Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: May 11, 2012 **Time:** 9:00 a.m. – 3:45 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho , Conf. Room D

Moderator: Perry Brown, MD

Committee Members Present: Perry Brown, MD-Chair; Dennis Tofteland, RPh; John Mahan, M.D; Catherine Hitt-Piechowski, PharmD; Elaine Ladd, PharmD; Tami Eide, PharmD; Mark Turner, MD, Jefferey Johnson,PharmD, PA-C; Troy Geyman, MD; Mark Johnston, RPh

Others Present: Paula Townsend, PharmD, Magellan Health Services; Mark England PharmD, Magellan Medicaid Administration; Jane Gennrich, PharmD, Medicaid; Wendy Golaszewski, Medicaid; Rachel Strutton, Medicaid; Teresa Martin, Medicaid

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
Committee Business		
➢ *Roll Call*	*Perry Brown, MD*	Dr. Brown completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➢ *Reading of Mission Statement*	*Perry Brown, M.D.*	Dr. Brown read the Mission Statement.
➢ *Approval of Minutes from the April 20, 2012 Meeting*	*Perry Brown, M.D.*	There were no corrections. The April 20, 2012 meeting minutes were accepted as proposed.
➢ DUR Board Update: Narcotic Analgesics	*Tami Eide, PharmD*	**Narcotic Analgesic DUR** Dr. Eide presented the results of the April 2012 DUR Board study on patterns of narcotic (opioid) use in chronic non-malignant pain. This study was done at the request of the P&T Committee and included the P&T Committee's recommend criteria parameters. The review focused on the top recipients by narcotic claim count and covered the time period of 5/1/2011 through 12/31/2011. Results from 87 patients reviewed: • Participants were on chronic opioids for an average of 9.8 years • Participants had an average of 2.6 different opioids • Daily morphine equivalents ranged from 10 mg to 1080 mg with an average of 202 mg • Participants have prescriptions from an average of two (2) prescribers each • Participants were on combinations of one to four other potentially addictive drugs

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<td>concurrently including benzodiazepines, muscle relaxants, and sedative hypnotics
• The most common diagnosis was lumbago or low back pain followed by chronic pain syndrome
• The average number of days prior to refill for most participants was 30 days.</td>
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<td>Public Comment Period</td>
<td>Perry Brown, M.D.
Wendy Golaszewski</td>
<td><u>Public Comment Period</u>
Three (3) people signed up to speak during the public comment period. No pharmaceutical industry representatives were approved to speak. Public testimony was received from the following speakers:

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<tr><th>Speaker</th><th>Representing</th><th>Agent</th><th>Class</th></tr>
<tr><td>Jackie Whitesell, MD</td><td>Self</td><td>All</td><td>Multiple Sclerosis Agents</td></tr>
<tr><td>Cheryl Bloom</td><td>Self</td><td>All</td><td>Multiple Sclerosis Agents</td></tr>
<tr><td>Caleb Simpson</td><td>Self</td><td>All</td><td>Multiple Sclerosis Agents</td></tr>
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<td>Drug Class Reviews and Committee Recommendations

➢ Analgesics, Narcotic long-acting</td>
<td>Paula Townsend, PharmD
Magellan Health Services</td>
<td>Drug Class Reviews and Committee Recommendations

<u>Analgesics, Narcotic long-acting</u>
Dr.Townsend provided a review of three new products: Nucynta ER (tapentadol ER), ConZip – a new formulation of tramadol with both immediate release and sustained release components and morphine ER capsules (generic for Kadian). The FDA will soon require REMS (Risk Evaluation and Mitigation Strategies) on many long-acting narcotic products, with a focus on provider education.

Committee Recommendations
The committee recommended that a definition for “failure of a preferred agent” beyond just filling the prescription be established. They recommended that approval criteria include an evaluation of the morphine equivalent of the failed drug as compared to the drug being requested . They also recommended removing the prior authorization criteria of “history of a preferred oral agent in previous 6 months for fentanyl transdermal”. Other than these recommendations the committee felt that there was no evidence based differences to support preferring any agent over another in this class.</td>
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<td>➢ Analgesics, Narcotic short-acting</td>
<td>Paula Townsend, PharmD
Magellan Health Services</td>
<td><u>Analgesics, Narcotic short-acting</u>
Dr.Townsend provided a review of one new product: Oxecta (oxycodone immediate-release) which is formulated to discourage common methods of tampering. There is no convincing evidence that this product has a reduced abuse liability compared to other IR oxycodone products. She also discussed the recent FDA action placing transmucosal immediate release fentanyl</td>
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		products on a restricted access program because of the risk of misuse, abuse, addiction and overdose problems. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Opiate Dependence Treatments	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Opiate Dependence Treatments</u>** Dr.Townsend announced that brand name Subutex SL (buprenorphine) had been discontinued by the manufacturer due to greater abuse potential than the combination product containing naloxone. Generic buprenorphine is still available. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Skeletal Muscle Relaxants	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Skeletal Muscle Relaxants</u>** Dr.Townsend provided a review of a new product Lorzone (chlorzoxazone 375 & 750 mg tablets). She announced the availability of tizanidine generic for Zanaflex. She also discussed recent DEA Action that places carisoprodol into the Schedule IV classification of the Uniform Controlled Substance Act. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. The Committee recommended continuing the current therapeutic criteria for carisoprodol including the new combination product with codeine.
➢ Antimigraine Agents	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antimigraine Agents</u>** Dr.Townsend provided a review of the FDA safety communication which stated that triptan, ergotamine and opiate overuse have been associated with exacerbation of headache- like symptoms. She presented one new clinical study that evaluated the effectiveness of Maxalt ODT in sumatriptan non-responders. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. The Committee recommended that the Medicaid Pharmacy

		Program review updated information on use of triptans in children and update prior authorization criteria to reflect recent labeling changes. The Committee also recommended a DUR to look at prophylaxis and cumulative triptan doses through different routes of administration.
➢ Antiemetics/Antivertigo Agents	*Paula Townsend, PharmD* *Magellan Health Services*	**Antimetics/Antivertigo Agents** Dr.Townsend provided a review of recent FDA Actions which includes warnings on transient ECG changes including QT prolongations and Torsade de Pointes with ondansetron and dose dependent PR or QRS interval prolongation, AV Block, cardiac arrest or ventricular arrhythmias with dolasetron. She also reviewed the 2011 American Society of Clinical Oncology (ASCO) updated treatment guidelines for moderate and highly emetogenic chemotherapy regimens. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Ulcerative Colitis Agents	*Paula Townsend, PharmD* *Magellan Health Services*	**Ulcerative Colitis Agents** Dr.Townsend announced that Lialda (mesalamine MMX is now approved for maintenance of remission in patients with ulcerative colitis. There was no other new clinical data to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Immunosuppressives, Oral	*Paula Townsend, PharmD* *Magellan Health Services*	**Immunosuppressives, Oral** There was no new significant clinical information to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Multiple Sclerosis Agents	*Paula Townsend, PharmD* *Magellan Health Services*	**Multiple Sclerosis Agents** Dr.Townsend announced the availability of two new products -Avonex Pen and the Avostartgrip titration kit, which is also available to be used with Avonex pre-filled syringes. FDA Action for Gilenya (fingolimod) including four new contraindications and monitoring changes based on recent post-marketing safety surveillance. She also noted that both JCV (John Cunningham

		Virus) and PML (Progressive Multifocal Leukoencephalopathy) have been associated with Tysabri. . **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Growth Factors	*Paula Townsend, PharmD* *Magellan Health Services* *Jane Gennrich, PharmD* *Idaho Medicaid*	**<u>Growth Factors</u>** Growth Factors is a new drug class for Committee review. Dr. Townsend provided a review of mecasermin (Increlex) which is indicated for treatment of growth failure in children with IGF-1 deficiency or who have developed neutralizing antibodies to growth hormone. Dr. Gennrich discuss the pharmacy program's proposed guidelines for use which will be used for prior authorization reviews. **Committee Recommendations** The committee approved prior authorization criteria and recommended that Increlex be listed as a preferred drug.
➢ Antibiotics, inhaled	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antibiotics, inhaled</u>** Dr.Townsend announced that Gilead has reported a shortage of Cayston. Gilead is not able to say when the supply issues will be resolved. New patients are not able to start on Cayston at this time. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Cephalosporins and Related Agents	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Cephalosporins and Related Agents</u>** Dr.Townsend announced that there is no new significant clinical information to review. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class The committee recommended moving Augmentin ES-600 suspension to preferred status if cost was not prohibitive to allow higher doses with the appropriate ratio of amoxicillin to clavulanate.
	Paula Townsend, PharmD	**<u>Fluroquinolones, oral</u>**

➢ Fluroquinolones, oral	*Magellan Health Services*	Dr.Townsend announced the availability of levofloxacin a generic for Levaquin. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. The committee recommended a DUR on the use of CIPRO Suspension for children under the age of 17.
➢ Macrolides/Ketolides	*Paula Townsend, PharmD* *Magellan Health Services*	**Macrolides/Ketolides** Dr.Townsend provided a review of new FDA safety concerns related to Zithromax (azithromycin). She also provided a review of the 2011 update of Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Tetracyclines	*Paula Townsend, PharmD* *Magellan Health Services*	**Tetracyclines** There was no new significant clinical information to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. The committee recommended changing the minimum age for tetracylines from 8 years to 9 years of age.
➢ Antibiotics, Topical	*Paula Townsend, PharmD* *Magellan Health Services*	**Antibiotics, Topical** Dr. Townsend provided a review of new treatment guidelines from the 2011 Infectious Disease Society of America which still recommends mupirocin as the drug of choice for impetigo in patients two months of age and older. **Committee Recommendations** The committee recommended that mupirocin ointment remain a preferred agent.
➢ Antibiotics, Vaginal	*Paula Townsend, PharmD* *Magellan Health Services*	**Antibiotics, Vaginal** There was no new significant clinical information to share with the committee. It was noted that Clinesse is not available.

		Committee Recommendations The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Antifungals, Oral	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antifungals, Oral</u>** Dr. Townsend announced that Ancobon was now available generically as flucytosine. She also reviewed an FDA announcement from August 2011 that classifies fluconzaole 400-800 mg/day as pregnancy category D. Lower doses are classified as pregnancy category C. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Antifungals, Topical	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antifungals, Topical</u>** Dr. Townsend provided a review of one new product Pedipirox-4, a new kit of ciclopirox solution with alcohol based lacquer remover pads, a nail file and foot powder. **Committee Recommendations** The committee recommended that Nystatin cream/ointment be preferred because of less chemical irritation clinical than other agents. They recommended that the new nail lacquer be non-preferred.
➢ Antiparasitics, Topical	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antiparasitics, Topical</u>** There was no new significant clinical information to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Antivirals, Oral	*Paula Townsend, PharmD* *Magellan Health Services*	**<u>Antivirals, Oral</u>** Dr. Townsend provided a review of two new clinical studies comparing daily famciclovir 250 mg bid with valacyclovir 500 mg daily.

➢ Antivirals, Topical ➢ Other Committee Business	*Paula Townsend, PharmD* *Magellan Health Services*	**Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. They suggested that amantadine be classified as an antiparkinson agent rather than as an antiviral agent for purposes of PDL comparisons. **Antivirals, Topical** There was no new significant clinical information to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. **Other Committee Business** Dr. Eide announced that Dennis Tofteland, RPh and Catherine Hitt Piechowski, PharmD would be leaving the committee as their contract terms are completed . They were thanked for their services. The meeting adjourned at 1:30 p.m.

Pharmacy and Therapeutics Committee
Public Comment
May 11, 2012

Jackie Whitesell, MD

I'm Jackie Whitesell, a neurologist here in Boise, and pretty new to the area, so I probably don't know all of you, but I'm here today. Can you guys hear me okay? Yeah? I'm here on behalf of myself and my MS patients, and I have just prepared a little thing here, so

I'll just read it real fast. I'd like to voice my support for equal and open access to the currently available therapies for MS. These include the injection therapies, which I think you're going to discuss today; Avonex, Rebif, Betaseron and Copaxone, and then the two newer medications, Tysabri and Gilenya. They all effectively reduce relapse rate and prevent neurologic disability. Several trials have indicated that early initiation of the interferon therapies, which are the injection medications, reduce the time to development of clinically definite MS and time to second attack. So, in my practice, I allow patients to select which medication they would like to be on based on the injection schedule and the side effect profile, and I think that's really beneficial in patient compliance, as patients are going to need to be on these medications for long periods of time, so it's always good if they are compliant with their medications. Uh, let's see, so the other important thing about having different medication options is that some of the injection therapies work in different manners, so if one is ineffective for a patient, it's always helpful to be able to switch to another one. The two new medications: Tysabri has actually revolutionized the treatment of refractory MS and gives us a great tool for treating patients who don't respond to the other medications. Gilenya, which is the most recent, also known as fingolimod, is the only oral approved medication for MS. It's been out for about a year and that also has been shown to be effective to reduce relapse rate in MRI activity. So, in summary, I would just like to express my support of maintaining open and equal access to all of the currently available medications for MS, and I know that several other neurologists in the community have also written letters supporting open and equal access, so I would just ask that you consider that. Thanks for your attention.

Committee Question:
Have you used Gilenya on any of your patients?

Jackie Whitesell, MD
I have a few on it. I don't use it as first line, but if patients have failed the injection therapies, that's when I think about Tysabri or Gilenya.

Committee Question:
Can I ask a question about the use of these medications? Is there much of a difference between the different interferon beta-1a's and -1b's, the actual, I mean I know there's a difference between 1a and 1b, but the actual products that are 1a or 1b?

Jackie Whitesell, MD
Well, there are different injection schedules, so one is every other day, and one is once a week. Avonex is the once-a-week medication and Rebif and Betaseron are every other day, so sometimes taking shots is a big thing for patients, so if they can choose once a week, that's important for them.

Committee Question:

But in terms of side effect profile or efficacy, they are expected to be the same?

Jackie Whitesell, MD
Similar. The Rebif and Betaseron are more high-dose medications, so they tend to have, sometimes, a little bit more in the way of side effects, but they are probably also maybe a little bit more effective, so.

Committee
Thank you.

Cheryl Bloom
Hi. My name's Cheryl Bloom and I'm one of those patients that has MS. I would like to thank you today for the opportunity to speak before you. I am a patient in the practice with Dr. Whitesell, I'm a patient of her partner's, Dr. River, and I was diagnosed with MS twelve years ago. I am an advocate for open and equal access to all of the medications. I have been on all of them, and I have not had success with all of them. My problem is that in order to get to where I need to be, I have had to suffer through the formularies that the insurance companies require us to go through, and have had to suffer through all the adverse side effects of all of them, because of the formularies that the insurance companies require us to go through, which is not fair, because I don't feel that we should have to be a guinea pig to the formularies, so open and equal access is something that we should have access to. We should not be forced to take drugs that we should not have to take. Thank you.

Caleb Simpson
Yes, I'm Caleb Simpson. I'm a licensed health insurance agent here in the state of Idaho. I own my own insurance agency. I've been in the insurance world since 2000, but that's not why I'm here today. Like my friend Cheryl, I was diagnosed with MS years ago. I went through several medications before finding a medication that helped me out, in fact I graduated high school, I was a star athlete, the captain of a couple of teams: Indiana basketball, go Hoosiers! Nine months later, I was diagnosed with MS. Nine years later, I was in a wheelchair with MS, but look at me now. That's because I finally found medications that helped me. Right now, I do happen to be on that pill, the Gilenya pill. I experienced great success with a couple of other medications, but had to eventually switch to the Gilenya because of risk pools of side effects. It's a weird, weird world, and I know the frustrations of how the formularies are. Yeah, I'm an insurance agent, but I didn't make those rules, and I just try to help people navigate their way through, and I want to say "Thank you" to the Idaho Medicaid. I have a lot of patients who are on Idaho Medicaid and so far, they haven't had to put up with step therapy requirements outside of whatever insurance thing they're on on the side. I beg you to continue the same thing. Open access. Let the patients and their doctors decide which medication they should be going on. That's really all I had to say. Thanks again for everything and making it possible for people to overcome disabilities and sometimes get out of their wheelchairs by finding a medication that works for them. Thanks.