ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: January 31, 2018

Prior Authorization: Qtern

Products Affected: Qtern (dapagliflozin/saxagliptin) film-coated tablet

Medication Description:

Qtern (dapagliflozin/saxagliptin) has been approved by the U.S. Food and Drug Administration (FDA) as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus (T2DM) whose blood glucose has been uncontrolled by dapagliflozin or in patients who are already being treated with dapagliflozin and saxagliptin separately.

Qtern (dapagliflozin/saxagliptin) combines a dipeptidyl peptidase-4 enzyme (DPP-4) inhibitor with a sodium-glucose cotransporter-2 (SGLT2) inhibitor that increases urinary glucose excretion by inhibiting SGLT2, the major transporter responsible for the reabsorption of filtered glucose from the kidney. The SGLT2 inhibitors are efficacious agents in reducing HbA1c, postprandial glucose, and fasting plasma glucose, as well as reducing systolic blood pressure and weight. DPP-4 inhibitors have modest glucose-lowering effects with HbA1c decrements of 0.5% to 1%. These agents are weight-neutral and have a low hypoglycemia risk when used as monotherapy or in conjunction with metformin.

Covered Uses:

- Type 2 diabetes mellitus (T2DM) in patients who are already being treated with dapagliflozin and saxagliptin.

Exclusion Criteria:

1. Treatment naïve patients
2. Type 1 diabetes mellitus (T1DM)
3. Patients with diabetic ketoacidosis
4. Patients with moderate to severe renal impairment (eGFR < 45 mL/min/1.73m^2), end-stage renal disease, or patients on dialysis

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed

Age Restrictions: 18 years of age or older

Coverage Duration: 12 months

Other Criteria:

Approve Qtern if the patient meets the following criteria:

A) Patient has a diagnosis of type 2 diabetes mellitus; **AND**

B) Patient is at least 18 years of age or older; **AND**

C) Patient has inadequate glycemic control with dapagliflozin 10 mg; **OR**

D) Patient has inadequate glycemic control with dapagliflozin and saxagliptin separately

References:

1. Qtern [package insert]. Wilmington DE; AstraZeneca; June 2019.
2. Garber AJ, Abrahamson MJ, Barzilay JI, et al. AACE/ACE comprehensive type 2 diabetes management algorithm - 2017. Available at: https://www.aace.com/publications/algorithm. Accessed December 11, 2017.

3. Qaseem A, Berry MJ, Humphrey LL, et al. Oral Pharmacologic Treatment of Type 2 Diabetes Mellitus: A Clinical Practice Guideline Update from the American College of Physicians. Ann Intern Med. 2017; 166:279-290. DOI: 10.7326/M16-1860. Available at: https://www.acponline.org/clinical-information/guidelines. Accessed on December 11, 2017.
4. Scirica BM, Bhatt DL, Braunwald E, et al. Saxagliptin and cardiovascular outcomes in patients with type 2 diabetes mellitus. NEJM 2013; 369:1317-1326. DOI: 10.1056/NEJMoa1307684.
5. Diabetes statistics. Available at: http://www.diabetes.org/diabetes-basics/statistics/. Accessed December 12, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/16/2020