Indian Health Service

National Pharmacy & Therapeutics Committee

Criteria for Use Examples for GLP1-GIP Agonists for Weight Loss

DISCLAIMER: These documents are intended to provide facilities with examples of Criteria for Use for semaglutide and tirzepatide in obesity management. All guidance documents are voluntarily provided and no one document is specifically endorsed by the NPTC.

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Colville Indian Health Center – Omak Campus

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Point of Contact: Ryan Buckner, PharmD

Colville Indian Health Center – Omak Campus

Semaglutide (Wegovy/Ozempic) for Weight Loss
Patient Info and Responsibilities Checklist

Semaglutide is a once-weekly injection that may help with weight loss. Length of treatment varies greatly depending on your individual health. You may experience significant weight loss on semaglutide combined with improved diet and exercise. If your weight loss levels out, your dose may be changed or stopped.

Treatment Requirements:

- Initial BMI ≥ 40 AND must have a plan to improve diet and exercise.
- Dietary info handout provided to patient.
- Must complete eye exam prior to treatment.

Monitoring Requirements:

- ☐ Nurse visit for weight check (every 3 months). No appointment needed.
- ☐ Labs (every 6 months).
- ☐ Eye exam (yearly).
- ☐ Weight loss appointment with provider (every 6 months).
- ☐ Report any adverse effects: **Possible thyroid tumors, including cancer,** sustained increase in resting heart rate, inflammation of pancreas, gallbladder problems including gallstones, low blood sugar, changes in vision in people with type 2 diabetes, nausea, diarrhea, vomiting, constipation, stomach pain, headache, tiredness, upset stomach, dizziness, feeling bloated, belching, gas, stomach bug, heartburn, runny nose or sore throat.

How long will I be on semaglutide?

- After reaching your max dose, may continue treatment if weight loss continues at ≥ 3% every 3 months, AND if no significant adverse effects develop, until weight loss goal is achieved.
- If your weight is at goal, OR your weight is no longer dropping by 3% every 3 months, your prescriber will stop semaglutide. Continuing diet and exercise changes is crucial.

My weight today: _____ Final weight goal: _____

3% weight loss (of current weight): _____

You should stop taking semaglutide if:

- Serious allergic reaction. (Swelling of lips/face/throat, trouble breathing, severe rash/itching, fainting or feeling dizzy, very rapid heartbeat).
- You have a severe adverse reaction: Sustained increase in resting heart rate, pancreatitis, gallbladder disease, worsened diabetic retinopathy, acute kidney injury.
- You are pregnant or planning to become pregnant within the next 2 months.

I have been informed of and agree to abide by the above monitoring parameters.

	/ /		/ /		
Signature	Date	Date of Birth	Patient Chart #	Prescriber	

Colville Indian Health Center – Omak Campus

U.S. Department of Health and Human Services
Indian Health Service

Colville Indian Health Center – Omak Campus

617 Benton St
Omak, WA 98841

From: **PHARMACY** To: _____
Ph: **509-422-7735** Ph: _____
Fax: **509-422-7738** Fax: _____
Total # of pages (inc. this cover page): ___

Date: _____ Re: *Attached Rx for* _____
(Name of Medication)

Memo:

Semaglutide is our preferred formulary GLP-1 agonist. This medication has some formulary restrictions and more info is needed so that it can be filled at IHS. **Please fill in the missing information and fax back.**

Diagnosis:_____ Recent eye screening for retinopathy? Yes / No (required)
Dietary info handout given to patient? Yes / No (required)

If DM2 or pre-diabetes: Recent A1c:_____Goal A1c:_____. No further info needed, unless prescribing weight loss dosing (2.4mg).

If for weight loss: Current weight:_____(lbs or kg?) Current BMI:_____

Goal weight:_____(lbs or kg?)

If current BMI < 40 or goal weight is a BMI < 40, then must provide additional justification on a separate sheet (e.g., lower BMI needed before getting a transplant or surgery; NAFLD).

Patient will need a weight check every 3 months to verify medication efficacy goal ≥ 3% body weight every 3 months (after titration to full dose). Semaglutide must be discontinued once patient meets goal or if it stops being effective. Patient to be strongly encouraged to maintain new lifestyle habits (decreased portion sizes and exercise), to counter rebound weight gain due to increase in appetite.

Crow Service Unit Semaglutide (Wegovy) Subcutaneous Injection
=Criteria for Use=
March 2024

Point of Contact:

- CDR (Daniel) Nathan Hamil, PharmD

Crow Service Unit Semaglutide (Wegovy) Subcutaneous Injection Criteria for Use March 2024

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote evidence based prescribing. The clinician should use this guidance and interpret it in the clinical context of the individual patient. Individual cases that are exceptions to the exclusion and inclusion criteria should be adjudicated according to the policy and procedures of the P&T Committee and pharmacy service.

The product information should be consulted for detailed prescribing information.
This criteria for use apply to semaglutide (Wegovy) for chronic weight management.

Baseline Criteria:

1) No outside prescriptions for semaglutide (Wegovy) shall be accepted. Patient must have established care and follow-up within CSU.
2) Prescriptions for semaglutide (Wegovy) shall be limited to no more than one month and shall not have refills.
3) Patients shall complete monthly weight checks to be reviewed by the prescriber prior to the next prescription of semaglutide (Wegovy) being ordered.
    a. Patients that do not keep monthly weight check appointments may not continue on semaglutide (Wegovy)
    b. Patients that do not achieve greater than or equal to 5% weight loss from baseline within three months of initiation of adjunctive semaglutide (Wegovy), in combination with diet and exercise, or if there are significant safety or tolerability issues, semaglutide (Wegovy) should be discontinued.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should NOT receive semaglutide (Wegovy) for chronic weight management.

1) Pregnancy[1] (requires negative pregnancy test in patients that can become pregnant)
    a. For patients who can become pregnant: pregnancy should be excluded prior to receiving semaglutide (Wegovy) and the patient provided contraceptive counseling on potential risks vs. benefits of treatment if the patient were to become pregnant.
2) Breastfeeding[2]
3) Type 1 diabetes
4) Personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2
5) Severe gastrointestinal dysmotility, including gastroparesis.
6) History of pancreatitis (does not pertain to patients for whom the cause of pancreatitis is known and no longer presents a risk)[3]
    a. Semaglutide (Wegovy) should be discontinued promptly is pancreatitis is suspected and should not be restarted if pancreatitis is confirmed.
7) The patient has a history of suicidal attempts or active suicidal ideation[4] (unless a mental health consultation supports benefits of semaglutide in a patient with a history of suicide attempts or recent suicidal ideation)

   a. If symptoms develop, discontinue semaglutide (Wegovy)
8) Concurrent use of another medication FDA approved for weight loss.
9) Known proliferative diabetic retinopathy, severe non-proliferative diabetic retinopathy, or diabetic macular edema unless risks/benefits have been discussed with the patient and is documented in the EHR with monitoring plans and follow-up with an eye specialist who is informed at the time of the initation[5]
   a. Recommend an optometry consult be placed prior to, or have been completed within one year of initiation of semaglutide (Wegovy)

Notations:

1) Weight loss offers no potential benefit to a pregnant patient and may result in fetal harm; refer to product information for more details.
2) Breastfeeding patients excluded from clinical trials for weight management; consider risk vs. benefits in individual patients.
3) Risk factors for pancreatitis include triglyceride levels > 1000 mg/dL, known gallstones with intact gallbladder, and alcohol abuse.
4) Per clinical trial exclusion criteria (lifetime history of suicidal attempt, recent suicidal behavior or ideation) and warnings/precautions in product information.
5) Before considering treatment with semaglutide in patients with diabetes, the provider should have the results of a diabetic eye exam on file within the past 12 months. Patients with a history of diabetic retinopathy should have planned follow-up with the eye provider to monitor for progression. Optometry/ophthalmology consult should be obtained any time there are concerns related to use in patients with diabetic retinopathy.

Inclusion Criteria

The answer to **ALL** of the following must be fulfilled in order to meet criteria for semaglutide (Wegovy)

1) Verifiable continued participation in a comprehensive lifestyle intervention (CLI) that targets all three aspects of weight management: diet, physical activity, and behavioral changes[1]
   a. Semaglutide (Wegovy) is an adjunct to a reduced calorie diet and increased physical activity for chronic weight management.
2) BMI is greater than or equal to 40 kg/m^2 with or without at least one weight-related comorbidity[2]
3) Medication regimen has been reviewed to identify and discontinue medications associated with weight gain when clinically safe and appropriate[3]
4) Patients with type 2 diabetes treated with semaglutide (Ozempic) **AND** requires additional weight loss to achieve greater than or equal to 5% reduction in initial body weight[4]
   a. In this case, semaglutide (Ozempic) would be discontinued and semaglutide (Wegovy), if all criteria met, be initiated

Notations

1) Participation in CLI) is an essential component to overall weight management. Use of weight management medications should only be prescribed in conjunction with CLI. Though there is insufficient evidence to recommend a specific number of CLI sessions, most CLIs offer at least 12 intervention sessions in the first 12 months of intervention.
2) Examples of weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, nonalcoholic fatty liver disease
3) If clinically appropriate, consider discontinuing medications that may precipitate weight gain

Gallup Indian Medical Center

Tirzepatide (ZEPBOUND) Criteria for Use

Point of Contact: Elizabeth Ketner, MD

Zepbound (tirzepatide) for Treatment of Chronic Weight Loss Implementation Proposal

Elizabeth Ketner, MD, MHS, Chairperson of GSU Pharmacy and Therapeutics Committee
February 2024

Background: Obesity is a complex disease defined as weight higher than what is considered healthy for a given height. Body mass index (BMI) is used as a screening and monitoring tool for overweight and obesity. In 2022 48% of American Indian and Alaska Native (AI/AN) people carried a diagnosis of obesity, with higher risk in women, people living in communities ≥30 minute drive from primary care, and people living in communities with high levels of poverty. Prevalence of obesity among AI/AN children and adolescents was the highest in the country at 18.4% in 2020. Health consequences include increased risk of endocrine disease, malignancy, osteoarthritis, respiratory disorders, infectious complications, reproductive challenges, dementia, and impaired mental health. DM2 is the most common morbidity due to obesity, with risk increasing as BMI increases. A 2010 study of AI children and adolescents showed the rates of death (from endogenous causes) were more than two times higher in children whose BMI was in the highest quartile compared to those in the lowest quartile. As little as 3-7% weight loss can reduce risk of obesity related complications, however >10% loss of body weight is known to improve DM2 and long term cardiovascular (CV) outcomes. In October 2023, the IHS National Pharmacy and Therapeutics Committee added Wegovy (semaglutide) for chronic treatment of obesity to the National Core Formulary (NCF) due to the severity of disease burden in Indian Country and the benefits that these drugs demonstrated for weight loss in large randomized controlled studies. In January 2024, after FDA approval of tirzepatide for the treatment of obesity, the NPTC guidance was changed to "Wegovy (semaglutide) OR Zepbound (tirzepatide) for weight management, with recommended local adoption of use criteria for use".

This implementation proposal will outline the following:

1. Proposed GIMC Criteria for Use for Zepbound (tirzepatide) for chronic weight loss management
2. Estimated utilization and cost of medication use
3. Proposed mechanisms for monitoring, continuing and discontinuing clinical use.

Proposed GIMC Criteria for Use:

Exclusion Criteria: If the answer to ANY item below is met, then the patient should NOT receive tirzepatide (ZEPBOUND) for chronic weight management.

1. Pregnancy
2. Lactation
3. Type 1 diabetes
4. Personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome 2
5. Severe gastrointestinal dysmotility, including gastroparesis
6. History of pancreatitis (does not pertain to patients for whom the cause of pancreatitis is known and no longer presents a risk)
7. Age < 18 years old

Gallup Indian Medical Center
Tirzepatide (ZEPBOUND) Criteria for Use

Inclusion Criteria: Patient must meet ALL criteria in order to be eligible for treatment with tirzepatide for chronic weight management.

1. Established with PCP at GIMC, visit within the last 12 months AND documented weight within the last 3 months.
2. NO history of type II DM or A1C >6.5% in the last 12 months.
3. BMI >/= 40 OR BMI >/= 35 with difficult to manage obesity related comorbidities*
4. Documentation of understanding that this medication is lifelong and that discontinuation will result in weight re-gain and possible weight gain above original weight.

*Current Qualifying Obesity related comorbidities: documented metabolic syndrome^, obstructive sleep apnea, metabolic dysfunction-associated steatotic liver disease

^Definition of metabolic disease: Must meet 3 of 5 criteria

1. Abdominal obesity, defined as a waist circumference >102 cm (40 in) in males and >88 cm (35 in) in females
2. Fasting Serum triglycerides >150 mg/dL or drug treatment for elevated triglycerides
3. Serum high-density lipoprotein (HDL) cholesterol <40 mg/dL in males and <50 mg/dL in females or drug treatment for low HDL cholesterol
4. Blood pressure >130/85 mmHg or drug treatment for elevated blood pressure
5. Prediabetes (A1C >5.6% and <6.5%)

Continuation Criteria

1. Weight loss of >3% within the first 3 months of starting the max tolerated dose[#] of the medication, if this goal is not achieved, medication may be discontinued.
2. Continued engagement in primary care, if patient misses 2 consecutive PCP appointments, medication may be discontinued.

[#] Max tolerated dose: The highest dose of a drug or treatment that does not cause unacceptable side effects. For tirzepatide, please escalate dose according to package insert instructions to the max tolerated dose or max dose needed for achievement of weight loss goal.

Estimated utilization for the above criteria:

Number of patients (estimated by iCare list query):
BMI ≥40 without DM, w/ PCP not on semaglutide = 884
BMI >35 + CoMo, w/o DM, w/PCP, not on semaglutide = 226
Total estimated eligible patients: 1154
Total estimated cost per month with current criteria: $577,000
Total estimated cost per year with current criteria: $6.9 million
** Typical uptake is 50%, however these are calculations for eligibility and assuming a 100% uptake

Estimated utilization for lower BMI cutoffs
Number of patients (estimated by iCare list query):
BMI ≥30 w/o DM + comorbidities, not on semaglutide = 430 (no PCP) -> 354 (w/ PCP)
BMI ≥35 w/o DM, not on semaglutide = 1,950
Total estimated eligible patients: 2380
Total estimated cost per month with current criteria: $1.2 million
Total estimated cost per year with current criteria: $14.2 million

Proposed mechanisms for monitoring, continuing and discontinuation

1. In order to initiate drug, a non-formulary request with a drug specific template will be utilized to streamline criteria for use documentation.
2. Only 3 refills will be allowed on the drug. Order renewal after 4 months will not be allowed unless patient has a documented weight since starting the drug (utilizing and EHR 'hard stop' requiring justification similar to creatinine requirements for reordering metformin).
3. If weight loss goal is not met within 3 months of use of the maximally tolerated dose[#], the provider will be contacted to discontinue the medication.
4. If a patient does not engage in care, as defined by missing 2 consecutive primary care appointments, refills will NOT be authorized by pharmacy.

[#] Max tolerated dose: The highest dose of a drug or treatment that does not cause unacceptable side effects. For tirzepatide, please escalate dose according to package insert instructions to the max tolerated dose or max dose needed for achievement of weight loss goal.