Iowa Medicaid Drug Utilization Review Commission
Meeting Minutes September 3, 2008

Attendees:

Commission Members
Bruce Alexander, R.Ph., Pharm.D., BCPP; Dan Murphy, R.Ph., Craig Logemann, R.Ph., Pharm.D., BCPS; Sara Schutte-Schenck, D.O., FAAP; Rick Rinehart, M.D.; Laura Griffith, D.O.; Mark Graber, M.D.; Laurie Pestel, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Thomas Kline, D.O.; Chad Bissell, R.Ph., Pharm.D.; and Pam Smith, R.Ph.

Guests
Jenny Vitzthum, Pharm.D. Candidate; Eileen Creager, DHS Bureau Chief; Colleen Kacher, IME; Sandy Pranger, IME; Chuck Wadle, Magellan; Nick Ford, IME; Kelly Espeland, IME; John Grotton, IME; and Melissa Biddle, IME.

Welcome & Introductions

Dr. Thomas Kline called the meeting to order at 9:35 a.m. at the Iowa Medicaid Enterprise. Dr. Kline introduced the newest DUR Commission member, Dr. Mark Graber, and highlighted his career accomplishments. Commission members, guests, and observers were welcomed and introduced.

The minutes from the August 6, 2008 meeting were approved, after a correction to the first paragraph on page 4 from Dr. Schutte-Schenck. (Motion by Dan Murphy, second by Bruce Alexander, unanimous approval by voice vote.)

Case Reviews

Pam Smith presented four intervention case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of $14,047.95 pre-rebate (state and federal).

Smoking Cessation Report for Legislature

The Commission was asked to review the proposed draft of the letter outlining the progress of the smoking cessation program due to the legislature January 15, 2009. They had several suggestions, including adding 3,9, and 12 month outcomes data as well as the 6 month data that was included, to paint a better picture of success rates overall. Also, Bruce Alexander suggested that the additional administration costs due to adding Chantix (varenicline) needed to be figured into the reported costs along with the prescription expenditures. Notes will be added to a couple paragraphs reiterating that the DUR Commission did not make the decision to cover Chantix (varenicline), since they, in fact, recommended the opposite action. The members also requested some additional reporting from Quitline, specifically Medicaid vs. non-Medicaid quit rates and comparisons with other Medicaid populations, as they felt it was

necessary to get a grasp on the program's efficacy to date before attempting to make changes to improve it.

ProDUR

The Commission agreed to place an edit on both strengths of Pristiq (desvenlafaxine) restricting them to 30/30 at the August meeting. Chad Bissell quoted the manufacturer's policy on splitting these tablets: "the Pristiq tablets must be swallowed whole with fluid, and not divided, crushed, or chewed." There was also a Wyeth representative in attendance who said the matrix delivery system would be compromised after splitting, making the tablets immediate release. The Commission commented that there is no evidence that the 100mg works any better than the 50mg. This is a mental health drug, but could still be limited by a potential clinical PA. This issue will be referred to the Mental Health Work Group, which consists of both child and adult psychiatrists.

Focus Studies

Underutilization of Inhaled Corticosteroids: 88 members of the 134 members who received a letter for the Underutilization of Inhaled Corticosteroids Focus Study for the time frame of 2/1/2007 through 7/31/2007 were re-evaluated. These 88 members were identified as having a diagnosis code for asthma. The list of 88 members was re-evaluated during the time frame of 11/1/2007 through 4/30/2008 to see who had corresponding physician office or emergency room visits pertaining to the treatment/management of asthma as a result of the intervention letter from the Commission. The results of the study show an increase in the amount spent on ER visits ($1146.67 pre-rebate state and federal) and a decrease in office visit expenditures ($1744.33 pre-rebate state and federal). Bruce Alexander suggested making adjustments for inflation in the future in studies such as this.

Quarterly Narcotic Utilization Report to Prescribers: Chad Bissell provided the Commission with an example of what this report would look like. It is hoped mailings to providers for members using narcotics either prescribed by 3 or more physicians and/or filled at 3 or more different pharmacies can begin going out by the end of the year. If there are too many members for the initial mailing using these criteria, the threshold may be raised to 5 or more initially. Chad will present additional information at the next meeting to determine whether the algorithm should look at 3 or more vs. 5 or more pharmacies and/or physicians.

Duplicate Antipsychotic Use in Kids: The list of 52 members who received a letter for the Duplicate Antipsychotic Use in Children Focus Study for the time frame of 5/1/2007 through 10/31/2007 was re-evaluated. The list of 52 members was re-evaluated during the time frame of 2/1/2008 through 7/31/2008 to see whose regimen of duplicate antipsychotics had remained the same and who discontinued using one or more antipsychotics. 18 members (5 of which had no claims during the re-evaluation period) discontinued use of 1 or more antipsychotic drugs, while 34 continued using the same regimen. This was referred to the Mental Health Work Group for review. Also, Bruce Alexander

suggested a follow-up study in 6 months focusing on the same members to see if the stats change.

Chronic Singulair Use without Asthma or Allergic Rhinitis Diagnosis: Pharmacy claims data for the drug; Singulair (montelukast), from 8-1-07 through 7-31-08 was reviewed and compared for medical claims data. Singulair is FDA approved for the treatment of asthma, allergic rhinitis, and exercised-induced bronchoconstrictions. There is insufficient data available to suggest Singulair would be effective for other disease states. During this time frame, 32,901 unique members received a total of 147,705 prescriptions for Singulair. For the members who had prescriptions for a documented non-FDA approved diagnosis, an additional review of the pharmacy claims history uncovered that 4,294 of those members also did not have any paid claims for beta-adrenergics. The Commission members believe this number is misleading, and possibly a claim coding issue, rather than misuse of the drug. The findings will be broken down by member age and dosage to highlight any true problem, to be discussed further at the next meeting.

Review of Recently Completed Focus Studies: The Commission would like to look at long-term PPI usage (perhaps exploring a link between a higher risk of community acquired pneumonia and PPI use), cognitive enhancers, and drugs used for restless leg syndrome for possible future studies.

Public Comment

There were no speakers in this public comment session.

Prior Authorization

Growth Hormone: The commission voted to revise the PA criteria as follows:

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

1. Standard deviation of 2.0 or more below mean height for chronological age.

2. No intracranial lesion or tumor diagnosed by MRI.

3. Growth rate below five centimeters per year.

4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter.

5. Annual bone age testing is required for a diagnosis of growth hormone deficiency. Bone age must be 14 to 15 years or less in females and 15 to 16 years or less in males is required. .

6. Epiphyses open.

Prior authorization will be granted for 12-month periods per member as needed.

The following FDA approved indication for growth hormone therapy are considered not medically necessary and requests will be denied:
1. Idiopathic short stature

If the request is for ***Zorbtive®*** *[somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome.*

The motion to accept was made by Dan Murphy, and seconded by Dr. Sara Schutte-Schenck. All other members were in agreement; however, Dr. Rick Rinehart abstained as he was not in the room when voting took place.

Linezolid (Zyvox): The commission voted to revise the PA criteria as follows:

Prior authorization is required for Zyvox®. Payment for Zyvox® will be considered when there is documentation that:
1. Prescriber is an infectious disease (ID) physician or has consulted ID physician (Telephone consultation is acceptable).
2. Patient has an active infection and meets one of the following diagnostic criteria:
*• Vancomycin-resistant Enterococcus (VRE) and no alternative regimens with documented efficacy are available and VRE is not in lower urinary tract**.*
*• Methicillin-resistant Staph aureus (MRSA) and patient is intolerant to vancomycin**
*• Methicillin-resistant Staph epidermis (MRSE) and patient is intolerant to vancomycin**
**Severe intolerance to vancomycin is defined as:*
− Severe rash, immune-complex mediated, determined to be directly related to vancomycin administration
− Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g., prolonged IV infusion, premedicated with diphenhydramine)

***VRE in lower urinary tract, considered to be pathogenic, may be treated with linezolid if severe renal insufficiency exists and/or patient is receiving hemodialysis or has known hypersensitivity to nitrofurantoin.*

The motion to accept was made by Dr. Rick Rinehart, and seconded by Craig Logemann. The roll call vote passed unanimously.

Serotonin 5-HT1-receptor Agonists: The commission voted to revise the PA criteria as follows:

Prior authorization is required for preferred serotonin 5-HT1-receptor agonists for quantities exceeding 12 unit doses of tablets, syringes or sprays per 30 days. Payment for serotonin 5-HT1-receptor agonists beyond this limit will be considered on an individual basis after review of submitted documentation. For consideration, the following information must be supplied:
1. The diagnosis requiring therapy.
2. Documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications.

Prior authorization will be required for all non-preferred serotonin 5-HT1-receptor agonists as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for non-preferred serotonin 5-HT1-receptor agonists will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred agents.

The motion to accept was made by Dr. Laura Griffith, and seconded by Dr. Rich Rinehart. Craig Logemann suggested rearranging the wording. The vote was unanimous.

Extended Release Formulation: The commission voted to revise the PA criteria as follows:

Payment for the extended release formulation will be considered only for cases in which there is documentation of previous trial and therapy failure with the immediate release product of the same chemical entity, unless evidence is provided that use of the immediate release product would be medically contraindicated.
Prior authorization is required for the following extended release formulation(s):
1. Seroquel® XR
2. Luvox® CR

The motion to accept was made by Bruce Alexander, seconded by Dr. Laura Griffith, and was approved by all the members.

Chantix: The commission compared the current Iowa Medicaid PA criteria to those used by the VA. No changes were made. However, Chad Bissell suggested putting an article in the next DUR Digest warning physicians of the dangers of prescribing Chantix (varenicline) in combination with mental health drugs.

Public Comment

There were no speakers in this public comment session.

Miscellaneous

SMAC Interim Update Notice: The State MAC rate decreased for Fluticasone Propionate Spray, and increased for Risperidone and Zaleplon.

DUR Digest – 2008 Vol. 21 No. 1: The Commission reviewed the draft and offered some corrections.

MedWatch: Chad Bissell turned the commission's attention to the safety notice included in their packet titled *FDA warns of risk of rhabdomyolysis when amiodarone administered with higher doses of simvastatin.*

A unanimous vote was made at 12:00 to adjourn the meeting and move to closed session (1st Laurie Pestel, 2nd by Dan Murphy).

The next meeting will be held at 9:30 a.m. on Wednesday, November 5, 2008 in Room 116 at the State Capitol in Des Moines.