Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Insulin degludec/liraglutide (Xultophy)

Notes:

- Quantity Limits: Yes

* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

** Per Kaiser National Clinical Practice Guideline, clinical ASCVD (secondary prevention) includes acute coronary syndrome (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral artery disease (PAD), all of atherosclerotic origin

- Subclinical atherosclerosis, such as elevated coronary artery calcium or aortic atherosclerosis, or patients at high risk for ASCVD (primary prevention) are NOT included in the definition of clinical ASCVD

^ Insulinopenia is defined fasting c-peptide less than or equal to 0.88 ng/mL (or 1.6 ng/mL in patients with creatinine clearance less than 50 mL/min) with a concurrent blood glucose of 70-225 mg/dL

Non-formulary **insulin degludec/liraglutide (Xultophy)** will be covered on the prescription drug benefit when the following criteria are met:

Must meet criteria for both individual agents liraglutide and insulin degludec.

Criteria for liraglutide:

- Diagnosis of Type 2 Diabetes Mellitus
- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- No history of suicidal attempt or active suicidal ideation
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (includes both metformin IR and XR)

And meets one of the following categories:

- Diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD)** AND:
  - Intolerance* or contraindication to an SGLT-2 inhibitor (e.g. Jardiance)
- Inadequate glycemic response on both basal and bolus insulin despite high dose requirements (total daily insulin dose of 1.5 units per kilogram of body weight or more OR greater than 200 units)
- Pediatric patient age 10 to 19 years

cps/awc
Revised: 6/8/23
Effective 8/3/23

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CRITERIA FOR DRUG COVERAGE

Insulin degludec/liraglutide (Xultophy)

Criteria for insulin degludec:

- Documented allergy or intolerance* to insulin glargine

-AND-

Meets one of the following criteria:

- Use in patients with type 1 diabetes mellitus as basal insulin
- Use in patients with any type of diabetes age 19 or younger
- Use in patients with type 2 diabetes mellitus AND insulinopenia^
- Use in patients with type 2 diabetes mellitus AND documented allergy or intolerance* to NPH insulin
- Use in patients with type 2 diabetes mellitus that experience recurrent nocturnal hypoglycemia (low blood sugar at night) with bedtime NPH insulin dosing defined as: 3 or more episodes of nocturnal CBG (capillary blood glucose at night) less than 70 over the preceding 30 days that persists despite NPH insulin dose reduction
    - For patients on 70/30 insulin, trial of NPH insulin (dosed am and bedtime) and Regular insulin (dosed breakfast and dinner) where the bedtime dose of NPH insulin resulted in recurrent hypoglycemia as defined above
- Use in patients with type 2 diabetes mellitus on NPH insulin that experience any episode of severe hypoglycemia defined as: hypoglycemia resulting in seizures, loss of consciousness, episode necessitating assistance from someone else, EMT (emergency medical technician), and/or use of glucagon (medication used to raise the concentration of glucose in the blood)
- Use in patient with type 2 diabetes mellitus that require long-acting insulin due to work (night shift work where hours of sleep are significantly and repeatedly varied over time, frequent time-zone traveler)

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