Rachel Strutton

Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: May 20, 2011 **Time:** 9:00 a.m. – 2:30 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, M.D.-Chair; Perry Brown, M.D.; William Woodhouse, M.D.; Dennis Tofteland, RPh; John Mahan, M.D.; Catherine Hitt-Piechowski, PharmD; Mark Johnston, RPh; Elaine Ladd, PharmD; Tami Eide, PharmD; Mark Turner, M.D.
Others Present: Steve Liles, PharmD; Mark England PharmD, Jane Gennrich, PharmD; Cody Scrivner; Rachel Strutton

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call*	Phil Petersen, M.D.	Dr. Petersen completed the roll call and called the meeting to order. He announced Scott Malm's resignation from the Committee and thanked him for his service to the P&T.
➢ *Reading of Mission Statement*	Phil Petersen, M.D.	Dr. Petersen read the Mission Statement.
➢ *Approval of Minutes from April 15, 2011 Meeting*	Phil Petersen, M.D.	There were no corrections. The April 15, 2011 meeting minutes were accepted as proposed.
➢ *Review of Draft Policy on Public Comment Process*	Phil Petersen, M.D.	Dr. Petersen led a discussion on the new Public Testimony Guidelines (see attached). This was provided to the Committee members prior to the meeting and also posted on the public website. He asked the Committee to review and provide comment. The new guidelines were approved with two changes. Dr. Eide's name is to be omitted and replaced with a designated Medicaid representative (currently Tami Eide). The second change is to the last paragraph, which should read "….The concerns should be presented concisely in less that 250 words….for delivery to the P&T Chair" as opposed to the Medicaid Chair as it currently reads. The new policy will be adopted for the October 2011 P&T meeting.

Public Comment Period

Phil Petersen, M.D.
Cody Scrivner

Public Comment Period

Three people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
James Harold M.D.	Self	All	Multiple Sclerosis Drugs
Sharon Cahoon	Self	All	Multiple Sclerosis Drugs
Taryn Magrini	National MS Society	All	Multiple Sclerosis Drugs

Drug Class Reviews and Committee Recommendations

Drug Class Reviews and Committee Recommendations

Analgesics, Narcotic long-acting

Steve Liles, PharmD
Provider Synergies

Analgesics, Narcotic long-acting
Dr. Liles provided a review of one new product (Butrans – transdermal buprenorphine) and a new formulation for OxyContin which is intended to reduce abuse/diversion. Embeda, a non preferred agent, has been removed from the market at this time.

Committee Recommendations
The Committee concluded that there was no new data to support evidence-based differences between the agents. The Committee requested a comprehensive drug utilization review (DUR) for all narcotic analgesics. This is outlined following the section of these minutes on opiate dependence treatments.

Analgesics, Narcotic short-acting

Steve Liles, PharmD
Provider Synergies

Analgesics, Narcotic short-acting
Dr. Liles provided review of three new products: Abstral (fentanyl sublingual), Zolvit (hydrocodone/acetaminophen) and Rybix ODT (tramadol ODT). He also stated that the FDA removed propoxyphene from the market in 2010 due to a low benefit to risk ratio. Three medications in this class have REMS (Risk Evaluation and Mitigation Strategies) required by the FDA – sublingual fentanyl, oxycodone oral solution, and Nucynta (tapentadol). All three of these medications require a Medication Guide to be given to the patient with each prescription filled. Dr. Liles also reviewed a clinical trial of Nucynta vs. immediate release oxycodone. This was a non-inferiority study which showed that Nucyna was non inferior to immediate release oxycodone and did have a lower rate of gastrointestinal side effects.

Committee Recommendations
The Committee concluded that there was no new evidence to support differences in efficacy,

		effectiveness or safety. The Committee recommended restricting narcotic-acetaminophen containing combination products to those that contain 325mg acetaminophen or less. The Committee recommended that implementation include a mailing to prescribers of a list of their patients currently receiving dosage forms with higher amounts of acetaminophen. The cover letter of the mailing should include a date after which these dosage forms will not be covered to allow prescribers to change their patients' drug therapy. The Committee also recommended that medications that are only FDA approved for a specific indication (e.g. sublingual fentanyl is only approved for breakthrough malignant pain) are restricted to that indication.
Opiate Dependence Treatments	Steve Liles, PharmD Provider Synergies	<u>Opiate Dependence Treatments</u> This is the first time that this drug class has been reviewed by the Committee. Dr. Liles provided a review of the two drugs in this class, buprenorphine/naloxone (Suboxone) and buprenorphine (Subutex). He also presented a general overview of medications used as part of opioid dependence treatment. **Committee Recommendations** The Committee expressed concern with the lack of evidence for long term effectiveness of these medications. The Committee agreed with the current prior authorization criteria for Suboxone. They recommended that these patients be re-reviewed every six months and that that reviews should include review of the Board of Pharmacy's Prescription Monitoring Program Reports on controlled substance usage (including paying cash for medications) and urine drug screens. They also recommended limiting the duration and dosing and monitoring those patients discontinuing dependence treatment for future narcotic use.
Committee Recommendation for Drug Utilization Review of Narcotic Analgesics		**Committee Recommendation for Drug Utilization Review of Narcotic Analgesics** The Committee recommended a comprehensive drug utilization review of short and long-acting narcotics. This was based on concern over the misuse/abuse of these agents that is not addressed through the preferred drug list. Components of the proposed review are outlined below. <u>*Patient Profiling*</u> o Number of patients on monthly (chronic) narcotics o Number of different agents used by individual patients o Total (cumulative) monthly doses of all concurrent narcotics o Number of prescribers per patient o Analysis of multiple scripts from multiple providers o Other addictive drugs prescribed concurrently o Diagnosis/indication for narcotic use and data backing that diagnosis o Patients with no relevant diagnosis for medication o Evaluation for evidence of illicit drug use o Relationships of long-acting narcotic use and break through narcotics use (lack of long acting and/or break through narcotics given continuously)

		o Hospital and EM admissions for overdose o Prescription fill history, including early refills. *Provider Profiling* o Prescribing pattern for non-pain clinic prescribers They also suggested utilizing several data sources outside Medicaid including outlier reports from the Board of Pharmacy Prescription Drug Monitoring Program, legal/arrest databases and hospital discharge medication records. Possible policy changes suggested for consideration after collection of the data included o Restriction of prescriptions to prescribers and pharmacies within Idaho state borders o Stricter refill policies (90% rather than current 75% threshold) o Expansion of lock-in program
Skeletal Muscle Relaxants	Steve Liles, PharmD Provider Synergies	Skeletal Muscle Relaxants There was no significant new clinical information to share with the Committee. Dr. Liles reiterated that none of these medications are FDA approved for long-term use. It was noted that our current methods to curb abuse of carisoprodol appeared successful. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class. The Committee requested that the department evaluate switches from carisoprodol to other agents and whether patients were paying cash to circumvent restrictions. They recommended continuing the current therapeutic criteria for carisoprodol.
Antimigraine Agents	Steve Liles, PharmD Provider Synergies	Antimigraine Agents Dr. Liles provided a review of two new products: Alsuma (sumatriptan autoinjector) and Cambia (diclofenac sachet for oral solution). There was no other new clinical data to share with the Committee. **Committee Recommendations** The Committee felt that there were no evidence based differences to support superiority of any of the drugs in this class. The Committee recommended that Cambia be non-preferred. The Committee also recommended that at least one triptan be available in each route (oral, injectable, intranasal). If changes are made to the preferred list, the Committee recommended that current patients are grandfathered to continue their present drug therapy. The Committee also agreed that the current age restriction of ≥ 12 years should be maintained and that use in children less than 12 years be considered with a neurology consult.
Antiemetics/Antivertigo Agents	Steve Liles, PharmD Provider Synergies	Antiemetics/Antivertigo Agents This is the first time that the Antivertigo Agents have been included in this drug class review. Dr. Liles introduced one new product - Zuplenz (ondansetron oral film). This drug was approved by the FDA on the basis of pharmacokinetic data – there were no clinical trials done.

		Committee Recommendations The Committee recommended removing step therapy (i.e. trial and failure of promethazine, metoclopramide or prochlorperazine) to the prior authorization requirement for ondansetron for hyperemesis gravidarum. The Committee recommended that ondansetron be available without prior authorization for one time acute use in all patients for a limited length of therapy. The Committee recommended that metoclopramide be available with no therapeutic criteria. They recommended that Transderm-Scop be preferred. The Committee also recommended adding OTC meclizine (antivertigo agent) to the list of OTC medications that Idaho Medicaid will cover. The Committee recommended that Marinol (dronabinol) continue to be non-preferred.
Ulcerative Colitis Agents	Steve Liles, PharmD Provider Synergies	<u>Ulcerative Colitis Agents</u> There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there were no evidence based differences to support preferring one agent over another in this class. They recommended that Pentasa continue to be a preferred agent based on where it works in the gastrointestinal tract.
Immunosuppressives, Oral	Steve Liles, PharmD Provider Synergies	<u>Immunosuppressives, Oral</u> Dr. Liles provided a review of the new product Zortress (everolimus) which is used after kidney transplants. **Committee Recommendations** The Committee felt that since use of the agents involves speciality practice that drug choice should be deferred to the specialist's discretion.
Multiple Sclerosis Agents	Steve Liles, PharmD Provider Synergies	<u>Multiple Sclerosis Agents</u> Dr. Liles provided a review of two new drugs: dalfampridine (Ampyra) and fingolimod (Gilenya). Gilenya is the first <u>oral</u> immune modifying drug available for MS. Ampyra is only FDA approved to improve walking in patients with MS and is used only as an adjunct to disease modifying agents. **Committee Recommendations** The Committee recommended that Gilenya be preferred. The Committee also recommended that Ampyra be non-preferred with therapeutic criteria, including re-evaluation after 3 months. The Committee concluded that Betaseron and Exactava could be moved to non-preferred but should be grandfathered for current patients.

Antibiotics, inhaled	Steve Liles, PharmD Provider Synergies	Antibiotics, inhaled There was no significant new clinical information to share with the Committee. Dr. Perry Brown shared with the Committee that there are additional inhaled antibiotics currently being investigated – levofloxacin, amikacin, ciprofloxacin, vancomycin, and amphotericin. The only two currently FDA approved are Cayston and TOBI, both of which are approved for use in Cystic Fibrosis. **Committee Recommendations** The Committee recommended leaving both agents as preferred for patients with cystic fibrosis as use of one over the other is dependent on microbiological cultures and sensitivity.
Cephalosporins and Related Agents	Steve Liles, PharmD Provider Synergies	Cephalosporins and Related Agents Dr. Liles provided a review of two new guideline updates: Acute Uncomplicated Cystitis from the Infectious Diseases Society of America (IDSA) and Sexually Transmitted Diseases from the Centers for Disease Control (CDC). He also reviewed the new indications for Amoxicillin/clavulanate XR for children 40kg or heavier who are able to swallow tablets whole. **Committee Recommendations** The Committee recommended that there be at least one agent preferred for each of the three cephalosporin classes. The Committee asked the department to review the current dosage limits for amoxicillin/clavulanic acid as more participants are being prescribed higher dosages due to increasing bacterial resistance in the community. If it is more cost effective to use the extra strength suspension of amoxicillin/clavulanic acid than the XR tablet, it was recommended that a Newsletter article describe this substitution. The Committee also recommended that Cefaclor remain non-preferred for safety reasons.
Fluroquinolones, oral	Steve Liles, PharmD Provider Synergies	Fluroquinolones, oral There was no new clinical data to share with the Committee. Dr. Liles noted that levofloxacin will be available generically later this year. **Committee Recommendations** The Committee recommended Cipro Suspension be switched from non-preferred to preferred status. The Committee requested adding the age criteria to the PA/Class Criteria section of the Preferred Drug List as a courtesy to prescribers.
Macrolides/Ketolides	Steve Liles, PharmD Provider Synergies	Macrolides/Ketolides There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class.

Tetracyclines	Steve Liles, PharmD Provider Synergies	Tetracyclines There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class and requested adding the age criteria to the PA/Class Criteria section of the Preferred Drug List as a courtesy to prescribers.
Antibiotics, Topical	Steve Liles, PharmD Provider Synergies	Antibiotics, Topical Previously, only Impetigo Agents have been discussed. This year, all topical antibiotics were reviewed, including OTC agents. **Committee Recommendations** The Committee concluded that there were no evidence based differences between the agents. The Committee recommended not covering the OTC topical antibiotic agents (they are not currently covered). The Committee also recommended that topical gentamicin ointment be non-preferred.
Antibiotics, Vaginal	Steve Liles, PharmD Provider Synergies	Antibiotics, Vaginal There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class.
Antifungals, Oral	Steve Liles, PharmD Provider Synergies	Antifungals, Oral There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee did not feel that there was evidence to support one agent over another. The Committee recommended terbinafine (oral) be switched to a preferred agent, unless cost is an issue.
Antifungals, Topical	Steve Liles, PharmD Provider Synergies	Antifungals, Topical There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee did not feel that there was evidence to support differences in efficacy , effectiveness or safety between the agents. The Committee recommended that antifungal/steroid combination agents be made non preferred agents and that prescribers use the separate components. Letters should be sent to current prescribers of these agents. The Committee also recommended that the combination products be restricted to patients $\geq$ 2 years old.

Antiparasitics, Topical	Steve Liles, PharmD Provider Synergies	Antiparasitics, Topical Dr. Liles provided a review of the updated American Academy of Pediatrics (AAP)2010 guidelines for head lice. Lindane is no longer recommended under these updated guidelines. **Committee Recommendations** The Committee recommended adding PA criteria of failure of all other preferred agents before Lindane would be approved.
Antivirals, Oral	Steve Liles, PharmD Provider Synergies	Antivirals, Oral Dr. Liles reviewed a double blind RCT on famciclovir vs valacyclovir for recurrent genital herpes. There was no other new clinical information for review. Based on no seasonal variation in the number of prescriptions for amantadine, it is presumed that this drug is being used for Parkinson's Disease not influenza. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class.
Antivirals, Topical	Steve Liles, PharmD Provider Synergies	Antivirals, Topical Dr. Liles provided a review of one new product - Xerese (Acyclovir/hydrocortisone). **Committee Recommendations** The Committee recommended that Abreva, which is available OTC, no longer be covered by Idaho Medicaid. The Committee recommended prior authorization criteria to discourage use of topical agents as the data supports oral antivirals over topical antivirals for efficacy. It was suggested that Skye Blue and Tom Rand infectious disease physicians be consulted on use. This topic will be re-discussed at the October meeting.
Effient (prasugral)	Steve Liles, PharmD Provider Synergies	Effient This medication was discussed at the April 2011 meeting but the clinical data was not reviewed at the time. Dr. Liles presented information on the efficacy which showed a decreased incidence of cerebrovascular events in patients with ACS (acute coronary syndrome) but an increased incidence of bleeding.

Pharmacy and Therapeutics Committee
Public Comment
May 20, 2011

James Harrold M.D.
Hello my name is Dr. Harrold and 5% of patients with MS have relapsing/remitting multiple sclerosis, and there are currently several medications available that all have been proven efficacious in reducing the relapse rates, and I'm just going to briefly go through the breakdown of how I generally describe these medications to patients:

The platform therapies that have been available for about ten years include interferon therapies, such as Avonex, Rebif and betaseron, and many patients have issues with compliance with all of the medications, so it's important to have each of these available because side effects are unpredictable, and if patients are not on these therapies, they can pretty much expect progressive worsening of neurological disability. So there are considered high-dose and low-dose interferon therapy: Avonex is an injectable intramuscular once a week, Rebif is subcutaneous three times a week, and betaseron is subcutaneous every other day. Some patients choose their therapy just simply based on how often they have to do it. Some patients just want it once a week and they will choose Avonex. Some are deathly afraid of an IM injection, so they won't choose Avonex and they will choose a subcutaneous injection with Rebif or betaseron or Copaxone. So back to high-dose/low-dose: Avonex is considered low-dose, and Rebif and betaseron are both considered high-dose interferon, and it is still debated if there is a substantial difference between high- and low-dose in terms of efficacy, but I think those medications all need to be on the formulary. If there is an exception, I would probably choose betaseron because there is up to a 20% incidence of developing neutralizing antibodies, which essentially render that drug ineffective, as well as all the interferons becoming ineffective, so once they develop neutralizing antibodies, you can't put a patient from betaseron to Rebif or Avonex. That whole group is excluded. Copaxone is important, because the interferons may cause flu-like side effects and may not be tolerated. Copaxone is a subcutaneous injection daily. It does not have flu-like side effects, but patients sometimes complain of injection site reactions, but they are completely different modes of action, and some patients won't respond to one class, and they will respond to the other. Then, for more aggressive patients, there is intravenous Tysabri, which is a once-a-month infusion. The initial four drugs that I mentioned have about a 30% reduction in relapse reduction, and Tysabri is probably more in the range of 60% reduction of relapses. Then, finally, there is a new oral medication called Gilenya and there are more oral therapies probably going to be FDA approved within the next couple of years. All of these drugs have different mechanisms of action, and it is really important for patients to have choices, because they don't all respond equally and they don't all tolerate these medications, and in this day and age where we have these therapies available, I think it's important to allow our patients access to these various medications, because it can be a very difficult to manage disease, and can lead to a lot of permanent medical disabilities. That's essentially all I have to say, but I am more than happy to answer questions.

Committee Question
I have a question. You said they should all be preferred, except maybe betaseron, you said. We have a letter from another neurologist, who basically says the same thing: They should all be preferred, and then he says, but maybe not betaseron. Is that enough of an issue of the neutralizing antibodies, is that enough of an issue that we should maybe move that to the other column?

James Harrold M.D.
Yeah, I mean I'm not here to say "Don't", but if you maybe choose one drug in the MS therapies to not be on the formulary, that would be it. The issue with neutralizing antibodies is essentially your body will produce a neutralizing antibody that nullifies the effect of interferon drugs, and the incidence, you know you can quote different statistics, but betaseron clearly has the highest incidence of neutralizing antibodies, upwards of 20%. Once the patient has been on betaseron and develops neutralizing antibodies, it renders the drug essentially ineffective and then you cannot simply switch then to Avonex or Rebif, because they're interferons, and it's kind of a class effect. So once you've thrown out three main drugs in MS therapy, all of the interferons, you're essentially left with Copaxone and some of these other therapies. So yeah, I think I guess, I don't know who wrote the letter, but it's interesting that betaseron is a more popular drug sort of on the East coast and West coast it's less popular, but that would be the reasoning, because of the neutralizing antibodies.

Committee Question
At any, I don't know, I don't know how much basic data you have access to, long-term data on oral...

James Harrold, M.D.
With Gilenya, what's the long-term..?

Committee Question
Yeah, do we have anywhere, any long-term data? In MS, it's always the long-term that we have the huge problems with us ending up pretty well disabled and in the nursing home.

James Harrold, M.D.
I believe most of the MS therapies, the clinical trials are set up to last essentially two years, and I think that's a good window at how the patients are going to do over the course of two years, but it's a lifelong disease, so sometimes you can't establish whether they're going to alter long-term disability, but no, I think Gilenya's probably had a 1-2-year study and shown efficacy of roughly 50% reduction in relapses, and I believe it did show reduction in disability. But it depends on which patients are enrolled and how aggressive their disease is. I think just by common sense, if you're reducing the number of relapses by 30-50-80%, that, long haul, you're going to have less disability. Disability is kind of hard to establish, because it's so based on gait, and if you have MS that involves your spinal cord, it's going to have a different course than if it involves your brain, and we just don't really have good measures to follow cognitive decline. Some of these drugs help with slowing the cognitive impairment, so when you look at
"Disability", it's mostly based on ambulation, it's based on EDSS score that's too heavily weighted on gait, so that's one of the problems with just looking at disability. It's more gait related and less looking at cognition, which is probably the Number 1 reason that patients file for disability, is cognitive, not because they can't walk. So I think it's going to get more and more complicated for neurologists. We have a hard time establishing which therapy's the best and comparing studies, and I think it's a case-by-case. If we find a drug that the patient's compliant with and works, then we'd like to keep them on it. We'd like to have access to putting patients on whatever therapy seems to be effective for them.

Committee Question
I have two questions. I am a general pediatrician and don't treat MS, but this information would be helpful. The first is, if we were to remove, and I'm not saying we will, but if we were to remove betaseron which is an interferon beta 1b, would it be important to have Extavia be preferred, and the second question I have is, right now, the only non-preferred ones are Ampyra, Extavia, and Gilenya, however you say it. The way that we have it set up is, that if you failed any of the preferred ones, you can have access to the non-preferred after just, you know, not doing well on the preferred. Is there any reason to have those, that they would absolutely consider using them first line?

James Harrold, M.D.
So, one comment, Ampyra doesn't belong on that list. Ampyra is a drug that works on potassium channels, on neurons, and improves gait. It has nothing to do with immunomodulatory therapy. It does not reduce relapse reduction. It's a symptomatic therapy. It's like giving somebody Ditropan for their bladder, so I'm not sure that Ampyra is classified with immunomodulatory therapies, but yeah, I'm not really sure how Medicaid has the first-line therapies set up. You're essentially saying that, the way it's set up, is that if you fail one of the first-line therapies, that you then have access to Extavia and Ampyra?

Committee Response
Yes, and Gilenya.

James Harrold, M.D.

I personally don't think, I think Gilenya needs to be a first-line therapy. As you probably caught on, when you come in and I tell you that you have MS, and I tell you there are several drugs available. How do you like needles? How would you like to learn to inject yourself? Let's have a nurse come out and show you and your spouse how to do injections for the rest of your life. And then they heard there's a pill. Just common human nature is "Sign me up for the pill" and so in regards to compliance, I think of Gilenya or there's going to be a couple more oral medications available and, granted, they don't have ten years' of data, but I have patients who will not go on therapy because they won't do injections and we want to send them to psychiatry to get over a needle phobia, but I think, I guess I would disagree with putting Gilenya on a second-tier therapy. I don't know that people need to fail Avonex or Copaxone or what have you before they have access to that drug. It is new, and we do have some reservations about it, but MS can be a serious disease, and if it's a matter of getting a patient access to a therapy that they will be compliant with, then I think, I don't know, I think it needs to be there. I believe Humana insurance will not approve Gilenya under any circumstances. I mean, they just haven't bought into it, but it has two-year data and we think it's going to be a good drug. I mean, any new drug out is only going to have a couple years' worth of data, so it will play itself out, but if it's a matter of getting patients compliant with something, I think it should be first-line.

Committee Question
Do you have any concerns about the safety with the medication?

James Harrold, M.D.
I think, yeah, all of these, I mean MS is a serious disease and these drugs may have serious side effects, but I think everybody got scared with Tysabri and PML, it's a brain infection, with reactivation of a JC virus. For patients on Tysabri, there's a risk of getting a brain infection which may be lethal, and Tysabri came out for several months, it got pulled from the market because of that unknown complication, and then it got restudied and brought back before the FDA and approved, and so everybody's gun shy about MS therapy. We don't have any reason to think that patients on Gilenya are going to get PML or have these side effects. There's a small risk of developing macular edema, like one in four thousand, and also the first dose, there's also a chance of bradycardia, but Gilenya's been pretty, so far, pretty safe, and I don't know. All I can tell you is that the FDA thought it was safe enough to put out on the market. There's no reassurance with any of these drugs when they first come out, that they're not going to have some hidden side effect that develops after five years on the market. Again, I would just ask you, if you come in and I tell you that you have MS, some people just really are reluctant to do injectable therapy, and the interferons do have flu-like side effects. I don't know how well people like having the flu every day. Copaxone, you have to do an injection every day and you get injection site reactions, where you have little bee stings all over your body. Some of these therapies are not, you know, people just take their licks with these medications, but sometimes they're not well tolerated, and the oral Gilenya's at least an option. So I think it could be considered as a first line, but as long as it's accessible, I guess after failing the first-line, I think that's a decision the Committee needs to make.

Committee Question
One more question, actually, Gilenya and Ampyra are in the non-preferred column because they have not been reviewed, so there has not been a decision made. Ampyra is not an immune modulating medication, but it's new to us, and I would like your thoughts on it since you're here?

James Harrold, M.D.
So Ampyra is a medication, as I said, that is kind of called "The Walking Drug", and it enhances nerve function by working on potassium channels. It's given 10 mg twice a day and the study was essentially measuring patients on and off the drug, walking I believe it was 30 feet, and it showed enhanced ability to walk. It just makes nerves function better, but it does nothing in terms of the long-term course of the disease, and essentially 50%, you know in the clinical studies, 50% of the patients responded to it. So when I prescribe it, I tell the patients "You've got a 50/50 chance of this improving your MS symptoms with walking, maybe tolerability of heat, maybe energy level", and I just frankly tell them, "If it doesn't work, we can't keep you on it for the rest of your life" and just let them decide how well they respond to the drug. These people don't want to take tons of drugs. They're already on several drugs, so I don't, I think it's worth having access to that medication, as long as it's not prescribed to everybody, and hopefully the physicians that prescribe it do tell their patients that it's only effective in 50%, so that if it's.

Committee Response
Well in review of the studies, I wasn't impressed, but are you impressed with it in your patients?

James Harrold, M.D.
I've had some patients that do feel like, for instance, like if they have significant leg weakness and they have difficulty transferring from a wheelchair, that and just standing for longer periods of time for taking a shower or those sorts of things, sometimes it will make that much of a difference that transferring from A to B is improved, and I have some patients that clearly feel like it's helpful in their daily life, and I think that's a better measure than having them walk down the hallway for 30 feet. But I think, I don't know, 50/50 is a reasonable estimate in the number of patients that respond to it. I'd probably say, in my experience, more like 30% have come back with a real, resounding, positive experience from it. I know it's very expensive, so if I were an MS patient, I would rather spend my money on an immunomodulating therapy that works as opposed to Ampyra. Ampyra, in my opinion, is kind of icing on the cake, and it's a case-by-case whether somebody is going to respond to it. Again, it's how we want to spend our health care dollar, and it depends on how expensive that is. It's not a wonder drug. It's, you know, they call it a "Walking Drug". It improves gait and everything, and for some patients it is successful, but hopefully I think that physicians have to not keep everybody on it when it doesn't work, and just say "when", because it can be over-utilized. You can put every patient on that.

Committee Response
Any other questions? Thank you. Okay, that concluded the medical practitioner category, now private citizen? Sharon?

Sharon Cahoon
So just for clarification, I work for a company that makes MS drugs, but I also have a couple of family members that have MS, so the question was who am I representing? So because I guess the comments weren't submitted on time, I won't speak on behalf of the company that I work for, but I will speak on behalf of patients, and I will echo what Dr. Harrold indicated, and that is that MS is a very bad disease. It affects young women in the prime of their lives. You know, a typical patient is a Caucasian female in her late 30s, and they want to know "Am I going to be in a wheelchair?" and "When am I going to be in a wheelchair?" and "Am I going to be able to play with my kids and dance at my kids' weddings?" and it's a scary disease, and I think that compliance and tolerability of the medications is important, because the patients need to be on therapy. They need it. The long-term data clearly shows that there is an impact on the disability as these patients age. Again, I work for one of the companies, but personally I would advocate that you allow patients to have the medication that they and their physician feel is most appropriate to allow them to treat this disease and hopefully prevent the progression of disability. Thanks.
Taryn Magrini
Hi, good morning. Thank you for allowing me the opportunity to speak. My name is Taryn Magrini, I'm the manager of Advocacy & Community Outreach for the National MS Society, in the Utah/Southern Idaho Chapter out at the Boise office. In a region where the prevalence of MS is estimated to be one in three hundred people, our chapter is the most dependable resource for program services, education, information and support to the roughly 4,000 people living with MS in Idaho and the nearly 30,000 family members and friends who love them. I have our disease management consensus statement, which I didn't submit on time. Am I still allowed to give that to you? No?

Committee Response
No, just your testimony, thank you.

Taryn Magrini
Alright, fair enough. Access to disease-modifying therapy for people with MS is one of the highest priorities for the National MS Society. This access should be equitable to all disease-modifying therapies, as the available agents differ significantly and are not interchangeable. There is variation in dosage, route of administration, tolerability and side effects. Any one therapy cannot be a replacement for the other. The Society believes that patient and physician together must determine the most efficacious course of treatment. Knowing that the symptoms vary greatly among the people affected by MS, and that an individual will have a unique reaction to any of the treatments, the Society strongly believes that all seven of the FDA-approved agents should be included in formularies and covered by third-party payers. The Society estimates that 5-10% of people with MS are on Medicaid. These people deserve to have all the options available to them to increase their chances of finding one that will help them live the fullest life possible. For their sake, please consider implementing open and equal access to all MS treatments by including all FDA-approved disease-modifying therapies for MS on the Medicaid Preferred Drug list. Thank you.

Committee Response
Actually, the reason that we don't let you do handouts is that we feel very strongly that The Committee needs to have time to read those before.

Taryn Magrini
Yes. Next year, I will be on top of that.

Committee Response
Thank you.

Taryn Magrini
Alright, thank you.

Committee
That's all our testimony? Okay.