Minutes of the March 31, 2006
Pharmacy & Therapeutics (P&T) Committee Meeting
SD Department of Social Services, Medical Services Division

Members present
Verdayne Brandenburg, MD; Dennis Hedge, PharmD; Richard Holm, MD; William Ladwig, RPh; Galen Goeden, RPh; James Engelbrecht, MD; Dana Darger, RPh.

DSS staff present
Larry Iversen; Mark Petersen, RPh; Jill Wellhouse.

HID staff present
Christina Daniels, PharmD; Candace Rieth, PharmD.

Administrative Business
Prior to the start of the P&T Committee meeting, the members discussed the impact of implementing the prior authorization (PA) process and deliberated about better ways to inform patients and providers about drugs requiring prior approvals. There was discussion about the role of the P&T Committee and providing educational seminars for South Dakota providers. It was decided that the role of educating providers is best facilitated through the DUR Board. The P&T meeting was called to order at approximately 12:30 pm. Bill Ladwig, chairman, directed the meeting. The minutes of the February 10, 2006 meeting were presented and approved as written.

Prior Authorization Update
As of March 1, 2006, Health Information Designs (HID) began processing prior authorization (PA) requests for the state of South Dakota. The initial implementation included non-sedating antihistamines and proton pump inhibitors. An analysis of the first twenty days of the program was provided to the P&T Committee members. There were a total of 419 PA requests, which included 150 antihistamine requests and 269 proton pump inhibitor requests. The approval rate was 25% and the denial rate was 75%. All PA requests are required to be turned around in 24 hours and HID responded to 99.05% of the requests in less than 8 hours. Ms. Daniels pointed out to the committee members that the initial cost savings report that was presented today is not as in-depth as what will be provided at a later date. HID will analyze the cost-shift and determine the actual cost-savings to the state. Ms. Daniels told the committee members that HID was almost ready to implement electronic PA and that it should be active by the next P&T Committee meeting.

Ms. Daniels asked if the committee was ready to implement the DAW-1 prior authorization, approved in a previous meeting. The committee requested further information and data. They agreed to discuss this at the next meeting.

Antihyperlipidemic Update

As a follow up to the February P&T Committee meeting, in which prior authorization of antihyperlipidemic agents was a topic, Ms. Daniels presented an overview of antihyperlipidemic use by dose to determine patterns of use in South Dakota. Atorvastatin accounted for 63% of all HMG-CoA prescriptions dispensed, rosuvastatin 12%, and simvastatin 15%. The committee was then presented with an overview of patients taking these medications more than once a day, thereby leading to increased risk of adverse effects. There were 135 patients taking atorvastatin BID or TID, 13 pravastatin patients, 30 rosuvastatin patients, and 12 simvastatin patients. At this time, the committee discussed how prior authorization would work with this group of medications. It was agreed that providers should be asked to try a generic statin first, with step therapy to a branded agent if the patient experiences significant side effects or if there is failure to meet the goal of therapy. Dr. Engelbrecht raised the question of patients stabilized on a branded medication; would these patients be required to try and fail a preferred agent or would all patients stable on a branded antihyperlipidemic be allowed to continue their current therapy? There was discussion about this issue and Mr. Petersen spoke briefly of what would constitute "stable therapy" and then discussed the length of the trial with a generic agent. The committee agreed to table the issue for now and revisit it at the next meeting.

Analysis of Oral Antibiotic Usage in South Dakota

Ms. Daniels presented a review of oral antibiotic use, with all dual eligible patients filtered out, over the last year. Azithromycin was the most costly for the year, but amoxicillin was the most used antibiotic (by prescriptions dispensed). There was brief discussion about the use of linezolid and whether it would be of benefit to have a prior authorization in place for this agent. It was decided that, at this time, no action would be taken. The committee requested that the antibiotics be reviewed again in one year and that usage trends be evaluated at that time.

Analysis of ACE Inhibitor and ARB Usage in South Dakota

There was discussion about the use of ACE inhibitors and ARBs in patients with hypertension, heart failure, and those with impaired renal function. Ms. Daniels noted that the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) considers both ACEIs and ARBs to be effective and gives no recommendation as to using one agent over the other. The American College of Cardiology (ACC) and the American Heart Association (AHA) state that ARBs should not be considered superior to ACE inhibitors in the treatment of heart failure and should not be used in patients who are ACE inhibitor naïve or in patients that are on an ACEI and tolerating it well. The American Diabetes Association (ADA) makes more specific recommendations and says that in hypertensive patients with type 2 diabetes and renal insufficiency ARBs should be used first-line, although ACEI are recommended first-line for other patients.

Ms. Daniels reviewed several trials which compare the ACEIs and the ARBs. The first was the ELITE II trial, which compared captopril 50mg TID to losartan 50mg QD. The

clinical endpoints were reviewed and discussed. The RENAAL, CALM II, VALIANT, and OPTIMAAL trials were also discussed.

Ms. Daniels reviewed the data specific for South Dakota, which showed that there were approximately 9000 prescriptions for ACEIs dispensed over the period of a year and 2700 prescriptions for ARBs dispensed during the same time period (all dual eligible patients filtered out). When comparing costs, the two were almost the same. Ms. Daniels then discussed the estimated cost shifts/savings after implementing a prior authorization program.

The committee discussed their thoughts on this issue. Dr. Holm agreed that most patients should be challenged with an ACEI, with certain exceptions, for example, patients with COPD. Dr. Engelbrecht felt that patients already stable on an ARB should be grandfathered in, and not required to be challenged with an ACEI. Dr. Brandenburg agreed, stating that patients who are already stable would require additional follow-up, possibly creating an increase in medical costs. In discussing grandfathering patients currently stable on ARBs that have not been tried on an ACEI, Mr. Iversen reminded the committee that the same standards should apply to all patients. Dr. Brandenburg asked that we look at the number of patients taking both an ACEI and an ARB for review at the next meeting.

Mr. Ladwig asked for comments from the audience. The first speaker was Richard Hesse from Merck, speaking about Cozaar®, and its effects in type 1 versus type 2 diabetic patients. Next to speak was Scott Andersen from Astra Zeneca, speaking about Atacand®, and its use in heart failure. He also spoke about new studies showing benefit from using an ARB added to a patient already stabilized on an ACEI. The last speaker was Jay Gandhi from Sanofi Aventis, speaking on behalf of Avapro® and its use in type 2 diabetics with macroalbuminuria.

The committee asked Ms. Daniels to clarify the annual numbers for the estimated cost shift/savings for the ARB class and bring those back to the next meeting.

Other Business

Ms. Daniels asked for suggestions on other topics to address in upcoming meetings. The committee decided to review the use of oral antihyperglycemics, use of beta-blockers, and recommendations for maximum units on drugs. In addition, information will be brought back regarding statins, ACE inhibitors and ARBs, and narrow therapeutic index drugs.

After discussion the next meeting date was set for May 12, 2006.

There were no further comments or questions and the meeting was adjourned at approximately 2:30 pm.