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Prior Authorization Criteria Update: Tirzepatide for Obstructive Sleep Apnea

Plain Language Summary:

- ZEPBOUND (tirzepatide) is a medicine used for weight loss in people that have obesity.
- People that have breathing problems during sleep, called obstructive sleep apnea (OSA), and have obesity may benefit from weight loss with ZEPBOUND.
- The weight loss from ZEPBOUND helps reduce the breathing problems caused by OSA.
- Tirzepatide causes stomach upset, like nausea, vomiting and diarrhea. These problems can be reduced by starting with smaller doses and gradually increasing the dose.
- People enrolled in the fee-for-service Oregon Health Plan, who have moderate or severe OSA and obesity and have tried to manage weight loss with diet and exercise but have not reached weight loss goals, may try ZEPBOUND.

Purpose of Update:

The purpose of this update is to review the evidence for tirzepatide (ZEPBOUND) use in obstructive sleep apnea (OSA) in adults with obesity and modify the prior authorization (PA) criteria if warranted.

Tirzepatide is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. It was originally approved in November 2023 to reduce excess body weight and maintain weight reduction in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.[1] In December 2024, tirzepatide received an additional FDA-approved indication to treat moderate to severe OSA in adults with obesity (body mass index [BMI] of 30 kg/m^2 or higher).[1]

Obstructive sleep apnea is a sleep disorder associated with partial or complete obstruction of the upper airway during sleep. It often results in excessive daytime sleepiness and is a risk factor for cardiovascular (CV) disease. Excess body weight is a risk factor for OSA.[2] Reducing excess body weight has been associated with improved OSA outcomes.[3]

The OSA indication for tirzepatide was based on two, small, phase 3, double-blind, randomized controlled trials (RCTs) (SURMOUNT-OSA) lasting 52 weeks.[2] In both trials, participants with OSA and obesity received weekly tirzepatide 10 mg, 15 mg or placebo. Participants had moderate OSA (apnea-hypoxia index [AHI] score of 15 or more events per hour) or severe OSA (AHI of 30 or more events per hour). Most participants (68%) had severe OSA, as indicated by AHI of 30 events or more per hour. The mean AHI was 51.5 events per hour in trial 1 and 49.5 events per hour in trial 2.[2] The primary endpoint was change in AHI from baseline. The definition of AHI is the number of apnea and hypopneas occurring in an hour of sleep. The frequency of AHI was measured by laboratory polysomnography at screening, week 20 and week 52.[2] In the first trial, participants with OSA and who were not receiving positive airway pressure (PAP) were included. In the second trial, participants who were receiving PAP were included. The mean age of participants was 51.7 years, 27.7% were female, 65.8% were

White and the mean BMI was 38.7 kg/m^2.[2] Individuals with type 1 or type 2 diabetes, weight change of more than 5 kg in the 3 months prior to screening or planned surgery for obesity or sleep apnea were excluded.

Results of the trials are reported in **Table 1** and were analyzed on the intention-to-treat population.[2] The average completion rate for both trials were 82.9%. In the tirzepatide group 91.5% completed the trial and 74.4% in the placebo group (percentages reported for the 2 trials combined). Tirzepatide was superior to placebo for the reduction in AHI from baseline to week 52 in both trials. In Trial 1, tirzepatide reduced the primary endpoint by 25 events per hour, compared to 5 events per hour for placebo. This exceeds the minimal clinically important difference (MCID) of 5 events per hour.[3] In Trial 2, tirzepatide reduced the AHI by -23.8 events per hour versus placebo (95% CI, -29.6 to -17.9 p<0.001).[2] Participants in the tirzepatide group had more AHI reductions of 50% or more compared to placebo (absolute risk reduction of 47 and 59; number needed-to-treat of 2 for both trials).[2]

Table 1. Comparative Evidence Table.

Ref./ Study Design	Drug Regimens/ Duration‡	Patient Population	N	Efficacy Endpoints	ARR/ NNT	Safety Outcomes	ARR/ NNH	Risk of Bias/ Applicability
1. Malhotra et al. TRIAL 1 (SURMOUNT-OSA)[2] DB, MC, PC, PG, RCT Phase 3	1. tirzepatide 10 or 15 mg weekly 2. placebo 52 weeks	Demographics: Median age 47.9 years, 67% male, 66% white, BMI 39.1 kg/m^2, severe OSA 63.1% Key Inclusion Criteria: • ≥ 18 years • Moderate to severe OSA (AHI ≥15 events per hour) • Obesity (≥ 30 kg/m^2) • Unable or unwilling to use PAP therapy Key Exclusion Criteria: • TIDM or T2DM • Change in body weight of 5 kg in the last 3 months • Planned surgery for sleep apnea or obesity	ITT: N=114 N=120 PP†: 1. 87.6% 2. 71.9% Attrition*: 1. 8.5% 2. 25.6%	Primary Endpoint: Change in AHI (events/hour) Tirzepatide: -25.3 Placebo: -5.3 ETD: -20.0 (95% CI, -25.5 to -14.2); P<0.001 Secondary Endpoint: Percent change in AHI Tirzepatide: -50.7% Placebo: -3.0% ETD -47.7% (95% CI, -65.8 to -29.6); P<0.001 Reduction of >50% in AHI events at week 52 Tirzepatide: 70 Placebo: 23 RR 3.3 (95% CI, 2.1 to 5.1); P<0.001 Percent change in body weight Tirzepatide: -17.7% Placebo: -1.6% ETD -16.1% (95% CI, -18.0 to -14.2); P<0.001	NA NA NA NA	Discontinuations due to adverse events: 1. 5 (4.4%) 2. 2 (1.7%) p-value not provided Serious adverse events: 1. 9 (7.9%) 2. 7 (5.8%) p-value not provided	NA NA	**Risk of Bias (low/high/unclear)**: Selection Bias: low; randomization via Web based interactive response system; groups similar at baseline Performance Bias: low; use of single-dose pen autoinjector in both groups. Detection Bias: unclear; unknown if outcome assessors were blinded. AHI scores were scored centrally via a standardized scale for hypopneas. Attrition Bias: unclear; high rates of attrition differences between groups. Unable to analyze patient population sample sizes and attrition separately due supplementary appendix link being broken. Reporting Bias: low; trials were conducted as prospectively designed. Other Bias: high; funded by Eli Lilly, the manufacturer of tirzepatide. **Applicability**: Patient: Enrolled patients were unable or unwilling to use PAP therapy. Intervention: patients were required to reach a dose of 10 mg or more of tirzepatide which may limit benefits to patients who can tolerate higher doses. Patients were also enrolled in lifestyle counseling. Comparator: placebo-controlled Outcomes: AHI is a commonly used to quantify the severity of sleep apnea. A decrease of 5 events/hour is considered clinically significant. Setting: Sixty sites across nine countries.

1. Malhotra et al. TRIAL 2 (SURMOUNT-OSA)[2] DB, MC, PC, PG, RCT Phase 3	1. tirzepatide 10 or 15 mg weekly 2. placebo 52 weeks	Demographics: Median age 51.7 years, 72% male, 73% white, BMI 38.7 kg/m^2, severe OSA 68.2% Key Inclusion Criteria: • ≥ 18 years • Moderate to severe OSA (AHI ≥15 events per hour) • Obesity (≥ 30 kg/m^2) • Using PAP and continued during trial Key Exclusion Criteria: • TIDM or T2DM • Change in body weight of 5 kg in the last 3 months Planned surgery for sleep apnea or obesity	ITT: N=120 N=115 PP†: 1. 87.6% 2. 71.9% Attrition*: 1. 8.5% 2. 25.6%	Primary Endpoint: Change in AHI (events/hour) Tirzepatide: -29.3 Placebo: -5.5 ETD: 23.8 (95% CI, -29.6 to -17.9); P<0.001 Secondary Endpoint: Percent change in AHI Tirzepatide: -58.7% Placebo: -2.5% ETD -56.2% (95% CI, -73.7 to -38.7); P<0.001 Reduction of >50% in AHI events at week 52 Tirzepatide: 86 Placebo: 27 RR 3.1 (95% CI, 2.1 to 4.5); P<0.001 Percent change in body weight Tirzepatide: -19.6% Placebo: -2.3% ETD -17.3% (95% CI, -19.3 to -15.) P<0.001	 NA NA NA NA	Discontinuations due to adverse events: 1. 4 (3.4%) 2. 8 (7.0%) p-value not provided Serious adverse events: 1. 7 (5.9%) 2. 12 (10.5%) p-value not provided	 NA NA	**Risk of Bias (low/high/unclear)**: Selection Bias: See above. Performance Bias: See above. Detection Bias: See above. Attrition Bias: See above. Reporting Bias: See above Other Bias: high: See above **Applicability**: Patient: Applies to patients who have been using PAP and continued use during trial. Intervention: See above. Comparator: See above. Outcomes: See above. Setting: See above.

Key: † Per protocol population for the two trials combined (supplementary appendix was unavailable); * Attrition rates were for the two trial combined (supplementary material was unavailable); ‡ dose was initiated at 2.5 mg weekly and increased by 2.5 mg every 4 weeks until reaching the maximum tolerated dose of 10 mg or 12.5 mg weekly during a dose-escalation phase in the tirzepatide group. Abbreviations: AHI = apnea-hypoxia index; BMI = body mass index; CI = confidence interval; DB = double-blind; ETD = estimated treated difference: ITT = intention to treat analysis; MC = multicenter; OSA = obstructive sleep apnea; PAP = positive airway pressure; PC = placebo-controlled; PP = per protocol population; RCT = randomized controlled trial; RR = relative risk.

The number of participants discontinuing tirzepatide due to adverse events was 5% compared to 2% in the placebo group in Trial 1 and 4% in participants taking tirzepatide compared to 8% taking placebo in Trial 2.[2] The most common adverse events were gastrointestinal and occurred more often in participants receiving tirzepatide. Serious adverse events were reported in 7.5% of all the treatment groups and there were no deaths. There were two cases of pancreatitis in the tirzepatide group and five cases of severe or serious depressive disorder or suicidal ideation or behavior reported (two in the tirzepatide group and three with placebo).[2]

Limitations to the study are small sample size and over 10% different in attrition rates between tirzepatide and placebo. Patients received regular lifestyle counseling which could cause results to be more effective in study patients compared to the general population. The study was funded by the manufacturer which lends itself to inherent bias. Long-term data on healthcare outcomes, such as CV effects, would be helpful. There is insufficient evidence to recommend tirzepatide for OSA in patients who do not have obesity.

In conclusion, evidence from 2, fair-quality RCTs provide moderate evidence that tirzepatide is effective for reducing AHI in adults with moderate to severe OSA with obesity. Additional long-term data on safety and efficacy is needed.

Recommendation:

- Amend tirzepatide clinical PA criteria to allow coverage of patients with OSA and obesity.
- After evaluation of pricing in executive session, make the ZEPBOUND version of tirzepatide preferred and subject to PA criteria pending acceptance of a supplemental rebate offer for OSA.

References:

1. ZEPBOUND (tirzepatide) [prescribing information]. Indianapolis, IN; Lilly USA, LLC. December 2024.
2. Malhotra A, Grunstein R, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity. *N Engl J Med*. 2024;391(13):1193-1205. doi: 10.1056/NEJMx240005.
3. Canadian Agency for Drugs and Technology in Health. Interventions for the Treatment of Obstructive Sleep Apnea in Adults: A Health Technology Assessment. 2017; volume 6, Issue 1 b. Available at: www.cadth.ca. Assessed January 30, 2025.

Weight Management Drugs

Goal(s):

- To provide guidance for the use of weight management therapies to ensure they are used in the most appropriate patient populations in which evidence supports efficacy and safety.
- Allow case-by-case review for members covered under the EPSDT program. Recommend use of GLP-1 receptor agonists only for FDA-approved indications supported by the evidence.
- To provide guidance for the use of weight management drugs, like semaglutide (WEGOVY) and tirzepatide (ZEPBOUND), to ensure coverage for the most appropriate patient populations in which evidence supports efficacy and safety for reduction in cardiovascular (CV) outcomes, nonalcoholic steatohepatitis (NASH, also called metabolic dysfunction-associated steatohepatitis [MASH]) and obstructive sleep apnea (OSA).

Length of Authorization:

- Up to 6 months
- Renewal up to 12 months

Requires PA:

- All drugs used for weight management.
- Refer to the Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonist PA Criteria for approval of semaglutide (OZEMPIC and RYBELSUS) and tirzepatide (MOUNJARO) for type 2 diabetes.

  Note: Semaglutide is not currently covered for adults who do not have established cardiovascular disease, non-alcoholic steatohepatitis (NASH), or type 2 diabetes. Tirzepatide is not currently covered for adults who do not have established obstructive sleep apnea or type 2 diabetes.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Drugs FDA Approved for Weight Management

Drug	Adults	Pediatrics
Liraglutide (SAXENDA)	Yes	Yes – 12 years and older
Naltrexone/bupropion (CONTRAVE)	Yes	No
Phentermine/topiramate (QSYMIA)	Yes	Yes – 12 years and older

Semaglutide (WEGOVY)	Yes	Yes – 12 years and older
Tirzepatide (ZEPBOUND)	Yes	No
Setmelanotide (IMCIVREE)	Yes	Yes – 2 years and older
Orlistat (Xenical)	Yes	Yes – 12 years and older

Table 2. BMI Cutoffs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (CDC Criteria)

Age (years)	Body mass index (kg/m2) at 95% percentile	
	Males	Females
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30

Table 3. Evidence-Supported Indications

Drug	Indications
Liraglutide	• Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older*
Semaglutide	• Established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) • Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older*

* NASH Requirements:
- Diagnosis by liver biopsy OR all of the following:
  - documentation that the patient does NOT have ongoing or recent (within 2 years) significant alcohol use or chronic or active viral hepatitis. Significant alcohol use can be patient-specific but is typically defined as greater than 21 drinks/week (or >30 g/day) in men and greater than 14 drinks/week (or >20 g/day) in women.

	○ provider attestation or documentation that other causes of hepatic steatosis are not suspected based on patient history/presentation or have been ruled out. Examples of other secondary causes of hepatic steatosis include, but are not limited to, Wilson's disease, lipodystrophy, abetalipoproteinemia, medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids). ○ documentation that the patient has, or is receiving drug treatment for, at least 3 of the 5 metabolic risk factors associated with MASH. Risk factors include: ▪ Overweight or obesity or increased waist circumference (BMI ≥ 25 kg/m^2 or ethnicity adjusted equivalent) ▪ Hypertension ▪ Type 2 diabetes mellitus ▪ Hypertriglyceridemia ▪ Decreased level of high density lipoprotein (HDL) • fibrosis stage 2 or 3 as shown by appropriate diagnostic test within past 24 month [appropriate tests may include biopsy, vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE), enhanced liver fibrosis test (ELF)] • medication being ordered by, or in consultation with, a hepatologist or gastroenterologist
Tirzepatide	• Moderate to severe obstructive sleep apnea (OSA) in adults with obesity

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this a request for continuation of therapy after an initial approval by FFS?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #3
3. Does the patient have a BMI corresponding to one of the following: 1) ≥30 kg/m^2 or 2) ≥25 kg/m^2 and comorbid conditions [e.g., diabetes mellitus, hypertension, dyslipidemia, fatty liver disease, or cardiovascular disease] or 3) a BMI at the 95th percentile or greater for age and sex (Table 2 above)?	**Yes:** Go to #4 Record baseline BMI	**No:** Deny; medical appropriateness

Approval Criteria		
4. Will the patient be engaged in a weight management lifestyle modification program in addition to pharmacotherapy? See clinical notes below	**Yes:** Go to #5	**No:** Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.
5. Is the member eligible for EPSDT review AND is the requested medication FDA-approved for their age (Table 1)?	**Yes:** Go to #6	**No:** Go to #11
6. Is the request for setmelanotide?	**Yes**: Go to #7	**No:** Go to #9
7. Does the patient have obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance OR does the patient have Bardet—Biedl syndrome (BBS)?	**Yes**: Go to #8	**No:** Deny; medical appropriateness.
8. Does the patient have a history of depression and/or suicidal ideation?	**Yes**: Deny; medical appropriateness.	**No:** Approve for up to 6 months.
9. Does the patient have comorbidities (e.g., hypertension, dyslipidemia, diabetes, fatty liver disease, depression, or sleep apnea)?	**Yes:** Approve for 6 months	**No:** Go to #10
10. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6-month timeframe*? * See Clinical Notes Below	**Yes:** Approve for 6 months.	**No:** Deny; medical appropriateness. Lifestyle modifications are recommended by guidelines.

Approval Criteria		
11. Is the request for a FDA-approved or compendia-supported indication as defined in Table 3?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss.
12. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6-month timeframe?	**Yes**: Go to #13	**No:** Deny; medical appropriateness
13. Is there documentation of a type 2 diabetes diagnosis?	**Yes:** Go to #15	**No:** Go to #14
14. Has the patient been screened for diabetes within the past year and do screening results indicate they do not have diabetes (e.g., HbA1c <6.5% or fasting blood glucose <126 mg/dl (7 mmol/L)?	**Yes:** Go to #15	**No:** Pass to RPh; Deny; medical appropriateness. Recommend screening and if positive recommend a GLP-1 RA indicated for glucose lowering (see GLP-1 RA/GIP RA PA criteria)
15. Is the request for tirzepatide (ZEPBOUND)?	**Yes:** Go to #19	**No:** Go to #16
16. Is the request for semaglutide (WEGOVY)?	**Yes:** Go to #17	**No:** Approve for up to 6 months
17. Is the patient currently taking semaglutide (OZEMPIC) 2.0 mg weekly and is able to tolerate the medication and is still desiring additional weight loss?	**Yes**: Approve for up to 6 months	**No:** Go to #18
18. Will the patient try semaglutide (OZEMPIC) for at least 4 months to ensure tolerability/compliance?	**Yes**: Approve Ozempic for up to 6 months * Load PA for OZEMPIC	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
19. Does the patient have obesity (BMI of 30 kg/m^2 or greater) and moderate to severe obstructive sleep apnea (OSA)? - Moderate OSA is defined as an apnea-hypopnea index (AHI) of 15 events/hour or more - Severe OSA is defined as an AHI of 30 events/hour or more	**Yes:** Approve tirzepatide (ZEPBOUND) for up to 6 months	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is this a request for continuation of therapy with a weight loss medication previously approved by FFS?	**Yes**: Go to #2	**No:** Go to **Approval Criteria** above
2. Is the person requesting the medication less than 18 years of age?	**Yes:** Go to #3	**No:** Go to #4
3. Has the patient lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss?	**Yes:** Go to #7	**No:** Deny; medical appropriateness
4. Is the request for ongoing treatment for someone with established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease), NASH or OSA?	**Yes:** Go to #5	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss. If eligible for EPSDT review: Go to #5
5. Has the patient lost or maintained a BMI reduction of 5% or more?	**Yes**: Go to #6	**No:** Deny; medical appropriateness
6. Has the patient been adherent to therapy based on provider attestation?	**Yes:** Go to #7	**No:** Deny; medical appropriateness

Renewal Criteria		
7. Is the patient continuing with a weight loss treatment plan (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet)?	**Yes:** Approve for up to 12 months.	**No:** Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.

***Clinical Notes**

Adapted from the following guideline on the treatment of adolescents with obesity:

- American Academy of Pediatrics. *Pediatrics*. 2023;151(2): e2022060640. Available at: https://publications.aap.org/pediatrics/article/151/2/e2022060640/190443/Clinical-Practice-Guideline-for-the-Evaluation-and?autologincheck=redirected

Recommended Behavior Strategies

Strategy	Description
1. Reduction in sugar-sweetened beverages (SSBs)	Higher intake of sugar-sweetened beverages (carbonated beverages, sweetened beverages, soda, sports drinks, and fruit drinks) is associated with greater weight gain in adults and children. The American Heart Association (AHA) recommends not more than 25 g (6 tsp) each day of added sugar and not more than 1, 8-oz serving of SSB per week. The AAP discourages the consumption of sports drinks and energy drinks for children and adolescents. The AAP statement on fruit juice notes that it is a poor substitute for whole fruit because of its high sugar and calorie content and pediatricians should advocate for elimination of fruit juice in children with excessive weight gain.
2. Choose My Plate	MyPlate is the US Department of Agriculture's (USDA) broad set of recommendations for healthy eating for Americans. These recommendations include multiple healthy diet goals: low in added sugar, low in concentrated fat, nutrient dense but not calorie dense, within an appropriate calorie range without defined calorie restriction, and with balanced protein and carbohydrate. The principles can be adapted to different food cultures. There is a surprising dearth of literature on the impact of these guidelines on health and BMI outcomes and on the most effective education practices. **Available at: USDA choose my plate.gov**
3. 60 minutes daily of moderate to	Aerobic exercise, especially for 60 min at a time, is associated with improved body weight in youth although its effect may be small and variable. It is also associated with better glucose metabolism profiles. High-intensity interval

vigorous physical activity	training in youth with obesity may improve body fat, weight, and cardiometabolic risk factors, although the effect is variable. The Physical Activity Guidelines for Americans recommends 60 min per day for children and adolescents.
4. Reduction in sedentary behavior	Reduction in sedentary behavior, generally defined as reduced screen time, has consistently shown improvement in BMI measures, although impact is small. Early studies focused on reduced television, a discrete activity that is simpler than current multifunctional electronic devices. The AAP recommends no media use under age 18 month, a 1-hour limit for ages 2–5 years, and a parent-monitored plan for media use in older children, with a goal of appropriate, not-excessive use but without a defined upper limit.
The activities most commonly associated with positive behavior change are: parental involvement in goal setting, problem solving, social support, demonstrating desired behaviors, and home environment modifications to support positive change.	
Abbreviations: AAP – American Academy of Pediatrics; BMI = body mass index; oz = ounce; tsp = teaspoon; USDA = United States Department of Agriculture	

P&T/DUR Review: 4/25 (KS); 8/24 (SS/SF); 6/24 (KS)
Implementation: 5/12/25; 9/1/24; 7/1/24