

**Exclusion Protocol for Victoza® (liraglutide)
Approved January 2021**

Background:

Victoza is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:

1. As an adjunct therapy to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus
2. To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Criteria for approval:

1. Victoza will be approved for all FDA listed indications
2. Victoza is not approvable with concurrent administration of GLP-1 (glucagon-like peptide-1) agonists (for example, Saxenda, Byetta, Trulicity, etc.)
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer reviewed evidence

Approval Duration: One year

Exclusions:

1. Dose greater than 1.8mg per day
2. Prescription is for weight loss

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of Victoza outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis

References:

1. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; August 2020.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Garvey, WT et al. Efficacy and Safety of Liraglutide 3.0 mg in Individuals with Overweight or Obesity and Type 2 Diabetes Treated with Basal Insulin: The SCALE Insulin Randomized Controlled Trial. *Diabetes Care* 2020;43:1085–1093. Accessed online December 21, 2020 at: <https://care.diabetesjournals.org/content/diacare/43/5/1085.full.pdf>
4. Whitten, JS. Liraglutide (Saxenda) for Weight Loss. *American Family Physician*; 2016 Jul 15;94(2):161-166. Accessed online December 21, 2020 at: <https://www.aafp.org/afp/2016/0715/p161.html>