

August 1, 2024



RE: Appropriate Use of GLP-1 Agonists

Dear Provider:

GLP-1 agonists have become part of the standard of care in the treatment of Type II Diabetes according to the American Diabetes Association (ADA) guidelines.¹ We would like to make you aware of the coverage and clinical considerations. The ADA now recommends other medications (including GLP-1 agonists) with or without metformin based on glycemic needs, are appropriate initial therapy for individuals with type II diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease¹. Inappropriate prescribing of drugs like Ozempic and Mounjaro for treatment of obesity alone has contributed to shortages of these products for patients with Type II diabetes.^{2,3}

While these products have proven to be effective for their respective indications, they are not without side effects/adverse reactions. The most common side effects are gastrointestinal-related, including loss of appetite, nausea, vomiting, and diarrhea. Additional issues have been identified with patients needing surgery when taking these medications. Due to the delayed gastric emptying feature of these drugs, it has been reported (at least anecdotally) that patients may have increased risk of regurgitation and pulmonary aspiration during general anesthesia and deep sedation³. As a result, the American Society of Anesthesiologists have set guidelines for the holding GLP-1 agonists prior to elective procedures⁴.

All of these products, when coverage is available, require a prior authorization (PA). We have noted, in recent months, many requests for GLP-1 agonists (particularly Ozempic and Mounjaro) that appear to be intended for use outside of the FDA-approved indications for the particular product. Trillium Community Health Plan in conjunction with Centene Pharmacy Solutions will be actively monitoring and reviewing PA requests to ensure these medications are used only per their FDA-approved indications. **Requests for documentation to substantiate attestations made in the PA request process may be required.** It is also important to note that coverage of the products with weight loss indications are not covered by Trillium Community Health Plan as pharmacologic treatment of obesity is an excluded benefit.

These products are available in a number of different forms and product names with varying FDA-approved indications (see Tables below).

Medication	FDA Approved Indication	Dosing Frequency/Route
DIABETES		
Dulaglutide (Trulicity)	Type II DM and pediatric patients ≥10 years of age with type 2 DM; reduction of cardiovascular mortality due to major cardiovascular events	Once weekly SQ injection

	(MACE) in type II DM patients with established CV disease or multiple CV risk factors	
Exenatide, extended-release (Bydureon BCise)	Type II DM, pediatric patients ≥10 years of with type 2 DM.	Once weekly SQ injection
Exenatide (Byetta)	Type II DM	Twice daily SQ injection
Liraglutide (Victoza)	Type II DM and pediatric patients ≥10 years of age with type 2 DM; reduction of CV mortality, non-fatal MI, or non-fatal stroke in persons with Type II DM and established CV disease	Once daily SQ injection
Lixisenatide (Adlyxin)	Type II DM	Once daily SQ injection
Semaglutide (Ozempic)	Type II DM; reduction of CV mortality, non-fatal MI, or non-fatal stroke in persons with Type II DM and established CV disease	Once weekly SQ injection
Semaglutide oral (Rybelsus)	Type II DM;	Once daily tablet
Tirzepatide (Mounjaro)	Type II DM	Once weekly SQ injection
OBESITY		
Liraglutide (Saxenda)	Obesity and pediatric patients ≥12 years of age with body weight >60 kg and an initial BMI corresponding to ≥30 kg/m ² for adults (obesity) by international cut-offs (Cole Criteria).	Once daily SQ injection
Semaglutide (Wegovy)	Obesity and pediatric patients ≥12 years of age with an initial BMI at the ≥95th percentile standardized for age and sex; risk reduction of major adverse cardiovascular events (cardiovascular death, nonfatal MI, nonfatal stroke) in adults with established cardiovascular disease and either obesity or overweight.	Once weekly SQ injection
Tirzepatide (Zepbound)	Obesity	Once weekly SQ injection

***Covered and preferred products are subject to change. Please check the current Trillium Preferred drug list for specific coverage details.**

References

1. American Diabetes Association (ADA) Standards of Care in Diabetes – 2024.
https://diabetesjournals.org/care/issue/47/Supplement_1
2. <https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=813>
3. <https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=972>
4. American Society of Anesthesiologists Consensus-Based Guidance on Preoperative Management of Patients (Adults and Children) on Glucagon-Like-Peptide-1 (GLP-1) Receptor Agonists <https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/american-society-of-anesthesiologists-consensus-based-guidance-on-preoperative>

Respectfully,

Trillium Community Health Plan Pharmacy Department