Minnesota Department of Human Services
DUR Board Meeting

September 15, 2021

Members Present
Daniel Jude, Pharm.D., Karen Pedersen, Pharm.D., Gregg Schaeppi.

DHS Staff Present
Mary Beth Reinke, Pharm.D., DUR Coordinator.

Other Attendants
Ariane Casey, Pharm.D., Kepro, Cory Chambliss, Kepro.

Public Comments: There were no public comments.

Approval of Minutes: The Board approved the minutes from May 12, 2021.

Old business:
Gabapentin intervention consisted of 440 criteria exceptions reviewed with a resulting 752 letters mailed on June 25, 2021. SUPPORT Act #2 consisted of 535 exceptions reviewed with 576 letters mailed August 6, 2021. Psychotropic Drugs in Youth was mailed August 6, 2021 which included 769 regular reviews and two special mailings (805 reviews) with a resulting 1,354 letters mailed.

New business:

<u>Diabetes Mellitus Management</u>

Intervention format will be individual patient profile review.

A. Duplicate Therapy within the Same Class
There were 46 occurrences.
Criteria:
- Inclusion: All patients with a claim for more than one diabetic medication [TZD, sulfonylurea, metformin, DPP-IV, SGLT2, alogliptin, exenatide, insulin-GLP1] in the same class for 30 days in the last 90 days within 25 days of each other.

DUR Board recommendation: approve.

B. Drug-Drug Interactions
There were 13 occurrences.
Criteria:
- Inclusion: All patients with a claim for an antidiabetic agent and an interacting medication for 30 days. [Information source is First Data Base (FDB): Level 1 DDI clinical module].

Messages:

Hydroxychloroquine can cause hypoglycemia and concurrent use with insulin or antidiabetic agents may enhance the effects of the hypoglycemic therapy. A decrease in the doses of insulin or the antidiabetic agent may be required. N equals 12

Inspra (eplerenone) is contraindicated for the treatment of hypertension in Type II diabetics with microalbuminuria due to the increased risk of developing persistent hyperkalemia. The principal risk of eplerenone therapy is hyperkalemia and use in this population may result in serious, sometimes fatal arrhythmias. N equals 1

DUR Board discussion and recommendations: replace the wording "diabetics" to "a person with diabetes" throughout this intervention.

C. Drug-Disease Interactions
There were 105 occurrences.
Criteria: Level 1 drug disease interactions per First Data Bank (FDB)

- Inclusion: All patients with a claim for an antidiabetic agent for 30 days in the last 90 days with an interacting disease condition in the last 180 days or on drugs suggesting the disease state in the last 90 days. [Information source is FDB: DDI clinical module].

Messages:

Metformin-containing products can cause lactic acidosis. Patients with renal impairment or a history of lactic acidosis may be at increased risk of developing lactic acidosis when receiving metformin therapy. The use of a metformin-containing agent is contraindicated in patients with severe renal impairment. The use of metformin coadministered with canagliflozin, dapagliflozin, or empagliflozin is contraindicated in patients with moderate to severe renal impairment. N equals 98

Assessment of renal function is recommended prior to initiation of Farxiga (dapagliflozin) therapy and periodically thereafter. The use of dapagliflozin is not recommended when the eGFR is less than 45 mL/min/1.73m2 and is contraindicated in patients with an eGFR less than 30 mL/min/1.73m2. N equals 4

Thiazolidinediones, alone or in combination with other antidiabetic agents, can cause fluid retention, which may exacerbate or lead to heart failure. Patients should be observed for signs and symptoms of heart failure. Discontinue thiazolidinedione therapy if any deterioration in cardiac status occurs. Rosiglitazone and pioglitazone are contraindicated in patients with NYHA Class III and IV cardiac status. N equals 1

Precose (acarbose) is contraindicated in patients with inflammatory bowel disease, colonic ulceration, partial intestinal obstruction, predisposition to intestinal obstruction, chronic intestinal diseases associated with marked disorders of digestion or absorption, or with conditions that may deteriorate as a result of increased gas formation in the intestine. N equals 1

Victoza (liraglutide) is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome (MEN 2). Liraglutide has been shown to cause thyroid C-cell tumors in rats and mice, and human relevance is unknown. It is recommended to counsel patients regarding the risk of medullary thyroid carcinoma and the symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, or persistent hoarseness). N equals 1

DUR Board recommendation: approve.

D. High Dose
There were 15 occurrences.
Criteria:

- Inclusion: all patients with a claim for an antidiabetic agent that exceeds the maximum daily dose for 30 days in the last 90 days.

Message:
[Drug name] may be over-utilized. The manufacturer's recommended maximum daily dose is [dose].

DUR Board recommendation: approve.

E. Minimum FDA Age Requirements
There were 4 occurrences.
Criteria:
- Inclusion: all patients under the specified age with a claim for an SGLT2, DPP-4, or GLP1 for 30 days in the last 90 days.

Message:
The safety and effectiveness of [drug name] have not been established in pediatric patients younger than [age] years of age.

DUR Board recommendation: approve.

F. Non-Adherence
There were 114 occurrences.
Criteria:
- Inclusion: all patients with a claim for a diabetic medication (for more than 60 days in the past 6 months) with less than or equal to 70 days or less in the last 90 days.

Messages:
Based on refill history, your patient may be under-utilizing [drug name]. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Based on refill history, your patient may be under-utilizing [drug name]. Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

DUR Board recommendation: approve.

G. Underutilization
a. Hypertensive Guideline Treatment
There were 479 occurrences.
Criteria:
- Inclusion
  All adult patients with a claim for an antidiabetic agent for 30 days in the last 90 days, with a diagnosis of hypertension or diabetic nephritis in the last 90 days.
- Exclusion
  All patients with a claim for an ACEI or ARB.

Message:
According to the JNC 8 report, the hypertension treatment goal for patients with diabetes is a blood pressure of less than 140/90 mm Hg. In order to achieve this goal, multiple antihypertensive agents may be required. Adding an ACEI or an ARB should be considered if no contraindications are present. These agents also have been shown to delay the progression of nephropathy in diabetic patients with microalbuminuria.

DUR Board recommendation: approve.
The ADA 2021 guidelines, Standards of Medical Care in Diabetes, is the basis of this intervention.

b. Hyperlipidemia Guideline/Treatment
There were 537 occurrences.
Criteria:

- Inclusion
  All patients aged 20 to 75 years with a claim for an antidiabetic agent for 30 days in the last 90 days within the specified age range. For those 20 to 39 years of age, identification requires a diagnosis of family history of atherosclerotic cardiovascular disease (ASCVD).
- Exclusion:
  All patients with a claim for a statin ASCVD drug in the last 90 days.

Messages:

The 2019 ACC/AHA Guideline on the Management of Blood Cholesterol recommends the use of moderate-intensity statin therapy as primary prevention to reduce the risk of atherosclerotic cardiovascular disease in diabetic patients **40 to 75 years** of age unless contraindicated. In the adult patients with diabetes who have multiple ASCVD risk factors, it is reasonable to prescriber high-intensity, statin therapy with the aim to reduce LDL-C levels by 50 percent or more. Refer to the AHA/ACC guidelines for agents and dosage. There were 498 occurrences.

The younger patient with diabetes may benefit from the addition of a statin to their drug regimen if no contraindications exist. The AHA/ACC Guideline on the Management of Blood Cholesterol states that it is reasonable to initiate statin therapy in patients **20 to 39 years** of age for primary prevention of atherosclerotic cardiovascular disease if the patient has a family history of premature ASCVD and LDL-C greater than or equal to 160 mg per dL. Refer to the ACC/AHA guidelines for agents and dosage. There were 39 occurrences.

DUR Board recommendation: approve.

c. Metformin
There were 225 occurrences.
Criteria:

- Inclusion
  All patients with a claim for a non-metformin hypoglycemic for 30 days in the last 90 days.
- Exclusion
  All patients with a claim for metformin in the last 90 days, or a contraindication in the last 180 days, or both.

Message:
A review of the patient's recent medication history reveals no evidence of metformin use. Metformin is recommended in almost all cases of type 2 diabetes, as first-line therapy from the time of diagnosis (after unsuccessful diet and lifestyle changes) and continuing with augmentation of therapy with additional hypoglycemic agents throughout the course of the disease as a means of achieving and maintaining glycemic control. Metformin use effectively decreases HbA1c levels, is associated with weight loss and improvement in lipid profiles as well as being available in cost-saving generic formulations.

DUR Board recommendation: approve.

DUR Board roll call vote was to approve the Diabetes Mellitus Management intervention as discussed.

The next meeting will be December 8, 2021. The meeting was adjourned.