



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, December 9, 2004
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Charles M. Arena, M.D.
Lowry Bushnell, M.D.
Derek G. Christensen, R.Ph.
Dominic DeRose, R. Ph.
Bradford D. Hare, M.D.

Jeff Jones, R.Ph.
Wilhelm T. Lehmann, M.D.
Bradley Pace, PA-C
Colin B. VanOrman, M.D.

Board Members Excused:

Karen Gunning, Pharm D.

Joseph K. Miner, M.D.

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

Rae Dell Ashley
Merelynn Berrett
Richard Sorenson
Duane Parke

Suzanne Allgaier
Tim Morely
Darlene Benson

Other Individuals Present:

Jeff Rosenbluet, M.D.
Alan Sloan, Purdue
Gary Oderda, U of U
Shannon Beatty, MedImmune
John Bond, MedImmune
Danny Ottosen, Mylan Bertek
Tim Smith, Pfizer

Nick Mamalis, M.D.
Allan Barruther, Purdue
Erin Fox, U of U
Craig Boody, Lilly
Pierre Thoumsin, Amgen
Oscar Fuller, CMS

Meeting conducted by: Derek Christensen

1. Minutes for October were reviewed, corrected and approved.
2. Erin Fox, Pharm D. presented the criteria set for sedatives/hypnotics. Erin noted that the clinical trials are very limited due to small sample sizes and short duration of time, the longest being 9 weeks. The agents break down into two groups based on the half life of each agent. Those with shorter half life are best for those patients that just have difficulty falling to sleep, but sleep all night. The longer half life agents are best for those patients that have difficulty sleeping the whole night. There is no need to use two agents simultaneously. All these agents can be abused. They all have a hang-over effect, but less so with zaleplon or

zolpidem. Treatment duration should be the shortest time possible with 2 weeks being longest recommended time. Duane noted that a year has passed since a limit of 30 doses/30 days was placed on these agents and in that time a savings of over \$400,000 has been posted. The DUR Board moved to accept the criteria set with no corrections.

3. Nick Mamalis, M.D., Moran Eye Center addressed the DUR Board regarding Restasis. Dr. Mamalis said that Restasis (cyclosporin 0.05%) is the first agent that actually works on the tear making glands to make more tears. Restasis is not indicated for simple dry eyes, but is indicated for keratonconjunctivitis sicca. It is useful for people who have had surgery to the cornea of the eye or who have had injury to the anterior segment of the eye. The Moran Eye Center was part of the original studies for Restasis . How long Restasis should be used is unknown, but for some people, it is probable that life long use is necessary. Ray Dell asked if Allergan is seeking new labeled indications to include cornea transplant. Dr. Mamalis did not know. An eye test with dye [a Fluorescein dye on the cornea with evaluation via the staining of the cornea with the slit lamp and a cobalt blue light] is used to differentiate those people with K. Sicca [CPT 370.33 keratoconjunctivitis sicca; 370.21/370.20 superficial punctate keratitis] and simple dry eye. The dye will show punctate staining or dissipate in less than 5 seconds with K. Sicca. Some people with K. Sicca disease have Sjogren's syndrome [CPT 710.2 Sjogrens syndrome] which can be diagnosed with blood antibody studies. Charles asked what percentage of the dry eye population is being discussed. Nick replied that true punctate keratopathy or K. Sicca is < 5% in the referral population, so the general population is much less. The corneal transplant patients are a similar population size. Duane asked if it is reasonable to use Restasis for a period of time and discontinue use for a period of time. Nick said it is too soon to make that determination. Charles noted that it sounds like Restasis controls the condition, not corrects the condition. Nick noted that standard artificial tears are ineffective for these conditions.
4. Jeff Rosenbluet, M.D., who runs the spinal cord service at the University of Utah and also sees most of the spinal cord injuries with wounds and South Davis Community Hospital address the DUR Board in regards to the use of oxandrolone for wasting of cachectic patients who are 20-30-40% below ideal body weight. Normal weight gain with optimum enteral feeding would be ½ - 1 pound per week which is pretty slow. Oxandrolone studies show excellent weight gain of 2-4 pounds per week. Jeff is seeking the use of oxandrolone for up to two months for these patients. Patients on this rapid weight gain show significant wound healing over conventional therapies which can take up to a year. Burn and spinal cord injuries both benefit. 100% of studies showed tremendous efficacy in lean body mass gain which then allows a much faster healing rate of decubitus sores. Oxandrolone is the only oral agent available. Jeff's units take care of 3/4 of the spinal cord injuries in Utah and estimated population would be 30-40 patients per year. Lowry noted that an initiative should be focused on building lean body mass. The DUR Board agreed to review the evidence and re-visit the topic during the first quarter of 2005.
5. Duane said the new agent Palledone, a long acting version of hydromorphone is on the market and the Division is concerned that Purdue is simply rolling out a long acting version of this old agent to replace OxyContin which is losing patent protection. The Division spent \$ 3.9 million dollars on OxyContin in FY04 with 1.2 million doses dispensed. Other formulations of oxycodone totaled \$370,900 and 637,300 doses for the same period. Tim presented issues and concerns regarding this agent. He noted that it is one of the most potent analgesics available. He note that the medical community has done a good job of minimizing the use of this agent due to its potential for abuse. Palledone is not indicated as a first line agent and then only to be use for moderate to severe level pain and is limited to

age 18 and over. The Division is seeking to prevent inappropriate use, to prevent premature use, to prevent opioid naive use, and to prevent adverse drug events. Tim noted that the Division seeks to limit the use to only severe pain, and then only after all other narcotic formulations have failed. There is a long list of contraindications such as acute or severe asthma, paralytic ileus, pregnancy, acute psychosis, and concomitant use of other long acting narcotic formulations. Palledone is a 24 hour formulation intended for long term use.

Brad said that Palledone may be a good agent for those clients who have not responded to other opioid formulations such as morphine, oxycodone, etc. He noted that the formulation is less abuse friendly. This is not a unique agent and should not be viewed differently from existing time release agents, but it does appear to be an expensive drug. (Work up a cost comparison for next month). Brad hasn't seen any information on the reliability of the claim for 24 hour analgesia. For cancer pain, doubling and tripling the dose will happen just as with other long acting opioids. Lowry noted that this seems to be a profit niche, not a clinical niche and it may be advisable to place this on prior approval as go to drug after other long acting agents have failed. Allan Barruther, Purdue, comment that Palledone is not a first line agent and should be used only when side effects of other agents give this the go ahead.

Next meeting set for January 13, 2005

Meeting adjourned.

12.98.94

The DUR Board Prior approval Subcommittee convened and considered 18 petitions.

