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**MS Learn Online**  
**Special Feature Presentation**  
**Ampyra: A New Medication to Improve Walking**  
**Patricia K. Coyle, MD**

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>>**Kate Milliken:** Hi, I'm Kate Milliken with a special MS Learn Online Presentation. The FDA has recently approved its first symptomatic therapy for walking. The new drug Ampyra, formerly known as Fampridine-SR, has been approved to treat mobility issues, a major symptom of MS. To learn about this new treatment, I sat down with Dr. Patricia Coyle, the Director of the MS Comprehensive Care Center here at SUNY Stony Brook.

>>**Dr. Coyle:** Well, Ampyra is a sustained release form of a chemical called 4-aminopyridine, or 4-AP, that's actually been used in MS for several decades. It turns out that when you partially demyelinate nerves, if you block the potassium channels, which are little pits or pores on the nerve surface, you can actually temporarily improve nerve conduction, and that is believed to be the basis for the temporary symptomatic improvements that Ampyra can give.

It's very important to realize that Ampyra is not an MS disease-modifying therapy. It doesn't prevent damage from the MS disease process, it doesn't change the course of the disease. This is really a symptom management. When Ampyra is in your system, the symptom may be better, and once it is out of your system, the patient is going to be back to square one. It's really not a disease-modifying agent.

>>**Kate Milliken:** Can you describe the clinical trial findings for Ampyra, both the benefits for mobility and the possible side effects?

>>**Dr. Coyle:** Sure. Well, there were actually two Phase III trials with Ampyra that entered MS patients who had problems with the 25-foot timed walk. They did it much slower than normal. And these patients were randomized to Ampyra or

placebo. And it turns out that in the Ampyra treated group, in 35% and 43%, respectively, in the two trials, they had a significant speed up in their ability to walk 25-feet. This compared to only 8% to 9% in the placebo arms. And this was viewed as a real benefit for those that had this ambulation speed up and walking response.

Now, Ampyra was basically very well tolerated. There was a very low dropout rate due to side effects. But one did see things like headache and back pain, difficulty with sleeping, nausea and dizziness, increase in urinary tract infections, and even increase in falls in some of the patients who were taking Ampyra.

>>**Kate Milliken:** How is Ampyra administered and how often does one have to take it?

>>**Dr. Coyle:** So, Ampyra comes in a 10 mg tablet, and that amount is taken twice a day. You are spacing it out around 12 hours.

>>**Kate Milliken:** There are a lot of different reasons that someone with MS may be having mobility issues: it could be numbness, it could be spasticity, it could be partial paralysis. Is there a particular person that Ampyra might work better for?

>>**Dr. Coyle:** Well, you're right, there really are a number of things that can interfere with the ability to walk, and often there is a combination. It turns out there really wasn't any predictable factor as to who would respond to Ampyra. And they entered all comers. The only issue was that they couldn't walk in a normal time frame. So, I think it is fair to say that it would be okay to try Ampyra in anybody that had a significant gait/ambulation problem in MS with the expectation that they might have improvement.

There was perhaps a little bit of a hint where it was suggested in the second Phase III trial that muscle strength in the legs was improving. So, perhaps that patient might be particularly helped. But there really weren't any valid predicting factors. So, it is probably okay to try it in anybody that has gait as a special issue with their MS.

>>**Kate Milliken:** Are there patients that Ampyra may not be good for?

>>**Dr. Coyle:** There are really two cases where you would not want to use Ampyra. One is if you have had seizures. That is probably the most feared side effect and the whole basis for trying to develop a sustained release form. That's a

very rare side effect if the level of Ampyra gets too high in the blood. So, if you have had prior seizures you probably don't want to use this.

The second is kidney damage. If the kidneys are not working properly, they're not filtering the blood, then you may get a higher than normal level of Ampyra, and that could lead to increased risk for seizures. So, in the MS patient that has preexisting kidney disease, it really shouldn't be used.

For the older MS individual, where their kidney function is not clear, it may be that their doctor will have to do a formal creatinine clearance, to make sure that their kidneys are working properly.

>>**Kate Milliken:** Will Ampyra be prescribed for people with progressive MS?

>>**Dr. Coyle:** Well, the good news is, Ampyra worked for all forms of MS. There was no limitation, relapsing and all of the progressive forms. So, yes, it can certainly be prescribed for progressive MS.

>>**Kate Milliken:** Can Ampyra be taken along with a disease-modifying therapy?

>>**Dr. Coyle:** That's a very good question and absolutely. The use of the disease-modifying therapies, a good proportion, many of the patients in the trials were on disease-modifying therapies and it didn't seem to interfere with the benefit at all.

Ampyra is not a replacement for disease-modifying therapy. You are using it to treat a symptom, so you certainly would never want to stop your disease-modifying therapy or consider Ampyra a switch for that.

>>**Kate Milliken:** Now that Ampyra is approved, when do you think it will be available?

>>**Dr. Coyle:** Well, Ampyra will be on the market in March of 2010, and this has been a very interesting journey, because it's almost a 20-year development of the sustained release form of the chemical 4-AP. So, it is very exciting that it comes to market in March of 2010.

>>**Kate Milliken:** Personally and professionally, how does it feel for you to be able to prescribe this new drug to your patients?

>>**Dr. Coyle:** Well, I think what's exciting about Ampyra is that this is the first approved treatment for the MS symptom of ambulation/walking difficulty. And it is always exciting to be involved with a first in MS. I think this is a sign of the advances that we are making in MS as we are understanding it better and treating all phases of the disease. Improving our disease-modifying therapies, but also improving our treatment of symptoms of MS. So, from that point of view it is very exciting and I think it's just a hint of what is going to be coming up in the future as well.

>>**Kate Milliken:** As with any treatment, be sure to consult your physician to determine whether Ampyra is right for you. We'd like to thank Dr. Patricia Coyle for speaking with us today. If you'd like more information on Ampyra please contact the National Multiple Sclerosis Society. For MS Learn Online I'm Kate Milliken, thanks for watching.