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## Evolving Treatment Paradigms in Idiopathic Hypersomnia

### Announcer:

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### Dr. Davis:

Hi, my name is Matt Davis. I am a Sleep Specialist and Neurologist. I'm in solo private practice in New Jersey. We're going to be talking about Evolving Treatment Paradigms in Idiopathic Hypersomnia.

Important point here whenever discussing idiopathic hypersomnia is that there are unique challenges in treating, not to mention diagnosing idiopathic hypersomnia as compared to narcolepsy. There's many fewer FDA approved medications, so our therapies really rely largely on off-label uses of wake-promoting agents. Prior to the approval of low-sodium oxybate recently, that was the exclusive way we were able to treat this was with off-label uses of some of these stimulant agents.

Of course, the other challenge here is that the non-pharmacologic measures that we often will recommend for narcolepsy really may not be as effective in patients with idiopathic hypersomnia because of some of the differences and substantive real quality differences in what this disorder is versus narcolepsy. So, for example, people with idiopathic hypersomnia are very prone to sleep inertia and long sleep time. And so short naps that we often recommend in narcolepsy, really may not be as effective in patients with idiopathic hypersomnia. But of course, it is very important as part of a treatment protocol to recommend to patients maintaining structure to their sleep schedule, having adequate total sleep time generally, regular exercise, these should all be part of the treatment paradigm.

The goals of treatment are another important point to make here that the Epworth score is the real go-to measure of sleepiness, which is of course important. But people with idiopathic hypersomnia have some different qualities to their disorder that the Epworth may not take into account. So, we always want to look at big picture; not just how sleepy are you, but how is your quality of life affected? What are you not able to do because of your sleepiness? Are you able to participate in life the way you want to? And that can be a measure of diagnosis, but also a measure of how treatment is going. Do we need to escalate? And how much improvement are we making? Then of course, treatment like any conditions should be chosen based on comorbid medical conditions and concurrent use of other medications.

So, the AASM, the Academy of Sleep Medicine, in 2021, did come up with some treatment guidelines for idiopathic hypersomnia. This is by no means comprehensive, I just picked out two of the more common medications that we use. So, the mainstay of treatment largely are these wake-promoting agents and stimulants prior to the approval of low-sodium oxybate. So, modafinil is a common go-to medication. There's relatively strong evidence for this. There's one randomized controlled trial previously, four observational studies. And we have really extensive real-world experience and evidence across other disorders of sleepiness like narcolepsy. We know the risk and benefit. It is a schedule IV substance because of the risk of abuse potential, but it really is a mainstay of therapy and often something we will try first line. Methylphenidate has somewhat more limited data, the AASM is giving this a conditional recommendation, because the quality of evidence isn't quite as good. But again, we still have extensive real-world experience using methylphenidate for other disorders of sleepiness and, of course, other CNS disorders generally. Slightly higher abuse potential, so it is scheduled as schedule II. But again, it's often used as an off-label therapy for idiopathic hypersomnia.

So, in 2021, the FDA did approve lower-sodium oxybate for adult patients with idiopathic hypersomnia. Initially, this was approved for narcolepsy and then it was subsequently approved for idiopathic hypersomnia. This was based on very strong placebo-controlled, double-blind, randomized-withdrawal trials. It showed efficacy in multiple endpoints in the Epworth Scale, in the Idiopathic Hypersomnia Severity Scale which really gets at some of those other quality of life measures, and the Patient Global Impression of Change. So, this, and interestingly, there was actually also an exploratory endpoint for sleep inertia, showing some improvement there as well specifically.

Lower-sodium oxybate does have a boxed warning, as does all oxybate therapies for CNS depression, risk of abuse and misuse, so it must be prescribed through a specialized safety program, which is the REMS program, but it's very nice now to have strong evidence for an FDA approved therapy for adults with IH.

I hope you found this information useful for your patients with IH. And thank you for your attention.

**Announcer:**

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