2014
Vol. 26, No. 2

DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review in Iowa

Ketoconazole Drug Safety Announcement

In July 2013, the U.S. Food and Drug Administration (FDA) issued a safety announcement regarding ketoconazole oral tablets. Specifically, the FDA is taking several actions including limiting the drug's use, warning that it can cause severe hepatic injuries and adrenal gland problems and advising that it can lead to harmful drug interactions with other medications. Oral ketoconazole should not be used as a first-line treatment for any fungal infection and should be used for the treatment of endemic mycoses only when alternative antifungal therapies are not available or tolerated. Topical ketoconazole products (creams, shampoos, foams, and gels) are not included in this safety announcement.

Hepatoxicity – Ketoconazole can cause liver damage, which may potentially result in liver transplantation or death. The FDA revised the Boxed Warning adding a contraindication for use in patients with liver disease and included recommendations for assessing and monitoring patients for liver toxicity. Serious liver damage has occurred in patients receiving low doses of ketoconazole for long periods of time as well as those receiving high doses over a short period of time.

Adrenal Insufficiency – Ketoconazole can block production of adrenal steroids through its inhibition of the cytochrome P450 isoenzyme system. This can be attributed to endocrinologic abnormalities seen in some patients, particularly when the drug is administered at high doses, including gynecomastia in men and menstrual irregularities in women. Adrenal function should be monitored in patients with adrenal insufficiency or those with borderline adrenal function should be monitored as well as in patients under prolonged periods of stress (major surgery, intensive care, etc.).

Drug Interactions – Serious and potentially life-threatening outcomes may occur. Ketoconazole is a potent inhibitor of CYP3A4, thus causing decreased clearance of other co-administered drugs that are metabolized by CYP3A4 resulting in increased drug concentrations predisposing patients to serious adverse reactions.

Ketoconazole oral tablets are indicated only for the treatment of the following fungal infections: blastomycosis, coccidiodomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis in patients in whom other treatments have failed or who are intolerant to other therapies.

Ketoconazole oral tablets should no longer be used for the treatment of any type of candidiasis or any superficial fungal infection.

The complete FDA Drug Safety Communication can be found at the following link:

http://www.fda.gov/downloads/Drugs/DrugSafety/UCM362444.pdf

Iowa Prescription Drug Monitoring Program

The Iowa Prescription Monitoring Program (PMP) is administered by the Iowa Board of Pharmacy. The PMP provides authorized practioners (prescribers and pharmacists) with information regarding their patients' use of controlled substances that can be used as a tool in determining appropriate prescribing and treatment of patients. The PMP allows practitioners to improve patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes, or may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner.

Prescription Data

Each licensed pharmacy that dispenses controlled substances to patients in the state of Iowa is required to submit prescription data electronically to the PMP. This includes nonresident pharmacies. There are a few instances where a pharmacy is exempt from reporting, such as a licensed hospital pharmacy; a licensed pharmacy dispensing a controlled substance for a patient residing in a long-term care facility or for a patient residing in an inpatient hospice facility; and a prescriber or other authorized person who administers or dispenses a controlled substance, including samples of a controlled substance, for the purposes of outpatient care. Prescription data is required to be submitted at least weekly for schedule II, III, and IV controlled substances and records are maintained for four years following the date of dispensing. All information contained in the PMP database is privileged and strictly confidential and is not subject to public or open records laws. The Iowa Prescription Monitoring Program Data Collection Manual can be found at the following link: http://www.state.ia.us/ibpe/pdf/IowaDataCollectionManual_2012.pdf.

Registered Practitioners

Registered practitioners may authorize up to three health care professionals (such as RN, LPN, CMA, or certified pharmacy technician) to act as the practitioner's agents for the purpose of requesting PMP information for their patients.

To register for access to the Iowa PMP go to the following website: https://pmp.iowa.gov/IAPMPWebCenter/.

Click the "Register" link and follow the on-screen instructions, complete the registration form, and submit your registration. You will receive a Username and Password via email following approval of your registration. Once registered for access to the PMP you may request a patient's prescription history, which only takes a few seconds to process. The PMP also has the ability to issue alerts. This function helps disseminate information to other health care professionals regarding particular patients, such as a patient you identify as being involved in diversion activities.

Authorized health care practitioners are not required by law to access PMP information regarding their patient's use of controlled substances. The PMP provides practitioners with another health care tool to assist them in identifying potential diversion, misuse, or abuse of controlled substances.

Additional information regarding the Iowa PMP program can be found on the Board of Pharmacy website at http://www.state.ia.us/ibpe/pmp_info.html

A user guide is available on the PMP website at the following link: http://www.state.ia.us/ibpe/pmp/webcenter_user_guide.pdf

Any questions regarding the Iowa PMP should be directed to the Iowa Board of Pharmacy at (515) 281-5944 or in writing at 400 S.W. Eighth Street, Suite E, Des Moines, IA 50309.

New and Updated Drug PA Criteria

Testosterone Products

Prior authorization is required for testosterone products. Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for symptoms of sexual dysfunction, erectile dysfunction and infertility will not be considered. Payment for a diagnosis of hypogonadism (testosterone deficiency) will be considered under the following conditions:

1. Patient is male and 18 years of age or older (or 12 years of age and older for testosterone cypionate); and
2. Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (Please attach lab results); and
3. Patient has at least one of the signs and symptoms specific to androgen deficiency
    a. Incomplete or delayed sexual development
    b. Breast discomfort, gynecomastia
    c. Loss of body hair, reduction in shaving frequency
    d. Very small (<5mL) or shrinking testes
    e. Hot flushes, sweats
    f. Height loss, low trauma fracture, low bone mineral density; and
4. Patient does not have:
    a. Breast or prostate cancer
    b. Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL
    c. Hematocrit > 50%
    d. Untreated severe obstructive sleep apnea
    e. Severe lower urinary tract symptoms
    f. Uncontrolled or poorly controlled heart failure

If criteria for coverage are met, initial authorization will be given for 3 months. Requests for continuation of therapy will require the following:

1. An updated testosterone level (Please attach lab result); and
2. Documentation of how the patient's specific symptoms have responded to therapy; and
3. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months.

Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis.

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

Insulin, Pre-filled Pens

Changes are italicized:
Prior authorization is required for pre-filled insulin pens. Prior authorization for non-preferred insulin pens will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent.
Prior authorization is granted when documentation indicates:

1. The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin, and
2. There is no caregiver available to provide assistance, *and*
3. *Patient does not reside in a long-term care facility.*

DUR Activities

Medicaid Statistics for Prescription Claims

from July 1, 2013 to September 31, 2013*

Number of claims paid: 1,059,690

Total dollars paid: $62,207,883

Percent generic prescriptions: 83.2%

Average amount paid per claim: $58.70

Average amount paid per claim, brand: $249.16

Average Amount paid per claim, generic: $20.11

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent	Top Therapeutic Class by Dollars Spent
Loratadine 10mg $8.45/RX	*Abilify* 20mg $1,326,484 $550.41/RX	Antipsychotics – Atypicals $6.4 million
Ventolin HFA $50.32/RX	Methylphenidate ER 36mg $1,153,426 $187.85/RX	Stimulants – Amphetamines – Long Acting $4.6 million
Hydrocodone/APAP 5-325mg $13.74/RX	*Lantus* Injection 100/ml $990,313 $271.47/RX	Anticonvulsants $3.7 million
Tramadol 50mg $10.00/RX	*Abilify 30*mg $936,896 $567.47/RX	Stimulants- Methylphenidate-Long Acting $3.0 million
Cetirizine 10mg $9.92/RX	*Cymbalta* 60mg $856,159 $253.15/RX	Antidepressants – Selected SSRIs 2.5 million

*All dollars reported are pre-rebate