



STATE MEDICAID DUR BOARD MEETING
THURSDAY, July 12, 2007
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
Dominic Derose, R.Ph.
Don Hawley, D.D.S.
Joseph Miner, M.D.
Colin VanOrman, M.D.

Tony Dalpiaz, Pharm D.
Bradford Hare, M.D.
Wilhelm Lehmann, M.D.
Bradley Pace, PA-C
Joseph Yau, M.D.

Board Members Excused:

Mark Balk, Pharm D.

Derek Christensen, R.Ph.

Dept. of Health/Div. of Health Care Financing Staff Present:

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Duane Parke, R.Ph.
Lisa Hulbert

Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Nanette Epstein
Jennifer Zeleny, CPhT

Other Individuals Present:

Craig Boody, Lilly
Lori Howarth, Bayer
Trish McDaid-O'Neill, AstraZeneca

Karen Bownan, AstraZeneca
Jeff Buell, J&J

Matt Johnson, Takeda
Elizabeth Stoltz, J&J

Meeting conducted by: Tim Morley

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1. Minutes for May10, 2007 were reviewed, corrected and approved.
 2. Housekeeping:
 - a. Introduction of New Members: Dr. Karen Gunning and Dr. Lowry Bushnell have completed their terms on the DUR Board. They have both accepted positions on the P&T Committee. Jeff Jones requested to step down. Dr. Joseph Yau, Neal Catalano, and Tony Dalpiaz are the new members of the DUR Board.
 - b. Election of a New Chair: Dr. VanOrman was elected as the new Chairman of the DUR Board.
 - c. Review of Board Functions: Tim Morley addressed the Board. A compilation of laws and rules effecting the DUR Board was distributed to Board members. By

Federal Law, the Medicaid Drug Program established by Title XIX of the Social Security Act is a program for medically necessary and categorically needy. The state must assign administration of the program to a single state agency by Federal Law. There are two types of services listed: mandatory services and optional services. Optional services include pharmacy services. The single state agency assigned is responsible for determining the amount, duration, and the scope of coverage to reasonably achieve its purpose. The agency may limit coverage based on medical necessity or utilization control procedures. Pharmacy services are optional. The federal charter does give the pharmacy program the authority to develop and use a prior authorization program, and to develop and implement a separate prior authorization program that implements a preferred drug list. The state agency must monitor and ensure effectiveness of the drug program. The state agency must operate a drug utilization review program that includes prospective DUR, retrospective DUR, provider education, and the administration of a DUR Board. That program must develop and use predetermined standards to assess appropriate and medically necessary drug use. The DUR Board determines what these predetermined standards are as they pertain to prior authorization criteria that may be utilized. The DUR Board should focus on appropriate and medically necessary uses. The regulations provide that appropriate and medically necessary does not mean unlimited cost. If there is a more cost-effective treatment that is equally effective and available, Medicaid is directed to pay for that service on a priority basis, rather than a more expensive treatment or service that accomplishes the same thing.

State law assigns the Division of Healthcare Financing as the state agency responsible for the Medicaid program. This is done through the Department of Health. The Division responsibilities are to administer an effective, impartial, efficient, and economical program; to safeguard against unnecessary or inappropriate use; deny claims failing to meet medical necessity or appropriateness criteria; and has the authority to accept or reject decisions of the DUR Board. The Medicaid program is subject to federal regulation, and Medicaid must meet their requirements as well. Medicaid is subject to audit. If an audit demonstrates that Medicaid has provided services or medications contrary to the way that the statute has set it up, the federal government can take back federal financial participation.

The Medicaid Drug Program is based on clinical and cost factors, which include medical necessity. Appropriate and medically necessary means, regarding prescribing, dispensing, and usage, that is in conformity with the criteria and standards developed. The DUR Board develops and applies predetermined criteria and standards, uses predetermined standards and criteria in a prior authorization program, and is an agent of the Division.

The DUR Board members were provided with a Conflict of Interest Disclosure Form. Medicaid's legal department requires that this be kept on file. Members with a conflict of interest are required to recuse themselves from voting on issues where they have a conflict of interest.

- d. P&T Committee Progress Report: Duane Parke addressed the Board. Senate Bill 42 gives the Division authority to create a Preferred Drug List. Rule 414-60(b) governs that program, and establishes a Pharmacy and Therapeutics (P&T) Committee with nine members: four physicians, four pharmacists, and one voting member from the

Division. The next scheduled meeting of the P&T Committee is on August 17th. The July meeting was cancelled due to vacation conflicts. Utah Medicaid has joined the Sovereign States Drug Consortium, which is a purchasing group of four states that procures bids from drug manufacturers. All four of the states use evidence-based medicine to arrive at what drugs they want on their preferred drug list. Because of this, it is conceivable to have four different preferred drug lists, since member states have the autonomy to choose their preferred drugs. Medicaid is looking at Proton Pump Inhibitors and Statins as the first classes for the PDL. There are some older drugs in these classes with available generics (e.g. H2-blockers and lower-potency Statins), and Utah will not be looking at these. The safety and efficacy of the drugs are paramount considerations. Medicaid looks forward to working with the representatives of the pharmaceutical industry in implementing the PDL.

Duane was asked to clarify the relationship between the P&T Committee and the DUR Board. The Division originally anticipated having prior approval authority to enforce the PDL. Because the DUR Board has the authority to administer prior approvals, the P&T Committee would have been under the domain of the DUR Board. Since there is no prior approval, the P&T Committee is a standalone committee.

The Board asked if there is any way to enforce the PDL without a prior approval. In order to get a prescription for a non-preferred drug, a prescriber will have to write, in his own handwriting “medically necessary - dispense as written” on the prescription. The pharmacist will then have to fill in fields indicating medical necessity and “dispense as written” to bill the prescription. Medicaid will audit pharmacies to ensure that this was written on prescriptions for non-preferred drugs. Medicaid will also audit physicians to ensure that medical necessity has been documented in the patient’s chart.

3. Soliris: Tim Morley addressed the Board. Soliris is a new product from Alexion pharmaceuticals indicated for paroxysmal nocturnal hemoglobinuria (PNH).

A representative of Alexion, Dr. Gus Khursigara, was invited to address the Board. Soliris is a biologic. It is the first and only drug indicated for the treatment of PNH to reduce hemolysis. The other treatment options that are available are not approved, and do not treat the hemolysis, which is the underlying mechanism that leads to the signs, symptoms, and risks of PNH. PNH is a debilitating disease. PNH blood cells are susceptible to lysis and destruction. This causes anemia and other symptoms including fatigue independent of anemia, pain, kidney problems, poor quality of life, hepatic disease, and blood clots. Blood clots are the leading cause of death in patients with PNH. Current treatments include transfusions, which replace red blood cells lost to hemolysis, but do not address the chronic hemolysis that leads to the other signs and symptoms of PNH, including thrombotic events. Other treatments that are available to PNH patients are corticosteroids. There have been no clear studies to demonstrate that corticosteroids reduce hemolysis or reduce the signs and symptoms of PNH. They have been used more for acute exacerbations of PNH due to stress or exercise. The International PNH Advisory Board do not recommend corticosteroids for treatment, because the long-term benefits don’t appear to outweigh the risks of corticosteroid therapy. Blood-stimulating agents, such as Epo, can be used to alleviate anemia in PNH patients. However, the concern with these agents is that they will cause the body to produce more of the PNH red blood cells, which create more hemolysis and produce more signs and

symptoms. Soliris is a biologic that has been designed to bind and inhibit the complement protein complement C5 in the terminal complement cascade. Blocking the terminal complement actually protects the PNH blood cells from lysing. 195 patients were studied on Soliris. All of these patients had a reduction in chronic hemolysis. The reduction of the chronic hemolysis has led to better anemic outcomes, improved fatigue, improvements in dystonia, pain, and quality of life, and a reduction in thrombotic events.

The Board asked Dr. Khursigara about the dosing regimen. It is an infusion product with an initiation and a maintenance dose. Initiation is every seven days for four weeks, and every two weeks thereafter. Randall Hutchings of Alexion addressed the Board. Soliris is an orphan drug; there are only about 3,000-4,000 patients in the United States and 10,000 patients worldwide. The cost of Soliris is approximately \$389,000 per year. It is typically given in a physician's office or a hospital outpatient setting. Soliris currently has a miscellaneous J-code; it will have a permanent J-code in January.

Tim Morley addressed the Board. Board members have been given a fact sheet for the drug, which includes the cost. The incidence of clinically symptomatic PNH is approximately 1:1,000,000, so one could expect to have 2.5 patients in Utah. The Board should consider whether or not to place this under prior authorization. The use will likely be minimal, but the costs of this medication is significant. Soliris is a life-long therapy. It may be rational to require that traditional treatments be tried prior to using Soliris.

The Board asked about the course of the disease, the life expectancy of the disease, and whether or not Soliris significantly changes that. The Board also asked about the age range of the patients. The median life span after diagnosis is 10 years. The median age range of patients is around 30. Diagnosis is very difficult, because it is such a rare disease. Damage already done by the disease will not be reversed, but thrombotic events have been reduced and quality of life is improved. There is no available data to demonstrate an increase of life expectancy on Soliris, but Soliris causes a reduction in events associated with mortality, such as thrombosis.

The Board did not think that it was good for patients to be on long-term corticosteroid or transfusion therapy, but was concerned about the adverse effects associated with Soliris. The Board wanted to determine a reasonable time line for a trial of older therapies. There is no evidence in the literature about these therapies. The Board wanted to know at what point PNH needs to be treated. This is between the patient and the physician; there are no guidelines or parameters set for when Soliris therapy is appropriate.

The Board accepted the prior authorization criteria proposed by the Division, and will review individual requests for Soliris.

4. Lialda: Tim Morley addressed the Board. Lialda is a new mesalamine product from Shire. It is a longer acting mesalamine product used in mild to moderate ulcerative colitis. It is more expensive than currently available mesalamine products; however it is a once-daily dosing as opposed to a three-to-four times daily dosing.

Dr. Keith Tolman addressed the Board. Dr. Tolman is a professor of medicine and pharmacology at the University of Utah. His primary practice is in gastroenterology and hepatology. He is on the speakers' bureau of Shire, as well some of Shire's competitors including Humira, Remicade, budesonide, and Asacol. Dr. Tolman distributed handouts to

the Board. Ulcerative colitis is a chronic disease of unknown etiology, often manifesting with bowel perforations, excessive bleeding, and colon cancer. Lialda is a mesalamine product. There is a 50+ year history of using salicylate products for ulcerative colitis. The “Step-up” therapeutic approach to the disease that is shown on the handouts uses salicylates first for mild to moderate disease, and works up to more potent drugs. There are no comparative trials with Lialda and other drugs, but the response rate for all of these similar drugs is typically around 40%. Lialda is unique because it is once-daily dosing with one or two tablets. Other drugs have required between 8-16 tablets per day four times per day, and has caused problems with adherence. There are data that show that adherent patients stay in remission 90% of the time, and patients who are non-adherent stay in remission 40% of the time. The cost-drivers in a chronic disease are complications of non-adherence. Many patients are non-adherent because of the number of doses per day required. Lialda is advantageous because it is dosed once daily.

Medicaid has only paid for 871 prescriptions at a total cost of \$210,000 for 252 patients for inflammatory bowel disease medications in the last fiscal year. If all of the prescriptions converted to Lialda at the maximum dose, the cost would be \$404,000, with an additional cost to patients of \$768 per patient. If only the mesalamine prescriptions were converted to Lialda at the maximum dose, the cost would be \$370,000 with an additional cost to patients of \$225 per patient. This area does not seem to have a large financial impact, and there is no way to estimate the cost benefit of increased compliance.

The Board asked if a longer-acting formula had an improved side effect profile. All mesalamine formulas have similar side effect profiles.

The Board asked if Lialda would be used for Crohn’s disease. Salicylate preparations are not quite as effective with Crohn’s disease. They are not effective at all with Crohn’s disease of the small intestine. Efficacy studies are underway, and one would expect them to be similar to other salicylates.

The Board felt that compliance was an issue, and that improved compliance would be beneficial to Medicaid, given the small number of patients that are being treated. No other mesalamine preparations currently require prior authorization.

The Board approved the coverage of Lialda without prior authorization restrictions.

Next meeting set for August 9, 2007

Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered five petitions.