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## **Prior Authorization Criteria Update: Semaglutide (Wegovy®) in Metabolic Dysfunction-Associated Steatohepatitis**

**Purpose of Update:** This update reviews evidence for the use of semaglutide (WEGOVY) in adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 and F3).

### **Plain Language Summary:**

- The Food and Drug Administration recently approved a medicine called semaglutide (WEGOVY) for adult patients who have metabolic dysfunction-associated steatohepatitis without irreversible scarring (cirrhosis) of the liver.<sup>1</sup>
- Metabolic dysfunction-associated steatohepatitis is a type of liver disease that is often associated with fat build up in the liver and is not caused by alcohol overuse, viruses, or other conditions that cause liver disease.
- Metabolic dysfunction-associated steatohepatitis is more common in people with other health conditions like obesity, type 2 diabetes, high cholesterol, and high blood pressure. These other conditions are sometimes called metabolic syndrome.
- In people with metabolic dysfunction-associated steatohepatitis who do not have irreversible severe scarring of the liver (e.g., cirrhosis), semaglutide reduced scarring (e.g., fibrosis) and other signs of liver disease in some patients who took this medicine for almost one and a half years (72 weeks).<sup>2</sup>
- Semaglutide is still being studied to see if it will reduce other serious risks of liver disease such as death and liver failure.<sup>2</sup>
- Nausea, diarrhea, constipation, and vomiting were the most common side effects of semaglutide.<sup>2</sup>
- The Drug Use Research and Management group recommends continuing to require prior authorization for semaglutide. Prior authorization means providers must explain why someone needs semaglutide before Medicaid will pay for it.

### **Conclusions:**

- Based on the interim analysis of a single, large, double-blind, placebo-controlled, multicenter RCT, there is moderate quality evidence that semaglutide resolves steatohepatitis without worsening fibrosis (number needed to treat [NNT] = 4) and reduces fibrosis without worsening steatohepatitis (NNT = 7) after 72 weeks of treatment at the weekly 2.4 mg dose of semaglutide.<sup>2</sup> Part 2 of this RCT will evaluate if cirrhosis free survival is improved over 240 weeks of treatment.<sup>2</sup> Potential unblinding due to gastrointestinal side effects and uneven attrition between groups already present at 72 weeks may complicate interpretation of longer-term results.

### **Recommendation:**

- Update PA criteria for semaglutide (WEGOVY)

### **Background**

The Oregon Health Plan (OHP) fee for service (FFS) program previously reviewed medications for metabolic dysfunction-associated steatohepatitis (MASH) in August of 2024, including the Food and Drug Administration (FDA) approved agent resmetirom and available phase 2 studies for glucagon-like peptide-1

receptor agonists (GLP1-RA) and dual GLP-1 RA/glucose-dependent insulinotropic polypeptides (GIP) agonists.<sup>3</sup> Based on review of evidence and compendial designations at that time, a pathway for off-label coverage of MASH was created for semaglutide and liraglutide.<sup>3</sup>

Semaglutide received an FDA expanded indication for MASH in noncirrhotic adult patients with moderate to advanced liver fibrosis (consistent with stages F2 and F3) in August 2025.<sup>1</sup> Like resmetirom, approval is under the accelerated approval pathway based on improvement of MASH and fibrosis; continued approval is dependent upon verification and description of clinical benefit in confirmatory trials. The evidence supporting this indication was an interim analysis from one ongoing, phase 3, multi-center, randomized, double-blind, placebo-controlled trial (ESSENCE trial; NCT04822181).<sup>2</sup>

In the ESSENCE trial, adults age 18 years and older with histologically documented steatohepatitis with fibrosis stage F2 or F3, a nonalcoholic fatty liver disease activity score (NAS) of 4 or more (score range 0-8; higher scores indicate greater likelihood of diagnosis) were randomized 2:1 to semaglutide 2.4 mg subcutaneously once-weekly (target dose after 16 week escalation) or placebo.<sup>2</sup> Randomization was stratified by diabetes comorbidity, fibrosis stage, and geographic region.<sup>2</sup> Patients were excluded for chronic liver disease unrelated to metabolic dysfunction-associated steatotic liver disease (MASLD), alcohol consumption above predefined thresholds (20 g/d or more in women, 30 g/d or more in men), model for end-stage liver disease (MELD) score of more than 12, aspartate aminotransferase (AST) or alanine aminotransferase (ALT) more than 5 times the upper limit of normal, an estimated glomerular filtration rate of less than 30 mL/min/1.73 m<sup>2</sup> of body surface area, hemoglobin A1C of more than 9.5%, history of acute pancreatitis, previous GLP1-RA use within 90 days, another MASH medication at an unstable dose, and certain other glucose or lipid or weight lowering medications (other than GLP1-RA) at unstable doses.<sup>2</sup>

The trial includes 2 parts. Part 1 primary endpoints are resolution of steatohepatitis (NAS of 0 for ballooning and 0-1 for inflammation) with no worsening of liver fibrosis, and a reduction of liver fibrosis (at least one stage; range 0 [no fibrosis] to 4 [cirrhosis]) with no worsening of steatohepatitis (no increase in ballooning, inflammation, or steatosis).<sup>2</sup> Patients received biopsies at screening and week 72 for the interim results, the first 800 randomized patients were included in this part 1 interim analysis of the total 1197 randomized patients. The primary endpoint for part 2 is cirrhosis-free survival at 240 weeks, to be reported at trial completion. Baseline characteristics appear balanced and key selected characteristics are included in **Table 1**.<sup>2</sup> Clinical results are in **Table 2**. At the time of interim analysis of the 1197 randomized, 31/802 semaglutide patients (3.9%) and 35/395 placebo patients (8.9%) had withdrawn from the trial.<sup>2</sup>

**Table 1.** Key Baseline Characteristics of Patients in ESSENCE Trial<sup>2</sup>

Characteristic	Semaglutide 2.4 mg weekly N=534	Placebo N=266
Age (mean)	56.3 y	55.4 y
Female	58.6%	54.1%
Race		
-White	26.6%	27.8%
-Asian	67.6%	67.3%
-Black	0.6%	0.8%
Hispanic or Latino	17.8%	19.2%
Body Weight (mean)	95.4 kg	97.6 kg
BMI	34.3	35.0
DM2	55.4%	56.8 %

Fibrosis Stage		
-F2	31.6%	30.5%
-F3	68.4%	69.5%
Abbreviations: BMI = body mass index; DM2 = type 2 diabetes mellitus; mg = milligram; y = year.		

**Table 2.** Phase 3 Trial Evidence for Use of Semaglutide in Adults with MASH

Study	Comparison	Outcomes	Results	Notes and Limitations
Sanyal AJ, et al. <sup>2</sup> (ESSENCE trial) NCT04822181  DB, PC, phase 3, MC, RCT	1. Semaglutide 2.4 mg SC once weekly N=534	<u>Primary Outcome</u>  Resolution of steatohepatitis without worsening of liver fibrosis at week 72	1. 62.9% 2. 34.3% Difference 28.7% 95% CI (21.1% to 36.2%) P<0.001 NNT 4	-Possible unblinding due to side effects and weight loss with semaglutide -Underrepresentation of Black patients -Geographic representation: Asia 25.1%, Europe 25.3%, North America 35.0%, South American 7.9%, other 6.8% -Histology endpoint data missing for 65/534 (12.2%) semaglutide and 42/266 (15.8%) placebo patients. -Missing data handled by reference-based multiple imputation informed by placebo data. -83.5% semaglutide patients maintained on target dose
	vs.  2. Placebo SC once weekly N=266	<u>Primary Outcome</u>  Reduction in liver fibrosis without worsening of steatohepatitis at week 72	1. 36.8% 2. 22.4% Difference 14.4% 95% CI (7.5% to 21.3%) P<0.001 NNT 7	
	2:1 randomization  All used prefilled pens	<u>Secondary Outcome</u>  Weight loss (% change in body weight) at week 72	1. -10.5% 2. -2.0% Difference -8.5% 95% CI (-9.6% to -7.4%) P<0.001	
Abbreviations: ARR = absolute risk reduction; CI = confidence interval; DB = double-blind; MASH = metabolic dysfunction-associated steatohepatitis; MC = multicenter; NNT = number needed to treat; PC = placebo-controlled; RCT = randomized controlled trial; SC = subcutaneous.				

Adverse events were reported in 86.3% of semaglutide and 79.7% of placebo patients.<sup>2</sup> Serious events were reported in 13.4% of each group and 2.6% of semaglutide-treated and 3.3% of placebo-treated patients discontinued the study due to side effects.<sup>2</sup> There were 3 deaths in the semaglutide-treated patients and 6 in the placebo-treated patients.<sup>2</sup> Nausea, diarrhea, and constipation were the most common side effects and more common in the semaglutide group (Table 3).<sup>2</sup>

**Table 3.** Adverse events (full safety set)<sup>2</sup>

Adverse Event, N (%)	Semaglutide N=800	Placebo N=395
Nausea	290 (36.3)	52 (13.2)
Diarrhea	215 (26.9)	48 (12.2)
Constipation	178 (22.3)	33 (8.4)
Vomiting	149 (18.6)	22 (5.6)
COVID-19	134 (16.8)	74 (18.7)
Decreased appetite	112 (14.0)	11 (2.8)
Abdominal pain	71 (8.9)	32 (8.1)
Fatigue	71 (8.9)	22 (5.6)
Headache	64 (8.0)	26 (6.6)
Abdominal distention	60 (7.5)	14 (3.5)

**References:**

1. Wegovy (semaglutide) prescribing information. Novo Nordisk Inc. Plainsboro, NJ. Nov 2025. Available at:[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2025/215256s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215256s023lbl.pdf).
2. Sanyal AJ, Newsome PN, Kliers I, et al. Phase 3 Trial of Semaglutide in Metabolic Dysfunction-Associated Steatohepatitis. *New England Journal of Medicine*. Jun 05 2025;392(21):2089-2099. doi:<https://dx.doi.org/10.1056/NEJMoa2413258>
3. Oregon Health Authority. New Drug Evaluation: Rezdifra (resmetirom). August 2024. Available at: [https://www.orpd.org/durm/meetings/meetingdocs/2024\\_08\\_01/archives/2024\\_08\\_01\\_Rezdifra\\_NDE.pdf](https://www.orpd.org/durm/meetings/meetingdocs/2024_08_01/archives/2024_08_01_Rezdifra_NDE.pdf).

## 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)]~~ (previously called nonalcoholic steatohepatitis [NASH]) 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, metabolic dysfunction-associated steatohepatitis (MASH)~~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. Liraglutide is not covered for adults who do not have type 2 diabetes or MASH.

### Covered Alternatives:

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

**Table 1. Drugs FDA Approved for Weight Management**

Drug	Adults	Pediatrics
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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 <u>(injection only)</u>
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/m <sup>2</sup> ) 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**

Note: Drugs prescribed for only weight management (overweight or obesity) are NOT currently covered

Drug	Indications
Liraglutide	<ul style="list-style-type: none"> <li><u>Metabolic dysfunction-associated steatohepatitis (MASH) Non-alcoholic steatohepatitis (NASH)</u> with stage 2 or 3 fibrosis in adults 18 years and older*</li> </ul>
Semaglutide	<ul style="list-style-type: none"> <li>Established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) <u>(tablets or injection)</u></li> <li><u>Metabolic dysfunction-associated steatohepatitis (MASH) Non-alcoholic steatohepatitis (NASH)</u> with stage 2 or 3 fibrosis in adults 18 years and older* <u>(injection only)</u></li> </ul>
* <u>MNASH</u> 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  $\geq$  25 kg/m<sup>2</sup> 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 months [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?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to #3
3. <u>Is the requested indication MASH AND does patient meet all components of Table 3?</u>	<u>Yes:</u> Go to #14	<u>No:</u> Go to #4

Approval Criteria		
<p>4. Does the patient have a BMI corresponding to one of the following:</p> <ol style="list-style-type: none"> <li>1) <math>\geq 30</math> kg/m<sup>2</sup> or</li> <li>2) <math>\geq 25</math> kg/m<sup>2</sup> and comorbid conditions [e.g., diabetes mellitus, hypertension, dyslipidemia, fatty liver disease, or cardiovascular disease] or</li> <li>3) a BMI at the 95<sup>th</sup> percentile or greater for age and sex (Table 2 above)?</li> </ol>	<p><b>Yes:</b> Go to #<u>54</u></p> <p>Record baseline BMI</p>	<p><b>No:</b> Deny; medical appropriateness</p>
<p>5. Will the patient be engaged in a weight management lifestyle modification program in addition to pharmacotherapy?</p> <p>See clinical notes below</p>	<p><b>Yes:</b> Go to #<u>65</u></p>	<p><b>No:</b> Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.</p>
<p>6. Is the member eligible for EPSDT review AND is the requested medication FDA-approved for their age (Table 1)?</p>	<p><b>Yes:</b> Go to #<u>76</u></p>	<p><b>No:</b> Go to #<u>124</u></p>
<p>7. Is the request for setmelanotide?</p>	<p><b>Yes:</b> Go to #<u>87</u></p>	<p><b>No:</b> Go to #<u>109</u></p>
<p>8. 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)?</p>	<p><b>Yes:</b> Go to #<u>98</u></p>	<p><b>No:</b> Deny; medical appropriateness.</p>

Approval Criteria		
9. Does the patient have a history of depression and/or suicidal ideation?	<b>Yes:</b> Deny; medical appropriateness.	<b>No:</b> Approve for up to 6 months.
10. Does the patient have comorbidities (e.g., hypertension, dyslipidemia, diabetes, fatty liver disease, depression, or sleep apnea)?	<b>Yes:</b> Approve for 6 months	<b>No:</b> Go to #1 <del>10</del>
11. 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	<b>Yes:</b> Approve for 6 months.	<b>No:</b> Deny; medical appropriateness. Lifestyle modifications are recommended by guidelines.
12. Is the request for an indication <u>meeting all components of #1</u> Table 3?  Note: drugs <del>when</del> prescribed for weight management (e.g., obesity or overweight) in the absence of another evidence-supported indication are not currently covered.	<b>Yes:</b> Go to #1 <del>32</del>	<b>No:</b> Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss.
13. 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?	<b>Yes:</b> Go to #1 <del>43</del>	<b>No:</b> Deny; medical appropriateness

Approval Criteria		
14. Is there documentation of a type 2 diabetes diagnosis?	<b>Yes:</b> Go to #1 <u>65</u>	<b>No:</b> Go to #1 <u>54</u>
15. 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)?	<b>Yes:</b> Go to #1 <u>65</u>	<b>No:</b> 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)
16. Is the request for tirzepatide (ZEPBOUND)?	<b>Yes:</b> Go to # <u>2019</u>	<b>No:</b> Go to #1 <u>76</u>
17. Is the request for semaglutide (WEGOVY)?	<b>Yes:</b> Go to #1 <u>87</u>	<b>No:</b> Approve for up to 6 months
18. 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?	<b>Yes:</b> Approve for up to 6 months	<b>No:</b> Go to #1 <u>98</u>
19. Will the patient try semaglutide (OZEMPIC) for at least 4 months to ensure tolerability/compliance?	<b>Yes:</b> Approve Ozempic for up to 6 months  * Load PA for OZEMPIC	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
20. Does the patient have obesity (BMI of 30 kg/m <sup>2</sup> 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	<b>Yes:</b> Approve tirzepatide (ZEPBOUND) for up to 6 months	<b>No:</b> 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?	<b>Yes:</b> Go to #2	<b>No:</b> Go to <b>Approval Criteria</b> above
<u>2.</u> Is the requested indication MASH?	<u>Yes:</u> Go to #9	<u>No:</u> Go to #3
<u>2.3.</u> Is the person requesting the medication less than 18 years of age?	<b>Yes:</b> Go to # <u>34</u>	<b>No:</b> Go to # <u>4-5</u>
<u>3.4.</u> Has the patient lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss?	<b>Yes:</b> Go to # <u>78</u>	<b>No:</b> Deny; medical appropriateness
<u>4.5.</u> Is the request for ongoing treatment for someone with established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease), <u>NASH</u> or OSA?	<b>Yes:</b> Go to # <u>56</u>	<b>No:</b> 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
<u>5.6.</u> Has the patient lost or maintained a BMI reduction of 5% or more?	<b>Yes:</b> Go to # <u>67</u>	<b>No:</b> Deny; medical appropriateness
<u>6.7.</u> Has the patient been adherent to therapy based on provider attestation?	<b>Yes:</b> Go to # <u>78</u>	<b>No:</b> Deny; medical appropriateness

Renewal Criteria		
<p><u>7-8.</u> Is the patient continuing with a weight loss treatment plan (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet)?</p>	<p><b>Yes:</b> Approve for up to 12 months.</p>	<p><b>No:</b> Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise.</p>
<p><u>9.</u> Does the provider attest that the patient has been adherent to therapy OR is adherence apparent from medication claims history?</p>	<p><b>Yes:</b> <u>Go to #10</u></p>	<p><b>No:</b> <u>Pass to RPh. Approve once, for 3 months.</u></p> <p><u>Request documentation of adherence.</u></p>
<p><u>10.</u> Has the patient had a complete metabolic panel, liver enzymes, or other appropriate biochemical or noninvasive imaging test within the past 12 months to assess for potential disease progression?</p> <p><u>Additional example tests: fibrosis-4 index (FIB-4), enhanced liver fibrosis test (ELF), vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE)</u></p>	<p><b>Yes:</b> <u>Go to #11</u></p>	<p><b>No:</b> <u>Pass to RPh. Approve once, for 3 months.</u></p> <p><u>-Recommend biochemical monitoring.</u></p>
<p><u>11.</u> If semaglutide initiation was more than 3 years ago, has the patient had noninvasive imaging (e.g., VCTE or MRE) or repeat liver biopsy to assess for progression of fibrosis in the past 3 years?</p> <p><u>If not applicable because semaglutide started less than 3 years ago skip to question #12</u></p>	<p><b>Yes:</b> <u>Go to #12</u></p>	<p><b>No:</b> <u>Pass to RPh. Approve once, for 3 months.</u></p> <p><u>Recommend noninvasive imaging or repeat biopsy.</u></p>

Renewal Criteria		
<u>12. Does the patient have evidence of stage F4 fibrosis (cirrhosis) OR has fibrosis stage worsened (e.g., stage F2 to F3) since starting semaglutide?</u>	<u>Yes: Pass to RPh. Deny; medical appropriateness</u>	<u>No: Go to #13</u>
<u>13. Is there documentation of a risk/benefit assessment for ongoing treatment with semaglutide with possible resolution of metabolic comorbidities?</u>	<u>Yes: Approve for 12 months</u>	<u>No: Pass to RPh. Approve once, for 3 months.</u>  <u>Recommend provide additional documentation.</u>

**\*Clinical Notes**

Adapted from the following guideline on the treatment of adolescents with obesity:	
<ul style="list-style-type: none"> <li>American Academy of Pediatrics. <i>Pediatrics</i>. 2023;151(2): e2022060640. Available at: <a href="https://publications.aap.org/pediatrics/article/151/2/e2022060640/190443/Clinical-Practice-Guideline-for-the-Evaluation-and?autologincheck=redirected">https://publications.aap.org/pediatrics/article/151/2/e2022060640/190443/Clinical-Practice-Guideline-for-the-Evaluation-and?autologincheck=redirected</a></li> </ul>	
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. <b>Available at: USDA choose my plate.gov</b>

3. 60 minutes daily of moderate to vigorous physical activity	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 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: 2/26 (SF); 4/25 (KS); 8/24 (SS/SF); 6/24 (KS)  
Implementation: TBD; 5/12/25; 9/1/24; 7/1/24