



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



MINUTES

Board Members Present:

Lowry Bushnell, M.D.
Mark Balk, Pharm D.
Derek G. Christensen, R.Ph.
Dominic DeRose, R.Ph.
Karen Gunning, Pharm D.

Don Hawley, DDS.
Wilhelm T. Lehmann, M.D.
Joseph K. Miner, M.D.
Bradley Pace, PA-C
Colin B. VanOrman, M.D.

Board Members Excused:

Bradford D. Hare, M.D.

Jeff Jones, R.Ph.

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

RaeDell Ashley
Rick Sorenson
Jennifer Zeleny

Suzanne Allgaier
Tim Morley
Nanette Waters

Other Individuals Present:

John Stockton, Genentech
Karen Bowman, AstraZeneca
Roy Linfield, Schering
James Gaustad, Purdue
Barbara Christensen-Barr, Novartis
Trish McDaid-O'Neill, AstraZeneca

Kara Clawson, Genentech
Craig Boody, Lilly
Steve Farmer, Amgen
Tim Smith, Pfizer
Alan Baily, Pfizer
Linda Craig, AstraZeneca

Fred Mow, BMS
Shannon C. (?) Pharm D.
Jeff Buel, J&J
Shannon Beatty, Medimune

Meeting conducted by: Lowry Bushnell, M.D.

1. Minutes for January 2007 were reviewed and approved.
2. Vectibix: Tim Morley addressed the Board. Vectibix is a medication for metastatic colorectal carcinoma from Amgen. It is an expensive medication. It is not available through the pharmacy program; it is an intravenous office-administered drug that is billable by J-Code to the medical program. Some of the HMO's and managed care organizations are allowing physicians to administer this drug without restriction and billing Medicaid for some of the cost. Medicaid would like to consider placing the J-Code under prior authorization to promote appropriate usage of this medication. Steve Farmer of Amgen addressed the Board. Vectibix is an important third-line

treatment for metastatic colorectal cancer. Some of the MCO plans are covering it outside of its labeled indication, and Amgen does not recommend or support this. He requested that Medicaid provide coverage for Vectibix in its approved indication as a third-line treatment of advanced colorectal cancer. Colorectal cancer is the #3 most diagnosed cancer and #2 killer of patients in the U.S.

Karen Gunning asked if there are any ongoing studies of Vectibix for other indications. Steve Farmer stated that there are.

RaeDell Ashley asked about the severity of the dermatological side-effects of Vectibix. Steve Farmer stated that about 94% have dermatologic side effects. If a patient experiences Stage 4 side effects, the therapy is discontinued until the issue is resolved. Therapy is then re-initiated. The dermatological toxicity actually indicates that it is being dosed correctly. There have been no fatalities associated with this.

Tim Morley stated that a data pull on Vectibix returned no data. Medicaid does not currently know to the extent to which it is being used. The dose is 6mg/kg every 14 days. The 400mg vials are likely to be used every time depending on the age and size of the patient. There is no pediatric indication for this product according to the FDA labeling. This is not a first-line treatment; however there are some other off-label uses that account for about half of the usage of Vectibix. Medicaid would like to place this under prior authorization to ensure that Vectibix is only being used for metastatic colorectal cancer. Physicians wishing to use Vectibix for other indications would be required to submit studies with data to back up the off-label use, as is done with other off-label usage requests.

The Board requested to know why Medicaid was requesting a six-month prior authorization period as opposed to a year. Because the endpoint of treatment is disease progression, Medicaid wants to ensure that it is only being used during progression-free disease.

Wendy Briar, medical oncologist, addressed the Board. She asked how long it would take to receive a prior authorization. The turnaround time on a PA is less than a day if all needed information is provided. She also stated that a six-month versus twelve-month authorization is inconsistent and may lead to confusion about when prior authorizations needed to be renewed. Most insurance plans grant authorization of a year, so she requested that the authorization period of Vectibix be changed to a year for consistency.

The Board passed the prior authorization criteria with the provision that the authorization be granted for a year.

3. Avastin: Tim Morley addressed the Board. Avastin is another agent for the treatment of metastatic colorectal cancer when given in combination of 5-FU/FIV. It can also be given in combination with carboplatin and paclitaxel for first-line treatment of non-squamous non-small cell lung cancer. It has more off-label uses than Vectibix, so Medicaid would like to place it under prior authorization for the same reasons as Vectibix. The criteria that Medicaid would like to pass is much simpler - it is based on the two approved indications and age of the patient.

Karen Claussen of Genentech addressed the Board. She asked that patients have access

to Avastin as both a first-line and second-line treatment of metastatic colorectal cancer as well as the non-squamous non-small cell lung cancer.

Tim Morley stated that the Board will be discussing the use of Avastin versus Lucentis as a treatment for macular degeneration in March. This is currently one of the most prevalent off-label uses of Avastin. If the Board were to decide to add macular degeneration to the approved uses of Avastin, it would be added to the criteria currently under consideration.

The Board passed the prior authorization criteria recommended by Medicaid.

4. Invega: Tim Morley addressed the Board. Invega is the active metabolite of risperidone packaged in extended-release tablet form. Available data does not indicate that Invega provides any advantage over risperidone, other than dosing schedule. Safety and efficacy data are the same as those of risperidone; however, Invega is much more expensive. A tablet ranges from \$10.00 to \$15.50 a tablet. Patients can take up to two tablets per day. Medicaid has only paid for two prescriptions for Invega so far. Medicaid has been unable to find any data comparing Invega to risperidone.

The Board questioned the rationale of paying for a drug that did not appear to offer a significant clinical benefit over an existing dosage form at a significantly higher cost. Medicaid was asked to provide the cost per tablet of risperidone. The cost is about \$3.00 per tablet. The availability of a generic would augment the price difference that had been discussed.

Karen Gunning felt that the criteria proposed for prior approval were reasonable, but suggested that the criteria should include a rationale for needing once-daily dosing.

Mark Balk asked how many of the risperidone patients were currently taking a once-daily dose. Medicaid is unable to answer this question, since the claims data only provide the number of units dispensed and days supplied.

Medicaid was asked if the POS would be programmed to accept only ICD.9 codes for schizophrenia. Tim Morley stated the ICD.9 code would not be needed if Invega was under a prior authorization. Medicaid was also asked how the treatment of other conditions would be handled for Invega. Karen Gunning stated that the FDA indication is only for schizophrenia.

Dr. Bushnell asked if there was anyone present from Janssen to address the Board, particularly to provide studies comparing Invega to risperidone. No one was present in the gallery to address this.

The prior authorization nurses asked how to determine that Invega is medically necessary. The Board suggested that PA be granted to patients who consistently fail to take multiple daily doses of an antipsychotic and cannot tolerate a single daily dose of risperidone.

The duration of the prior approval was set at one year. The Board passed this criteria.

5. Claims Education: Tim Morley addressed the Board. The Deficit Reduction Act requires that J-code billing for drugs on a HCFA 1500 claim form include the NDC from the

packaging of the drug administered. Medicaid claims are currently being submitted without an NDC or with an incomplete NDC. The Board was asked to assist Medicaid in educating providers about including a correct NDC on each claim that is submitted.

Next meeting set for March 8, 2007

Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 2 petitions.