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DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review in Iowa

Prescription Drug Use on the Rise Over the Past 10 Years

Based on a study released by the U.S.Centers for Disease Control and Prevention, the number of Americans who took at least one prescription drug in the past month increased to 48% in 2007-08, an increase of 10% from 1999-2000. Use of two or more drugs increased from 25% to 31%, and the use of five or more drugs increased from 6% to 11%. In 2007-08, nearly one-half of Americans used at least one or more prescriptions in the month prior to the survey, with one out of every five children and nine out of every ten older Americans using at least one prescription drug.

The most commonly used drugs used by age were bronchodilators for children (0-11 years), central nervous system stimulants for adolescents (12-19 years), antidepressants for adults (20-59 years), and cholesterol lowering drugs for adults aged 60 and over.

Annual Call for New Commission Member

Attention Physicians: Are you looking for a new professional opportunity?

CMS requires state Medicaid programs to have a drug utilization review (DUR) program consisting of prospective DUR, retrospective DUR, and an educational program. The goal of the DUR program is to ensure appropriate medication therapy, while permitting appropriate professional judgment to individualize medication therapy. In Iowa, the DUR Board is referred to as the Iowa Medicaid DUR Commission. The Iowa DUR Commission is composed of four Iowa licensed physicians and four Iowa licensed pharmacists who serve up to two, four-year terms, as well as a representative from the Department of Human Services. The Commission meets on the first Wednesday six months of the year from 9:30 a.m. to 1:30 p.m.

The DUR Commission is currently seeking a Physician who serves Medicaid Members to join the committee. Any Physician interested in serving in this capacity should send a resume or curriculum vitae, as well as a letter indicating their interest to Pam Smith at the address shown below. Candidates that would like more information about the Commission or who would like to speak to a present Commissioner are encouraged to call.

The deadline for applications is April 1, 2011.

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The Use of Clopidogrel in Acute Coronary Syndrome and Cerebrovascular Disease

Clopidogrel (*Plavix)* plays an important role in the management of cardiovascular and cerebrovascular diseases. National and international treatment guidelines recommend clopidogrel either as monotherapy or as combination therapy with aspirin, depending on the patient's risk for thromboembolic events. The American College of Chest Physicians Evidence-Based Clinical Practice Guidelines[1] recommends the following with regard to platelet-aggregation inhibitors:

- For patients with acute coronary syndrome (ACS), aspirin should be given indefinitely unless contraindicated. (Grade 1A)
- For patients with Post-ST-Segment Elevation ACS, clopidogrel should be used for up to 12 months following hospital discharge. (Grade 2B)
- For patients with Non-ST-Segment Elevation ACS, combination therapy with aspirin and clopidogrel should be used for 12 months. (Grade 1A)
- For patients who undergo percutaneous coronary intervention (PCI) with drug-eluting stents, aspirin plus clopidogrel for at least 12 months (Grade 1A), or indefinitely if no bleeding or intolerable side effects occur (Grade 2C).
- For patients who undergo PCI with bare metal stents, aspirin plus clopidogrel should be used for 3 to 12 months. (Grade 1A)
- For patients allergic to aspirin or who experience intolerable side effects with aspirin, clopidogrel should be used instead of aspirin for as long as antiplatelet therapy is needed. (Grade 1A)

The American College of Chest Physicians Evidence-Based Clinical Practice Guidelines[2] recommends the following with regard to platelet-aggregation inhibitors when used for cerebrovascular disease:

- Aspirin, aspirin/extended-release dipyridamole, dipyridamole and clopidogrel are all acceptable options for therapy in patients who have experienced noncardioembolic stroke or TIA. (Grade 1A)
- Long-term use of the combination of aspirin and clopidogrel should be avoided. (Grade 1B)

The DUR regularly reviews patient profiles where it is observed members have been using clopidogrel beyond one year, with or without aspirin. The cost of using clopidogrel, based on AWP pricing, is $195 per month for once daily dosing whereas aspirin costs pennies per day. From January 1, 2010 through June 30, 2010, there were 4,047 paid claims for clopidogrel. The DUR recently sent letters to prescribers and pharmacies of members who have been using clopidogrel for greater that one year that did not have a diagnosis that supported its extended use. The DUR asked if clopidogrel could be discontinued and, if not contraindicated, switched to aspirin.

References:

1. Becker RC, Meade TW, Berger PB, et al. The primary and secondary prevention of coronary artery disease: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl):776S-814S.
2. Albers GW, Amarenco P, Easton JD et al. Antithrombotic and thrombolytic therapy for ischemic stroke: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008 Jun;133(6 Suppl): 630S-69S.

FDA Updates, Specialty Drug List, Lidocaine Patch PA

FDA Update

- The FDA is requiring the manufacturer of Avandia® (rosiglitazone), GlaxoSmithKline (GSK), to undertake a restricted access program under the agency's Risk Evaluation and Mitigation Strategy (REMS) initiative to include elements to ensure the safe use of the product. Under the REMS, rosiglitazone will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos® (pioglitazone). The decision comes after the results from various published studies showed an increased risk in cardiac events in patients taking rosiglitazone. Current users of rosiglitazone who are benefiting from the drug will be able to continue using the medication if they choose to do so.
- New information has been added to the existing Boxed Warning of Arava® (leflunomide) regarding the risk of severe liver injury. The new boxed warning recommends against using leflunomide in patients with preexisting hepatic dysfunction and patients with liver enzymes greater than two times the upper limit of normal. It emphasizes the importance of monitoring liver function after the initiation of therapy.
- The FDA announced it would include information on the risk for developing aseptic meningitis as a result of Lamictal (lamotrigine). This information will be included in the Warnings and Precautions section of the drug label and in the Medication Guide.
- The label for prescription and over-the counter proton pump inhibitors (PPIs) will be updated to include safety information on the potential increased risk of hip, wrist, and spine fractures. The increased risk is seen primarily in older patients with PPI use greater than one year, and with high doses of PPIs (doses greater than 1.5 doses per day).

Specialty Drug List

In December 2009, Iowa Medicaid developed the Specialty Drug List that is subject to a different reimbursement rate than other covered medications. Specialty drugs include biological drugs, blood-derived products, complex molecules, and select oral, injectable, and infused medications identified by the Department. These specialty drugs are reimbursed at the lowest of Federal Upper Limit (FUL) plus dispensing fee, State Maximum Allowable Cost (SMAC) plus dispensing fee, Average Wholesale Price (AWP) minus 17% plus dispensing fee, or usual and customary price. This list includes Hepatitis C agents, Multiple Sclerosis agents, Biologicals, and numerous other medications. The complete list can be found on the Iowa Medicaid Preferred Drug List (PDL) website at iowamedicaidpdl.com under the Specialty Drug List link on the left hand side of the page.

Update to the Lidocaine Patch PA

The DUR recently voted to change the PA criteria for the Lidocaine Patch. Lidoderm® is indicated for the relief of pain associated with post-herpetic neuralgia. The American Academy of Neurology published a practice parameter for the treatment of post-herpetic neuralgia in September 2004. TCAs, long acting opioids, gabapentin, pregabalin, and lidocaine patch were found to have medium to high efficacy in the treatment of post-herpetic neuralgia. While the lidocaine patch has been used for diagnoses other than post-herpetic neuralgia, clinical evidence supporting unapproved uses of lidocaine patches is either lacking or of poor quality. Below are the updated PA criteria for lidocaine patch. The changes are italicized.

Prior authorization is required for topical lidocaine patches (Lidoderm®). Payment will be considered for a diagnosis of pain associated with post-herpetic neuralgia following a previous treatment failure with a preferred agent at therapeutic dose from *two* of the following: tricyclic antidepressant, opioid, gabapentin, *carbamazepine*, or *valproic acid*. A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

Medicaid Statistics for Prescription Claims

from July 1, 2010 to September 30, 2010

Number of claims paid: 906,224

Total dollars paid: $52,465,816

Percent controlled substances: 19.04%

Average amount paid per claim: $57.89

Average amount paid per claim, brand: $196.45

Average Amount paid per claim, generic: $11.46

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent (Pre-Rebate)	Top Therapeutic Class by Dollars Spent (Pre-Rebate)
ProAir HFA $46.22/RX	*Abilify* 5mg $935,466 $440.22/RX	Antipsychotics – Atypicals $9.2 million
Hydrocodone/APAP 5-500 $4.65/RX	*Concerta* 36mg $884,032 $203.79/RX	Stimulants – Amphetamines – Long Acting $3.5 million
Lexapro 20mg $89.35/RX	*Abilify 10mg* $808,900 $442.02/RX	Anticonvulsants $2.8 million
Tramadol 50mg $5.54/RX	*Adderall* XR 20mg $773,245 $259.83/RX	Antidepressants – Selected SSRI's $2.7 million
Loratadine 10mg $7.31/RX	*Lexapro* 20mg $735,684,822 $89.35/RX	Stimulants – Methylphenidate-Long Acting $2.3 million