Saxenda® (liraglutide) – Expanded indication

- On December 4, 2020, the FDA announced the approval of Novo Nordisk's Saxenda (liraglutide), as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with:

    - body weight above 60 kg and
    - an initial body mass index (BMI) corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs.

- Saxenda was previously approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a 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 comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia).

- Limitations of use for Saxenda include:

    - Saxenda contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other glucagon like peptide 1 (GLP-1) receptor agonist.
    - The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.
    - The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

- The approval of Saxenda for the expanded indication was based on a 56-week, double-blind, randomized, placebo-controlled study in 251 pubertal pediatric patients aged 12 to 17 years, with BMI corresponding to 30 kg/m^2 or greater for adults by international cut-off points and BMI of 95th percentile or greater for age and sex. After a 12-week lifestyle run-in period, patients were randomized to Saxenda or placebo once-daily. The primary endpoint was change in BMI standard deviation score (SDS).

    - The mean change in BMI SDS from baseline to week 56 was -0.23 in the Saxenda group and -0.00 in the placebo group. The estimated treatment difference in BMI SDS reduction from baseline between Saxenda vs. placebo was -0.22 (95% CI: -0.37, -0.08; p = 0.0022).

- Saxenda carries a boxed warning for risk of thyroid C-cell tumors.

- Saxenda should be initiated with a dose of 0.6 mg subcutaneously (SC) daily for one week with dose escalation to minimize gastrointestinal adverse reactions.

- For pediatric patients, the recommended maintenance dosage of Saxenda is 3 mg SC daily. Pediatric patients who do not tolerate 3 mg daily may have their maintenance dose reduced to 2.4 mg daily. Saxenda should be discontinued if the patient cannot tolerate the 2.4 mg dose.

    - If pediatric patients do not tolerate an increased dose during dose escalation, the dose may also be lowered to the previous level. Dose escalation for pediatric patients may take up to 8 weeks.
    - The change in BMI should be evaluated after 12 weeks on the maintenance dose and Saxenda should be discontinued if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

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    - Prior to initiation of Saxenda, patients should be trained on proper injection technique.

- Refer to the Saxenda drug label for adult dosing, and additional dosing and administration recommendations.

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