CRITERIA FOR DRUG COVERAGE

Insulin degludec/liraglutide in single-patient-use pen (Xultophy)

Notes:

- Liraglutide is a mildly effective hypoglycemic. It has shown benefit in type 2 diabetes patients with existing cardiovascular disease. Insulin degludec is a long acting insulin that is non-preferred.

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

- Diagnosis of type 2 diabetes, and
- Diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD) [conditions include: acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)], and
- Documented intolerance to insulin glargine, and
- 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**, or 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), and
- Patient has a recent HbA1c under 9, and
- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), and
- On maximally tolerated metformin dose (1500-2500mg) for at least 3 months (or allergy or intolerance* to metformin), and
- Taking an SGLT2-I (empagliflozin or canagliflozin) or failure/contraindication to taking an SGLT2-I*, and
- On maximally tolerated dose or patient has an allergy or intolerance* to statin, and
- On maximally tolerated dose or patient has an allergy or intolerance* to ACE/ARB

* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
** For patients on 70/30, trial of NPH (dosed am and bedtime) and R (dosed breakfast and dinner) insulin where the bedtime dose of NPH resulted in recurrent hypoglycemia as defined above