

Liraglutide (SAXENDA)

Criteria for Use

July 2016

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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 cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE 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 AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

These Criteria for Use apply to liraglutide as Saxenda for use as a weight loss drug. Please consult the liraglutide (Victoza) documents for information on its use solely in the management of diabetes mellitus.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vaww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive liraglutide.*

- Pregnancy (Category X; i.e., known pregnancy or positive pregnancy test)¹
- Type 1 diabetes
- The patient is taking insulin.
- The patient has Type 2 diabetes but does not meet the liraglutide (Victoza) Criteria for Use
- History of hypersensitivity to liraglutide, other GLP-agonists or excipients²
- Personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Severe gastrointestinal disease, including gastroparesis
- History of pancreatitis³
- The patient has a history of suicidal attempts or active suicidal ideation.
- The patient is taking another weight loss medication (concurrently), e.g., orlistat, phentermine, or lorcaserin, or a stimulant, e.g., amphetamine or methylphenidate.

¹Category X as weight loss is contraindicated during pregnancy.

²It is unknown at this time if patients who experienced a hypersensitivity reaction to one GLP-1 agonist can safely use liraglutide.

³Relative exclusions to use include triglyceride level > 1000mg/dL, known gallstones with intact gallbladder, and alcohol abuse.

Inclusion Criteria *The answers to all of the following must be fulfilled in order to meet criteria.*

- The patient is participating in a clinically supported weight management program that targets all three aspects of weight management (i.e., diet, physical activity, behavioral changes). Weight management treatment programs that target only one or two aspects of weight management are not acceptable. See *Issues for Consideration* for additional information.
- The patient's BMI is greater than or equal to 30 kg/m² **OR**
- The patient's BMI is greater than or equal to 27 kg/m² in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, metabolic syndrome, obstructive sleep apnea, or degenerative joint disease (osteoarthritis).
- The patient's medication regimen has been reviewed to identify and discontinue medications associated with weight gain when clinically safe and appropriate.

Renewal Criteria *All must be met*

- The patient continues to participate in MOVE! or acceptable non-VA weight management program. Initial follow-up is to be in 2 to 4 weeks after starting liraglutide, then monthly for 3

July 2016

Updated version may be found at <http://vaww.pbm.va.gov> or www.pbm.va.gov

months. The patient is to be weighed at each follow-up visit.

- The patient has achieved a 4% loss of baseline body weight after 16 weeks. If less than 4% weight loss it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
- The patient has no contraindications to liraglutide including hypersensitivity or the development of renal impairment; severe gastrointestinal disease, including gastroparesis; pancreatitis or has a had a suicide attempt or active suicidal ideation.

Criteria for Refills every 6 months

- The patient has maintained 67% of their initial weight loss or >5% loss of their baseline total body weight to date or has continued to lose weight.

AND

- The patient's BMI is ≥ 24 kg/m²

- Discontinue if pregnant.

Dosage and Administration

Dose Titration

- The recommended dose of liraglutide (Saxenda) is 3 mg taken once daily by subcutaneous injection.
- When initiating liraglutide (Saxenda) in patients taking secretagogues (such as sulfonylureas), consider reducing the dose of the secretagogue by 50% to reduce the risk of hypoglycemia and monitor blood glucose.
- Initiate dose titration with 0.6 mg daily for 1 week; increase the daily dose by 0.6 mg per week until reaching the target dose of 3 mg. Slow titration rate to every other week if the patient does not tolerate weekly dose escalation.
- Discontinue if a 3 mg dose cannot be achieved or is not tolerated; the efficacy of lower doses for weight loss have not been established. Patients prescribed liraglutide for type 2 diabetes and weight loss should have their dose lowered to 1.8 mg daily.

Monitoring

- Weight
- Blood pressure (orthostatic) and/or signs/symptoms of hypotension in patients taking antihypertensives or other medications that can lower blood pressure
- Resting heart rate
- Glucose and/or signs/symptoms of hypoglycemia
- Mood (symptoms of depression) and sleep disorders

Issues for Consideration

- The prescriber is familiar with Risk Evaluation and Mitigation Strategies (REMS) Program http://www.accessdata.fda.gov/drugsatfda_docs/rem/s/Saxenda_2016-02-01_REMS_full.pdf
- Clinically supported (i.e., includes group or individual contact with a coach or clinical staff) weight management program that targets all three aspects of weight management : diet, physical activity, behavioral change (e.g., VA MOVE!, Weight Watchers, TOPS club, HMR Program, Optifast, Curves Complete, etc.). Clinically-supported web-based or mobile application weight loss programs are acceptable (e.g., face-to-face or telephone encounters, secure messaging with a clinician or clinically-supervised coach, or home telehealth interaction with a clinician. Weight management treatment programs that target only one or two aspects of weight management (e.g., Nutrisystem, Curves Fitness, etc.) are not acceptable.

Guidance to determining participation in VA or non-VA weight management program:

Veterans who have documentation of weight management program participation within the past year on at least one occasion.

- Acceptable documentation could include:
 - Clinic notes specifying the provision of weight management counseling or treatment in group or individual formats. Methods of delivery could include face-to-face visits, phone calls, home telehealth, or clinical video telehealth encounters.
 - Evidence that the patient is participating in MOVE! Telephone Lifestyle Coaching (MOVE! TLC).
 - Evidence that the patient is participating in a home telehealth version of MOVE! (sometimes called TeleMOVE! and may be delivered through an in-home messaging device or interactive voice response).
 - Evidence that the patient is using the MOVE! Coach mobile application in conjunction with clinical support provided in-person, by phone, or via secure messaging (MOVE! Coach with Care).
 - Notation from the clinician that the patient is participating in a non-VA, clinically-supported (i.e., includes group or individual contact with a coach or clinical staff) weight management program that targets all three aspects of weight management (e.g., Weight Watchers, TOPS Club, HMR Program, Optifast, Curves Complete, etc.).
 - Clinically-supported web-based or mobile application weight loss programs are acceptable.
 - Weight management treatment programs that target only one or two aspects of weight management (e.g., Nutrisystem, Curves Fitness, etc.) are not acceptable.
-
- Liraglutide (Saxenda) should not be used in combination with another GLP-1 agonists.
 - Liraglutide has not been studied in combination with meglitinides, alpha-glucosidase inhibitors, DPP-4 inhibitors or SGLT2 inhibitors. Additionally, there could be a potential for increased risk of dehydration due to GI side effects (nausea, vomiting, diarrhea) of liraglutide and diuresis from the SGLT2 inhibitors.
 - Patients should be instructed to report any unexplained persistent severe abdominal pain which may or may not be accompanied by vomiting to their provider immediately. Discontinue agent if pancreatitis is suspected while using these products. Do not restart if pancreatitis is confirmed.
 - Use with caution in patients taking oral medications that require rapid gastric absorption or have a narrow therapeutic index
 - Avoid initiating in individuals whom the potential for dehydration poses a considerable risk (e.g., frail elderly, multiple co-morbid conditions, etc.)
 - Use cautiously in patients who have undergone bariatric surgery due to the potential interaction liraglutide may have on the gastrointestinal motor complications and gastric hormone changes associated with bariatric interventions. With bariatric surgery, GLP-1 is increased along with changes in GI motility and the potential for hypoglycemia if a liraglutide is given.
-

Prepared: July 2016. Contact: Todd Semla, MS, Pharm.D., VA Pharmacy Benefits Management Services

July 2016

Updated version may be found at <http://vaww.pbm.va.gov> or www.pbm.va.gov