Drug Use Research & Management
Oregon State University College of Pharmacy

Abbreviated Drug Review

Drug Product

Saxenda® (liraglutide) inj solution (subcutaneous) | Indication not funded

Indications

- **Chronic Weight Management:** to be used as an adjunct to reduced-calorie diet and increased physical activity for chronic wt. management in adults with initial body mass index (BMI) of 30 kg/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity.

Dosage

- 0.6 mg subcutaneously once daily for 1 week, then increased by 0.6 mg/day weekly until target dose 3 mg once daily.

Background

- Glucagon-like peptide-1 (GLP-1) is an incretin hormone that amplifies nutrient-induced insulin secretion, inhibits glucagon release, and slows gastric motility.
- Liraglutide is a GLP-1 receptor agonist designed to promote weight loss primarily through appetite suppression.
- Victoza® = identical strength/formulation of liralglutide but is approved by FDA for Type 2 diabetes mellitus (T2DM) at target daily dose of 1.8 mg.

Efficacy

- **Trial 1839**: (n=3731): obese or overweight subjects with weight-related comorbidity
  - % weight change:-5.4% (95% CI, -5.8 to -4.95; p<0.0001)
  - 5% weight loss: OR 4.80 (95% CI, 4.12 to 5.60; p<0.0001)
  - 10% body weight: OR 4.34 (95% CI, 3.54 to 5.32; p<0.0001)
- **Trial 1922** (n=846): Obese or overweight subjects with T2DM
  - % weight change: -4.0% (95% CI, -4.8 to -3.1; p<0.0001)
  - 5% weight loss: OR 6.8 (95% CI, 4.3 to 10.7; p<0.0001)
  - 10% weight loss: OR 7.1 (95% CI, 3.5 to 14.5; p<0.0001)
- **Trial 1923** (n=422): obese or overweight subjects with ≥1 weight-related comorbidity
  - % weight change: -6.1% (95% CI, -7.5 to -4.6; p<0.0001)
  - 5% weight loss: OR 3.9 (95% CI, 2.4 to 6.1; p<0.0001)
  - Maintained 5% BW loss: OR 4.8 (95% CI, 3.0 to 7.7; p<0.0001)

- Three Phase 3 RCTs studied liraglutide 3 mg daily versus placebo in approximately 4800 patients over 56 weeks.
- **Primary endpoints :**
  - **% change from baseline body weight (BW)**
  - **proportion subjects losing at least 5% baseline BW**
  - **proportion subjects losing at least 10% baseline BW***
  - **maintenance of weight loss (minimum 5%) achieved after a 4-12 week run-in using a low calorie diet****

*** = trial 1839 and 1922 only**

Safety

Back Box Warning: Thyroid C-cell tumors in rats and mice.
Contraindications: History of medullary thyroid carcinoma; Multiple Endocrine Neoplasia syndrome type 2; pregnancy.

Caution in patients with thyroid C-cell tumors; acute pancreatitis; acute gallbladder disease; serious hypoglycemia; renal impairment; suicidal behavior/ideation.
Common AEs: Nausea 40%, vomiting 15%; 6.4% req'd discontinuation of therapy due to GI issues

Evidence Gaps/Limitations

As with most weight loss drugs, there are no long-term cardiovascular and mortality outcomes. The drug should impact A1C outcomes related to T2DM by nature of the drug's mechanism of action; however, the Victoza® formulation has FDA approval for that indication.

Recommendation

Restrict use for OHP-funded conditions through Prior Authorization. Use Victoza® for management of T2DM.

References

1. Saxenda (liraglutide) [Prescribing Information]. Plainsboro, NJ;Novo Nordisk Inc., January 2015.
2. FDA Center for Drug Evaluation and Research Summary Review. Available at:http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206321Orig1s000SumR.pdf. Accessed November 24, 2015.