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# Oxybates: 1 Molecule, 3 Formulations – Efficacy

**Announcer:**
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**Dr. Thorpy:**
This is CME on ReachMD, and I'm Dr. Michael Thorpy. Here with me today is Dr. Clete Kushida.

There have been now 3 forms of oxybate that have been approved for the treatment of narcolepsy. There was a recently approved medication, which is a once-nightly formulation.

Clete, can you give us an overview of the clinical trial data regarding the efficacy of the 3 oxybate formulations?

**Dr. Kushida:**
Yes. Thank you, Michael. So first I'll talk about Xyrem, and for Xyrem, there's been a number of double-blind, placebo-controlled, multicenter, parallel-group trials, as well as some randomized withdrawal trials, and they have looked at endpoints such as frequency of cataplexy attacks and both subjective and objective daytime sleepiness. And for all those endpoints, there has been statistically significant improvement for those measures.

The next formulation that I'm going to be talking about is Xywav, which is the low-sodium formulation of sodium oxybate. And for that, there's also been a few trials. Most recently is a placebo-controlled, double-blind, randomized withdrawal study in 134 adults with narcolepsy with cataplexy that was published in 2021 by Bogan. And what that study showed was that there was efficacy of this low-sodium oxybate preparation for the frequency of cataplexy attacks as well as excessive daytime sleepiness by the Epworth Sleepiness Scale.

Now lastly, I want to be talking about Lumryz, which is the once-nightly formulation, and for that particular study there's been most recently a study of 212 patients that were randomized to receive Lumryz versus placebo, and it was studied in a double-blind, randomized, placebo-controlled, two-arm, multicenter study to assess both the efficacy and safety of Lumryz. And there were 3 co-primary endpoints. One was the objective Maintenance of Wakefulness Test, second was Clinical Global Impression Improvement measure, and the last was the mean change in weekly cataplexy attacks. And across all those primary endpoints there was a significant improvement compared to placebo in all those measures.

**Dr. Thorpy:**
Thank you, Clete, for that overview. So we have these 3 formulations of oxybate that can be used for narcolepsy, and as you have indicated, they are efficacious for not only the excessive daytime sleepiness but also the cataplexy, and the overall patient impression is very high with regards to these agents. In addition to their treating cataplexy and sleepiness, we also know that the oxybate tends to improve nighttime sleep, as these agents are generally given at night. And typically, they've been given in twice-nightly doses, but now with this new Lumryz, as you mentioned, it's a once-nightly formulation. So that holds some advantages for some patients, that they only need to take the medication when they go to bed and not in the middle of the night.

Well, this has been a great bite-sized discussion. Unfortunately, our time is up. Thanks for listening.

**Announcer:**
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