Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: May 19, 2017

Time: 9:00 a.m. – 3:30 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, MD-Chair; Tami Eide, PharmD; Christopher Streeter, MD; Paul Driver, PharmD; Perry Brown, Jr., MD; Stephen Carlson, PharmD; Cali Bradberry, PA; Brian Crownover, MD; Ryan Heyborne, MD; Berk Fraser, R.Ph., Board of Pharmacy (for Alex Adams).

Committee Members Absent: Andrei Rudyi, PharmD

Others Present: Sarah Martinez, PharmD, Magellan Health Services; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Clay Lord, Division of Medicaid; Keshia Schneider, Division of Medicaid; Mark England, PharmD, Magellan Medicaid Administration.

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	*Phil Petersen, MD*	Dr. Petersen called the meeting to order.
Committee Business ➢ *Roll Call*	*Phil Petersen, MD*	Dr. Petersen completed the roll call and welcomed the P&T Committee members.
➢ *Reading of Mission and Confidentiality Statements*	*Phil Petersen, MD*	Dr. Petersen read the Mission and Confidentiality Statements.
➢ *Approval of Minutes from April 21, 2017 Meeting*	*Phil Petersen, MD*	The April 21, 2017 minutes were reviewed and accepted.
Idaho Opioid Equivalent Dosing Project	*Mark England, PharmD., Magellan Medicaid Administration*	**Idaho Opioid Equivalent Dosing Project** Dr. England provided a summary of the measures in place to manage opioid utilization, including quantity limits on all drugs and PA on specific drug classes. Idaho Medicaid will be adopting the recommended CDC Opioid Guideline goal of not more than 90 morphine milligram equivalents (MME) per day. The CMS MME standard will be

		used as the standard for the adjudication rules and for staff calculations. Initially the 90 MME limit will apply to new prescriptions. Participants currently exceeding the 90 MME dosage will be grandfathered for a period of one year while the prescribers are contacted and encouraged to taper the patient's dosage. Dr. England also summarized the various software and reporting tools to be used by Idaho Medicaid for monitoring and tracking purposes.
Public Comment Period	*Phil Petersen, MD* *Keshia Schneider*	**Public Comment Period** No pharmaceutical industry attendees were pre-approved to provide testimony. Larry Green, MD provided testimony related to his practice, which is primarily providing treatment to multiple sclerosis patients. A transcript of his testimony and Q&A appears on the last two pages of these minutes.
Drug Class Reviews and Committee Recommendations	*Sarah Martinez, PharmD* *Magellan Health Services*	**Drug Class Reviews and Committee Recommendations** Committee members were asked to base their recommendations for each drug class on the answers to the following questions: 1. Is there comparative evidence to support clinically significant differences in efficacy or effectiveness between agents? If yes, what are the differences? 2. Is there comparative evidence to support clinically significant differences in safety between agents? If yes, what are the differences? 3. Are there any agents that the committee feels strongly must be preferred or non-preferred? 4. Are there any recommendations for changes to PA requirements?
➢ *Hypoglycemics, Metformins*	*Sarah Martinez, PharmD*	**Hypoglycemics, Metformins** There were no new agents in this class to report. Dr. Martinez reviewed the 2017 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches which is largely unchanged from the 2016 edition. She also reviewed the 2017 American College of Physicians recommendations for type 2 diabetes oral treatment which now lists metformin as first line. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended against preferring fixed dose combinations of metformin with other agents.
➢ *Hypoglycemics, Incretin Mimetics/Enhancers*	*Sarah Martinez, PharmD*	**Hypoglycemics, Incretin Mimetics/Enhancers** Dr. Martinez reviewed several new drugs for this class.

		Xultophy (insulin degludec/liraglutide) is a fixed dose combination incretin mimetic with a long-acting insulin. Dr. Martinez reviewed three 26-week trials including 1,393 patients with type 2 diabetes mellitus who had been receiving liraglutide, any basal insulin, or insulin glargine. All three studies saw improvements with hemoglobin A1c (HbA1c) values and percent of patients achieving a HbA1c < 7%. The studies with liraglutide or insulin degludec as comparators showed a greater decrease in fasting plasma glucose levels and the study with insulin glargine as the comparator showed similar mean changes in fasting plasma glucose. . Adlyxin (lixisenatide) is a new incretin mimetic indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Dr. Martinez reviewed dosing, contraindications, adverse effects and drug interactions. She reviewed the GetGoal-X open-label, non-inferiority study and the ELIXA randomized, multicenter, double-blind, placebo-controlled trial designed to assess the effects of lixisenatide on cardiovascular morbidity and mortality in patients who had already experienced an event. Soliqua (insulin glargine/lixisenatide) is a fixed dose combination incretin mimetic with a long-acting insulin. Dr. Martinez reviewed the efficacy studies for this combination. **Product/Guideline Updates** Dr. Martinez reported that Nesina, Kazano, and Oseni are now available generically. She reviewed FDA updates to the warnings and precautions sections of products containing saxagliptin and alogliptin regarding the increased risk of heart failure, which may be higher in the presence of existing heart or kidney disease. She also reported that the 2017 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches now places greater emphasis on the use of Victoza due to LEADER trial results. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. If cost-effective they would like to see a once weekly incretin mimetic and a combination agent preferred.
➢ *Hypoglycemics, Insulin*	*Sarah Martinez, PharmD*	**Hypoglycemics, Insulin** Dr. Martinez reported on Basaglar (insulin glargine) as the first insulin product approved through an abbreviated approval pathway under a 505(b)(2). FDA regards it as a "follow-on" agent to Lantus rather than a biosimilar.

		Dr. Martinez reported that the 2017 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches is largely unchanged from the 2016 edition. She also reported that Tresiba (insulin degludec) is now indicated for treatment of patients one year and older (previously indicated only in adults). **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Hypoglycemics, SGLT2*	*Sarah Martinez, PharmD*	**Hypoglycemics, SGLT2** Dr. Martinez reported on one new agent in this class, Invokamet XR (canagliflozin/metformin). It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes who are not adequately controlled on a regimen containing Invokana or metformin or in patients already taking both. **Product and Guideline Updates** • Jardiance (empagliflozin) is now indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes and cardiovascular disease. The 2017 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches place greater emphasis on the use of Jardiance due to its outcomes trial results. • Invokamet (canagliflozin/metformin) is now indicated for first-line use in patients for whom use of metformin and Invokana is appropriate initial therapy (previously indicated for patients inadequately controlled with one of the components). • The FDA has strengthened the existing warnings for products containing Invokana and Farxiga (dapagliflozin) regarding acute kidney failure. • The FDA announced that based on two large clinical trials, use of canagliflozin carries higher risk of foot and leg amputations in diabetic patients. Product warnings to this effect are imminent. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended that the criteria for these drugs be changed to require a failure of metformin specifically before a SGLT2 would be approved.
➢ *Hypoglycemics, TZD*	*Sarah Martinez, PharmD*	**Hypoglycemics, TZD**

		There are no new agents in this class. **Product Updates** • The 2017 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches is largely unchanged from the 2016 edition. • The 2017 American College of Physicians recommendations for type 2 diabetes oral treatment list metformin as first line, with TZDs among the second line options. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Platelet Aggregation Inhibitors*	*Sarah Martinez, PharmD*	**<u>Platelet Aggregation Inhibitors</u>** Dr. Martinez discussed a new agent in this class, Yosprala (aspirin/omeprazole). It is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk for developing aspirin-associated gastric ulcers. She discussed dosing, administration, contraindications and warnings for use. **Guideline Updates** Dr. Martinez discussed the 2016 ACC/AHA guidelines for the treatment of peripheral artery disease which recommend the use of aspirin and clopidogrel for the reduction of cardiovascular events in patients with symptomatic peripheral artery disease. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They specifically did no see a reason to prefer Yosprala. They recommended that although dipyridamole had no advantages, listing it as preferred indicated endorsement over other agents and the Department should consider listing it as non-preferred.
➢ *Hereditary Angioedema Agents*	*Sarah Martinez, PharmD*	**<u>Hereditary Angioedema Agents</u>** Dr. Martinez reported that the U.S. Hereditary Angioedema (HAE) Association Medical Advisory board and leaders of the HAE Patient's Association developed HAE pediatric recommendations, including treatment of attacks and prophylaxis. The consensus recommendation recognized that pdC1-INH is currently the only agent FDA-approved to treat all pediatric ages. Therefore, pdC1-INH 20 U/kg is the preferred treatment of choice for short-term prophylaxis prior to medical, surgical or dental procedures. The consensus

		recommendations also indicated that pdC1-INH is appropriate for long-term prophylaxis in the pediatric population. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended at least one preferred agent for prophylaxis and one for acute treatment. They recommended that a link be provided to the Guidelines in the PDL and on the PA form.
➢ *Antivirals, Oral*	*Sarah Martinez, PharmD*	**Antivirals, Oral – Antiherpetic and Anti-influenza** Dr. Martinez reported that brand name Famvir production has been discontinued by the manufacturer and that Tamiflu is now available generically. Generic famciclovir is still available. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Antivirals, Topical*	*Sarah Martinez, PharmD*	**Antivirals, Topical** Dr. Martinez reported that there were no significant product or clinical updates for this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended all remain non-preferred as oral therapy is preferred and more effective.
➢ *Antibiotics, Inhaled*	*Sarah Martinez, PharmD*	**Antibiotics, Inhaled** Dr. Martinez reviewed the Cystic Fibrosis (CF) Foundation guidelines for cystic fibrosis which include both nebulized tobramycin and aztreonam as recommended prophylaxis for *Pseudomonas aeruginosa*. They also recommend alternate-month administration of both tobramycin and aztreonam in patients persistently infected with *P. aeruginosa*. This recommendation is a grade B recommendation which translates to high certainty that net benefit is moderate or moderate certainty that net benefit is substantial. The Cystic Fibrosis Foundation also published guidelines regarding the diagnosis of CF, recommending that diagnoses associated with CFTR mutations in all individuals be established by CFTR function evaluation and sweat chloride test.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. It was stated that Tobi Podhaler may have advantages in adherence as administration time is shorter and should be considered if economically feasible. They recommended that at least one form of both inhaled tobramycin and aztreonam be preferred.
➢ *Antibiotics, Topical*	*Sarah Martinez, PharmD*	**Antibiotics, Topical** Dr. Martinez reported that there is no new clinical information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended that gentamicin be available for gram negative infections.
➢ *Antibiotics, Vaginal*	*Sarah Martinez, PharmD*	**Antibiotics, Vaginal** Dr. Martinez reported that there is no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Cephalosporins and Related Agents*	*Sarah Martinez, PharmD*	**Cephalosporins and Related Agents** Dr. Martinez reported that Ceftin (Cefuroxime) and Cefzil (Cefprozil) are no longer indicated for the treatment of secondary bacterial infection of acute bronchitis (the FDA no longer grants this indication). **Committee Recommendations** The committee concluded that there were no significant differences in efficacy with these agents as long as there was good representation for the variety of infections. They maintain that cefaclor remain non-preferred for safety reasons.
➢ *Fluoroquinolones, Oral*	*Sarah Martinez, PharmD*	**Fluoroquinolones, Oral** Dr. Martinez reported that the FDA has advised that the serious side effects associated with fluoroquinolones generally outweighs the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. She also reported that updated WHO guidelines for the treatment of chlamydia, gonorrhea, and syphilis no longer recommend fluoroquinolone use. She stated that the risk for

		attempted and completed suicide has been added to warnings and precaution section of the Levaquin package insert. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety among the agents. The committee recommended a follow-up DUR of pediatric use to evaluate whether utilization has gone up in pediatric patients since the removal of the age restrictions.
➢ *Macrolides*	*Sarah Martinez, PharmD*	**Macrolides** Dr. Martinez reported that E.E.S. 200 suspension is now available generically. **Committee Recommendations** The committee concluded that erythromycin had disadvantages of more gastrointestinal adverse effects and the need for more frequent daily dosing, but in general the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Tetracyclines*	*Sarah Martinez, PharmD*	**Tetracyclines** Dr. Martinez reported that there is no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. There was some discussion around antibiotic stewardship using the DUR board for education and monitoring and possible use of quality measure such as HEDIS.
➢ *Antibiotics, GI*	*Sarah Martinez, PharmD*	**Antibiotics, GI** Dr. Martinez reported that there is no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended adding injectable vancomycin to be compounded into an oral solution as a preferred option. They recommended keeping the current Xifaxan criteria, but adding failure of other agents to the criteria for Dificid.
➢ *Antifungals, Oral*	*Sarah Martinez, PharmD*	**Antifungals, Oral** Dr. Martinez reported no new products and no recent information of significance in this

		class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness between the agents. They recommended that oral ketoconazole remain non-preferred consistent with the FDA safety communication. They recommended that at least one griseofulvin product be available as preferred.
➢ *Antifungals, Topical*	*Sarah Martinez, PharmD*	**Antifungals, Topical** Dr. Martinez reported that Naftin (naftifine) cream is now indicated for treatment of tinea corporis in patients two years and older (previously 12 years and older). **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Antiparasitics, Topical*	*Sarah Martinez, PharmD*	**Antiparasitics, Topical** Dr. Martinez reported that Lycelle is now available without a prescription and that production of lindane lotion has been discontinued by the manufacturer. It is still available as a shampoo. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Immunosuppressants, Oral*	*Sarah Martinez, PharmD*	**Immunosuppressants, Oral** Dr. Martinez reported that there were no new products and no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Multiple Sclerosis Agents*	*Sarah Martinez, PharmD*	**Multiple Sclerosis Agents** Dr. Martinez reported one new injectable agent in this class, Zinbryta (daclizumab). Zinbryta is indicated for the treatment of adults with relapsing forms of multiple sclerosis, generally reserved for patients with inadequate response to two or more other multiple sclerosis drugs. Contraindications include pre-existing hepatic disease or impairment or history of autoimmune hepatitis or autoimmune condition involving the liver. She reviewed warnings

		for adverse effects and drug interactions as well as clinical studies. There is a boxed warning for hepatic injury and other immune-mediated disorders. Zinbryta is given subcutaneously once a month, and is available as a 150 mg prefilled syringe. Dr. Martinez also reviewed information concerning Tysabri (natalizumab). This agent is not new, but has been added into the multiple sclerosis class for completeness. She reported that Ocrevus was just recently approved by the FDA and will not be reviewed by the committee until next year. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Antimigraine Agents, Triptans*	*Sarah Martinez, PharmD*	**Antimigraine Agents, Triptans** Dr. Martinez reviewed the new injectable product, Zembrace SymTouch (sumatriptan) and the new nasal product, Onzetra Xsail (sumatriptan). **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Analgesics, Narcotic long-acting*	*Sarah Martinez, PharmD*	**Analgesics, Narcotic long-acting** Dr. Martinez reported one new product in this class, Xtampza ER (oxycodone). She reviewed the indications, contraindications, adverse effects and drug interactions associated with this agent as well as dosing parameters. She described the abuse deterrent mechanism in this formulation. Dr. Martinez reported that a black box warning will be added to labels of all products containing opioids and benzodiazepines stating that concomitant use of opioids and benzodiazepines has resulted in serious adverse effects, including respiratory depression and death. She reported on updates to the American Society of Interventional Pain Physicians (ASIPP) opioid prescribing guidelines for management of chronic, non-cancer pain. Methadone is recommended only after failure of another opioid; long-acting opioids should be avoided during initiation; and long-acting or high dose opioids should only be used in special circumstances.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended continuing prior authorization of all agents and gave input on the PA form. They recommended keeping methadone as non-preferred and not adding additional agents to the preferred list. They did not see advantages to formulations with abuse deterrents for decreasing abuse. They recommended next steps after current activities be to decrease duration of all opioids and eliminate use of long-acting formulations.
➢ *Analgesics, Narcotic short-acting*	*Sarah Martinez, PharmD*	**Analgesics, Narcotic short-acting** Dr. Martinez reported the following product updates: • A black boxed warning will be added to labels of all products containing opioids and benzodiazepines stating that concomitant use of opioids and benzodiazepines has resulted in serious adverse effects, including respiratory depression and death. • The FDA issued a Safety Communication restricting the use of codeine and tramadol medications in children due to the increased risk of slowed or difficult breathing and death in patients less than 12 years of age. Single-ingredient codeine and all tramadol-containing products are approved for adults only. Contraindications regarding the use of codeine for pain/cough and tramadol for pain in patients less than 12 years of age, and tramadol for the treatment of pain after tonsillectomy or adenoidectomy in patients less than 18 years of age have been added to product labeling. **Committee Recommendations** It was noted that Idaho Medicaid has already instituted prior authorization requirements for all codeine and tramadol containing products for patients less than 18 years old and that was commended and endorsed by the committee. The committee felt that there were significant safety issues with codeine and codeine combinations and that those agents should be non-preferred. They recommended hydromorphone tablets be non-preferred due to patterns of diversion and misuse.
➢ *Opiate Dependence*	*Sarah Martinez, PharmD*	**Opiate Dependence** The only new product in this class is Probuphine, a buprenorphine implant. Dr. Martinez reviewed indications, warnings, clinical comparison studies, adverse effects and drug interactions. She also reported that Zubsolv (buprenorphine/naloxone) is now available at a lower dose, 0.7 mg/0.18 mg.

		Dr. Martinez reviewed a recent position paper publication from the American College of Physicians (ACP) on prevention and treatment of substance use disorders involving illicit and prescription drugs. Key pharmacologic recommendations include expansion of access to naloxone, expansion of access to medication-assisted treatment for opioid use disorders, establishment of a national prescription drug monitoring program (PDMP), and use of evidence-based guidelines for pain management. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended continuing to follow the SAMHSA guidelines and not pay for buprenorphine without naloxone except for pregnant women.
➢ *Skeletal Muscle Relaxants*	*Sarah Martinez, PharmD*	**Skeletal Muscle Relaxants** Dr. Martinez reviewed the updated guidance from the American College of Physicians (ACP) which recommends nonpharmacological therapy (e.g., heat, massage) as first line treatment of acute/subacute low back pain lasting 12 weeks or less. NSAIDs or skeletal muscle relaxants may be used, but acetaminophen is no longer recommended. For chronic pain, first-line therapy is also nonpharmacological. NSAIDs may be added if needed, then tramadol or duloxetine. Opioids should only be considered if prior therapy fails and potential benefits outweigh risks. **Committee Recommendations** The committee recommended cariosprodol remain non-preferred. It was suggested that tizanidine be restricted to spasticity in spinal cord injury patients due to hypotensive effects. The committee felt that time limits should be imposed on the medications used for muscle spasms based on approval studies and the package inserts.
➢ *Antiemetics/Antivertigo Agents*	*Sarah Martinez, PharmD*	**Antiemetics/Antivertigo Agents** Dr. Martinez reported that Emend is now available as a powder packet. In addition, Emend is now available generically. Zofran solution (brand) has been discontinued by the manufacturer. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Cystic Fibrosis, Oral*	*Sarah Martinez, PharmD*	**Cystic Fibrosis, Oral**

		Dr. Martinez reported that Orkambi is now approved for use in patients six years of age and older (previous indication was 12 years of age and older). **Committee Recommendations** The committee concluded that both agents should be listed as preferred, but continue with prior authorization based on Department guidelines for use.
Other Committee Business	*Tami Eide, PharmD*	**Other Committee Business** The meeting adjourned at 2:47 p.m. Next meeting will be on October 20, 2017.

Pharmacy and Therapeutics Committee Meeting
Public Comment

Larry Green, MD

My name is Larry Green. I'm a neurologist, I've been practicing for 39 years, and I'm still practicing. The majority of my practice has to do with multiple sclerosis, and that's why I'm here. I'm not being compensated for this presentation, but as far as disclaimer, I do speak for a number of drug companies. I consider myself an educator of patients and an educator of my peers. Out of my practice, I have around 400 MS patients. I'm the guy that my colleagues refer to when a patient has serious disease and needs active treatment. So, my purpose today is to give you sort of a Cliff's Notes of the up-to-date management of this disease, and not just isolated individual drugs.

What I'm advocating for is open access. That probably produces some financial panic among the Committee, but I'll explain to you exactly why. When I go into my office and I go into an exam room, and I have a patient in a wheelchair with 15 years treated by just an injectable therapy, but has continued to progress, that is just outright wrong. We know that one in three patients, no matter what you start them on, will fail, and so you need to be able to switch, and we'll talk in a minute about switch therapy, I know I have a limited amount of time… We also know that there is a specific phenotype of characteristics that patients present with in their early phase before they get their diagnosis, that will predict a level of disability over time, if you're in that failure group. So, what we advocate is switching therapy, but we need to look at all the different drug therapies. We know you can't pick just one drug in each class, because they all have different mechanisms of action, and if that mechanism of action seems to hit the mark in some patients, and when you hit that mark, what happens is their MRI scans stabilize, their physical progression stabilizes, and in my world—I do a lot of cognitive work—their cognition improves. Sometimes, early on, when this is done, those patients will gain some function. The bottom line is they remain employable, and they remain taxpayers.

However, many of these drugs have different side-effect characteristics, tolerability characteristics, and we have to throw in the co-morbidity that these patients carry along with them. Switch therapy is what we do; the algorithms for switch therapy are very complicated, and you'll see no manuals on how to switch. It's individualized, and each provider has his own ideas and perhaps his own biases about what drug to use in each individual patient. This is a highly unpredictable disease, and the only way we know whether a patient may or may not respond is to have the access to put them on those therapies.

Once you do this, you reach a state we call NEDA, which stands for no evidence of disease activity. It's not a cure, it's sort of a new buzzword for perhaps remission. I like to think of it more as control. The most important thing is that these people tolerate, and they become employable and remain that way. So as opposed to my patient that I refer to, that's in my office, that's now 15 years in a wheelchair, the discussion is very brutal, because they ask me about these new infusional therapies, and they hear about people getting up out of their chairs, and they walk again. And I have to tell them, I'm sorry, but because of your management, you're going to be where you are, and these new therapies are not going to be

helpful for you. Seat belts don't work after the accident.

So, what I'm advocating is open access. That doesn't mean carte blanche to spend whatever we need, but an appropriate, organized system of managing these patients by using switch therapy, incorporating a whole series of complicated factors to get patients so that they reach this NEDA state.

I appreciate your time, and I'll entertain any questions.

Dr. Brown, P&T Committee: In terms of the way that you and other physicians approach MS, so the way it's set up now, basically I'm just wondering if there is ever a situation in which the first drugs you would use for a new diagnosis who hasn't been treated before would be anything other than Interferon Beta-1b or Copaxone.

Dr. Green: Absolutely. When I talked about the phenotypic characteristics, that's quite lengthy, it has to do with the relapses they've had, the interval between relapses, whether they recover completely from relapse, what their disease burden is on their MRI scan when they first present. There's also demographic things; it's more common in females than males, but a male often has a tendency to be very aggressive, particularly if you're an older male at onset, an older black male at onset, and I see some of my colleagues that have this idea that injectable therapy is always the way you start. And ladies and gentlemen, I'll tell you what you're determined to have is that individual in a wheelchair if you do such.

So, I will frequently start with an oral therapy, and when patients come in with what we call a very hot disease, which I had just recently, I will start with infusional therapy. Because by the time they reach even a walker, or a cane, these more aggressive therapies are not very helpful. If you went in to your oncologist and you have cancer, and you said, well, I'm going to start you with this kind of okay drug, and you fail, well, let's start you with a little stronger drug, and you fail, and then finally you get around to using a very effective therapy, it's too late. And I use that same model of discussion when I talk to patients.