2016
Vol. 28, No. 2

DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review in Iowa

FDA Safety Alerts/Communications

Hepatitis C Treatments

The FDA is warning health care providers that hepatitis C treatments *Viekira Pak* (dasabuvir/ombitasvir/paritaprevir/ritonavir) and *Technivie* (ombitasvir/paritaprevir/ritonavir) can cause serious hepatic injury mostly in patients with underlying advanced hepatic disease. The FDA is requiring AbbVie, the manufacturer of these drugs, to include warnings about serious hepatotoxicity to the *Viekira Pak* and *Technivie* drug labels.

Health care professionals should closely monitor for signs and symptoms of worsening liver disease such as ascites, hepatic encephalopathy, variceal hemorrhage, and/or increases in direct bilirubin in the blood.

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm468757.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Tramadol in Children Aged 17 and Younger

The FDA is investigating the use of tramadol in children ages 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. Tramadol is not FDA-approved for use in children. Health care professionals should consider prescribing alternative FDA-approved pain medications for children.

http://www.fda.gov/Drugs/DrugSafety/ucm462991.htm

Kayexalate (Sodium Polystyrene Sulfonate) Interaction Studies

The FDA is requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth. While reviewing another potassium-lowering drug, the FDA found that it bound to about half of the medications tested, some of which are commonly used in patients. This prompted the FDA to require similar studies with Kayexalate. If these studies confirm significant interactions, the FDA will require all manufacturers of sodium polystyrene sulfonate products to update the drug labels to include information about these drug interactions.

http://www.fda.gov/Drugs/DrugSafety/ucm468035.htm

New Drug Prior Authorization Criteria

Edoxaban (Savaysa®):
Prior authorization is required for edoxaban (Savaysa®). Payment will be considered for patients when the following criteria are met:

1. Patient does not have a mechanical heart valve; and
2. Patient does not have moderate to severe mitral stenosis; and
3. Patient does not have active pathological bleeding; and
4. A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and
5. Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
7. Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.

Atrial Fibrillation

1. Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with
2. Presence of at least one additional risk factor for stroke, with a CHADS2 score ≥1; and
3. Patient does not have a creatinine clearance (CrCl) > 95 mL/min.
4. Requests will be considered for the following dosing:
    a. 60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or
    b. 30mg once daily in patients with a CrCl of 15 to 50 mL/min

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with
2. Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).
3. Requests will be considered for the following dosing:
    a. 60mg once daily; or
    b. 30mg once daily in patients with any of the following:
        i. CrCl 15 mL/min to 50 mL/min
        ii. Body weight ≤60 kg

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Topical Corticosteroids
Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

DUR Activities

Medicaid Statistics for Prescription Claims

from July 1, 2015 to September 30, 2015*

Number of claims paid: 1,743,151

Total dollars paid: $117,951,586

Percent generic prescriptions: 86%

Average amount paid per claim: $67.67

Average amount paid per claim, brand: $356.34

Average Amount paid per claim, generic: $21.03

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent	Top Therapeutic Class by Dollars Spent
Hydrocodone/APAP 5-325mg 33,540 prescriptions	*Lantus* Injection 100/ml $2,793,331	Antipsychotics – Atypicals $10.3 million
Tramadol 50mg 22,791 prescriptions	*Harvoni* 90-400mg $2,619,556	Anticonvulsants $6.3 million
Ventolin HFA 20,967 prescriptions	*Humalog* Injection 100/ml $2,382,511	Diabetic – Insulin $5.8 million
Loratadine 10mg 20,005 prescriptions	*Abilify* 20mg $1,649,250	Stimulants – Amphetamines – Long Acting $5.5 million
Omeprazole 20mg 17,716 prescriptions	*Spiriva* $1,616,846	Hepatitis C Agents $4.3 million

*All dollars reported are pre-rebate