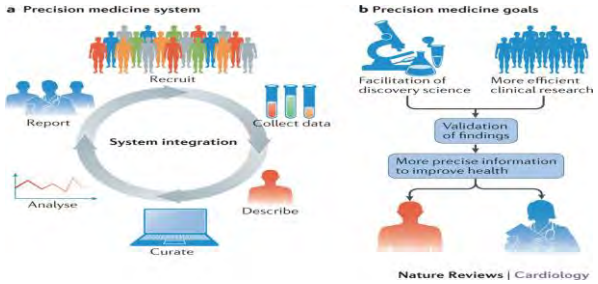
# Metabolic/Bariatric Surgery Recommendations: American Academy of Pediatrics 2023

| BODY MASS INDEX (BMI) CRITERIA | COMORBID CONDITIONS CRITERIA |
|---|---|
| Class 2 obesity (BMI ≥35 or 1.2 times 95$^{th}$ percentile)* | Clinically significant disease (i.e., diabetes, insulin resistance, high blood pressure/cholesterol, obstructive sleep apnea, depressed quality of life) |
| Class 3 obesity (BMI ≥40 or 1.4 times 95$^{th}$ percentile)* | Not required but commonly present |

* Whichever is lower

Hampl et al, Pediatrics, 2023

# A Role for Precision Medicine




- "Emerging approach for disease treatment and prevention that accounts for individual variability in genes, environment, and lifestyle for each person[1]"
- Identification and characterization of **sources of variability in response**
- Synthesis and application of this information to **select appropriate treatment(s)** with goal of maximizing benefit and minimizing risk
- <u>Right treatment to right patient at right time</u>

[1] National Institutes of Health

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# Obesity is a Chronic Disease

*"Obesity is a multi-causal chronic disease recognized across the life-span resulting from long-term positive energy balance with development of excess adiposity that over time leads to structural abnormalities, physiological derangements, and functional impairments. The disease of obesity increases the risk of developing other chronic diseases and is associated with premature mortality. As with other chronic diseases, obesity is distinguished by multiple phenotypes, clinical presentations, and treatment responses."*

Jastreboff et al, Obesity (Silver Spring), 2019

# Summary

- **Obesity affects around 20% of U.S. children and adolescents**
  - Class 2/3 (severe) obesity fastest growing category
  - Higher prevalence in muscular dystrophy
- **Higher obesity susceptibility in muscular dystrophy**
  - Additional factors to consider (i.e., decreased mobility, higher metabolic complications, higher sleep-disordered breathing)
  - Importance of prevention/management strategies
- **Consider multi-factorial causes when developing individual treatment plans**
- **Treatment Options**
  - Pediatric weight management clinics
  - Lifestyle modification
  - Anti-obesity medications
  - Metabolic/Bariatric surgery

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# ACKNOWLEDGMENTS

CENTER FOR PEDIATRIC OBESITY MEDICINE (CPOM)

Center for Pediatric Obesity Medicine

NIH National Institute of Diabetes and Digestive and Kidney Diseases

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