

Date: Enter Date

Regarding: Patient Name

To whom it may concern,

I am writing on behalf of my patient Patient Name to appeal the denial of coverage of: 1) Qsymia (phentermine/topiramate), 2) Saxenda (liraglutide), 3) Wegovy (semaglutide), 4) phentermine for the treatment of childhood obesity. Medication is FDA- approved for treatment of obesity in children 12 years (16 for phentermine monotherapy) and older defined as an initial body mass index (BMI) at the 95<sup>th</sup> percentile or greater standardized for age and sex. Patient Name is XXX years old and his/her BMI is at the XXX percentile, thus meets FDA criteria for treatment with this medication. Furthermore, Patient Name's BMI is more than 20% greater than the 95<sup>th</sup> percentile, thus meeting criteria for severe obesity, which is associated with greater risk of hypertension, dyslipidemia, non-alcoholic fatty liver disease, obstructive sleep apnea, prediabetes and subclinical atherosclerosis.<sup>1</sup> Name already has the following comorbidities of: List comorbidities 1) impaired fasting glucose with a fasting blood glucose greater between 100 and 126 mg/dL and a hemoglobin A1c between 5.7 and 6.4%, 2) nonalcoholic fatty liver disease, 3) hypertension, 4) polycystic ovarian syndrome, 5) obstructive sleep apnea. All of these complications are directly linked with increased morbidity and premature mortality in this population.

In January of 2023, the American Academy of Pediatrics released their clinical practice guidelines recommending the use of weight reducing pharmacotherapy for youth ages 12 and older with Class II or III obesity.<sup>2</sup> Untreated adolescent obesity has a high rate of tracking into adulthood with its antecedent cardiometabolic complications. The disease of obesity severely affects patients' quality of life both physically and psychosocially. Data suggests that treatment of adolescent obesity is economically beneficial to the individual and the society as it saves long term costs of treatment of obesity complications. There are currently, multiple FDA approved medications for the indication of severe obesity in youth. These will be used under my supervision and regular monitoring.

**GLP-1 Receptor Agonists:** Two FDA-approved GLP-1RA are available for use in youth ages 12 and older with obesity; liraglutide 3 mg daily (Saxenda) and semaglutide 2.4 mg weekly (Wegovy). Clinical studies in the pediatric population demonstrated significant reduction in body weight with both medications.<sup>3,4</sup> While semaglutide 2.4 mg once weekly demonstrated improvement in cardiometabolic factors (hemoglobin A1c, lipids, transaminases), once daily liraglutide did not show a difference in these factors compared to placebo. Given advantages in efficacy and better adherence to once weekly medication I am specifically requesting approval of coverage of Wegovy for Name.

**Phentermine monotherapy:** Phentermine is approved in the United States for adolescents >16 years with severe obesity for a duration of up to 12 weeks. Phentermine acts on appetite control centers in the hypothalamus; clinical studies have demonstrated efficacy in weight reduction in adolescents in limited trials.<sup>5</sup>

**Phentermine/Topiramate Combination:** Phentermine/topiramate extended-release capsule (Qsymia) is a fixed-dose combination of phentermine and topiramate approved for treatment of obesity in children 12 years and older. The once-daily formulation of phentermine (a sympathomimetic amine) and topiramate is designed to combat obesity by decreasing appetite and increasing satiety. Clinical trials have shown Qsymia to be effective in treatment of obesity in adolescents.<sup>6,7</sup>

All weight management medications should be used in conjunction with a reduced-calorie diet and increased physical activity. Name is receiving ongoing counseling on diet and activity as recommended in 2023 American Academy of Pediatrics and 2017 Endocrine Society Clinical Practice guidelines for Pediatric Obesity Management.

Alternative language: All weight management medications should be used in conjunction with a reduced-calorie diet and increased physical activity. Name is participating in a multi-disciplinary weight management program as recommended in 2023 American Academy of Pediatrics and 2017 Endocrine Society Clinical Practice guidelines for Pediatric Obesity Management.<sup>8</sup>

I strongly urge the expedited approval of Medication for Name, as he/she clearly meets criteria for use and delay is compromising their clinical care. I appreciate your collaboration and support of his/her treatment. Thank you for

partnering with me in the care of **Patient Name**. I am happy to set up a time to discuss **his/her** treatment course further. Please let me know what questions you have.

**Physicians Name**

**Title**

**Address**

**Institution**

## References:

1. Daniels SR, Kelly AS. Pediatric severe obesity: time to establish serious treatments for a serious disease. *Child Obes.* 2014 Aug;10(4):283-4.
2. Hampl SE, Hassink SG, Skinner AC, Armstrong SC, Barlow SE, Bolling CF, Avila Edwards KC, Eneli I, Hamre R, Joseph MM, Lunsford D, Mendonca E, Michalsky MP, Mirza N, Ochoa ER, Sharifi M, Staiano AE, Weedn AE, Flinn SK, Lindros J, Okechukwu K. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. *Pediatrics.* 2023 Feb 1;151(2):e2022060640.
3. Weghuber D, Barrett T, Barrientos-Pérez M, Gies I, Hesse D, Jeppesen OK, Kelly AS, Mastrandrea LD, Sørrig R, Arslanian S; STEP TEENS Investigators. Once-Weekly Semaglutide in Adolescents with Obesity. *N Engl J Med.* 2022 Dec 15;387(24):2245-2257.
4. Kelly AS, Auerbach P, Barrientos-Perez M, Gies I, Hale PM, Marcus C, Mastrandrea LD, Prabhu N, Arslanian S; NN8022-4180 Trial Investigators. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. *N Engl J Med.* 2020 May 28;382(22):2117-2128.
5. Ryder JR, Kaizer A, Rudser KD, Gross A, Kelly AS, Fox CK. Effect of phentermine on weight reduction in a pediatric weight management clinic. *Int J Obes (Lond).* 2017 Jan;41(1):90-93.
6. Hsia DS, Gosselin NH, Williams J, et al. A randomized, double-blind, placebo-controlled, pharmacokinetic and pharmacodynamic study of a fixed-dose combination of phentermine/topiramate in adolescents with obesity. *Diabetes Obes Metab.* 2020;22(4):480–91.
7. Kelly Aaron S, Bensignor Megan O, Hsia Daniel S, et al. Phentermine/topiramate for the treatment of adolescent obesity. *NEJM Evid.* 2022;1(6):EVIDoa2200014.
8. Styne, D.M.; Arslanian, S.A.; Connor, E.L.; Farooqi, I.S.; Murad, M.H.; Silverstein, J.H.; Yanovski, J.A. Pediatric Obesity—Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. *J. Clin. Endocrinol. Metab.* 2017, 102, 709–757.

**Created by:** Alaina Vidmar, MD, Yun Yan, MD, Laura Page, MD, Anna Ryabets-Lienhard, DO, and Ryan Miller, MD