OVERVIEW
Glyxambi and Qtern are sodium-glucose co-transporter-2 inhibitor (SGLT-2) and dipeptidyl peptidase-4 (DPP-4) inhibitor combination products indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both individual medications are appropriate.

POLICY STATEMENT
A step therapy program has been developed to encourage the use of a Step 1 (metformin-containing) product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

Automation: This policy contains automation for patients who have received or are currently receiving a DPP-4 inhibitor (e.g., Januvia, Nesina, alogliptin, Onglyza, Tradjenta), a DPP-4 containing product (e.g., Janumet, Janumet XR, Oseni, alogliptan/pioglitazone, Kazano, alogliptin/metformin, Kombiglyze XR, Jentadueto, Jentadueto XR), an SGLT-2 inhibitor (Farxiga, Invokana, Jardiance), or an SGLT-2 containing product (e.g., Xigduo XR, Synjardy, Invokamet, Invokamet XR) other than Glyxambi. Include this section in all Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1: metformin, metformin extended-release, Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet, Glucovance, metformin/gliburide, Avandamet, metformin/glipizide, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, Janumet, Janumet XR, Prandimet, repaglinide/metformin, Kombiglyze XR, Jentadueto, Jentadueto XR, Kazano, alogliptin/metformin, Synjardy, Xigduo XR, Invokamet, Invokamet XR.

Step 2: Glyxambi, Qtern

CRITERIA
1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.

2. If the patient has received or is currently receiving a DPP-4 inhibitor (e.g., Januvia, Nesina, alogliptin, Onglyza, Tradjenta), DPP-4 containing product (e.g., Janumet, Janumet XR, Oseni, alogliptin/pioglitazone, Kazano, alogliptin/metformin, Kombiglyze XR, Jentadueto, Jentadueto XR), an SGLT-2 inhibitor (Farxiga, Invokana, Jardiance), or an SGLT-2 containing product (e.g., Xigduo XR, Synjardy, Invokamet, Invokamet XR) other than Glyxambi or Qtern, authorization for the Step 2 product may be given.
3. If according to the prescribing physician the patient has clinical or laboratory evidence of hepatic disease, authorization for the step 2 product may be given.

4. If according to the prescribing physician the patient has acute or chronic metabolic acidosis, authorization for the step 2 product may be given.

5. If according to the prescribing physician, the patient is alcohol dependent (chronic or pattern or binge drinking), then authorization for the step 2 product may be given.

6. If according to the prescribing physician, the patient has cardiomyopathy, heart failure, unstable angina, or has experienced a myocardial infarction, then authorization for the step 2 product may be given.

7. Authorization for the step 2 product may be given for patients with a condition other than one listed in the criteria above that could potentially increase the risk of hypoperfusion, hypoxemia, or dehydration (thus potentially increasing the risk of developing lactic acidosis) [e.g., peripheral arterial disease, left ventricular dysfunction, coronary artery disease, stroke].

8. No other exceptions are recommended.

References

- Glyxambi® [prescribing information]. Indianapolis, IN: Eli Lilly and Company; January 2015.