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Safety, Efficacy, and Black Box Warnings: Challenges Associated With Off-Label Treatments of AAD

### Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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### Dr. Portsteinsson:

This is CME on ReachMD and I'm Dr. Anton Porteinsson. Joining me today is Dr. Brendan Montano.

Brendan, what are some of the challenges associated with off-label treatments for agitation in Alzheimer's disease?

### Dr. Montano:

Just that they're that, off-label, and some of them unfortunately because of that, have serious adverse events – potential adverse events that are associated with them. For instance, there's a whole black box warning for literally all of the antipsychotics, early ones and later ones, that talk about the risk even of death. And so, for a physician or someone who is working as a provider, to put this type of medication into the treatment algorithm, they're taking a risk when they go off-label. That's why we look for evidence-base of safety. And I think that it's a challenge, a big challenge for us that we have to always instruct not only the patient, but even more important, the caregiver who is responsible for that patient, if we are going to use something off-label that has risk associated with it and there's known serious robust clinical trial experience to support the use of that medication, that would be problematic.

### Dr. Porteinsson:

Yeah. Agitation in Alzheimer's disease, and even related dementias, can be such a critical problem. It can be a near-emergency, and I often see that the people that are trying to provide the care, so providers, they grasp for anything and it's unfortunate because we see a lot of inappropriate prescribing. We see not only medications used that have poor evidence-base, but a lot of well-established side effects, such as some of the antipsychotics. But the same applies for example, mood-stabilizing anticonvulsants or benzodiazepines. These are medications that do not consistently show benefit but have, like I said, a myriad of adverse effects. So, it's important to understand, what is the evidence-base and which medications have shown a positive effectiveness.

### Dr. Montano:

And in Connecticut, we are now undergoing a real dramatic change in the use of cannabis, not only for medical reasons but recreationally, and cannabis is not without risk and has unfortunately, a lot of interactions in enzyme systems as well and can have drug-drug interactions. And so, we are challenged with a lot of loved ones coming and saying, well, I think if I can give him some marijuana in the evening, that will be something helpful.

### Dr. Porteinsson:

It's actually interesting because I saw a patient earlier today where the caregiver did that exactly, and when you have a broken brain, this person had a fairly advanced Alzheimer's disease, the psychedelic impact of THC was quite dramatic for them and they got very,

very distressed. So, you have to be cautious.

Right now, there's only one medication that is FDA approved for the treatment of agitation in Alzheimer's disease and that is brexpiprazole. Multiple other drugs are often used off-label, such as the atypical antipsychotics, in some instances the conventional antipsychotics, and various antidepressants as well. It's critical to understand what's the data supporting these medications, what's the data that informs us about the adverse events, and the fact from a medical legal perspective, that when a medication is available and is approved, you need to make patients aware of it and they may decide along with you to choose a different treatment, but they need to know about that.

Again, this has been a great, but brief discussion. I hope we gave you something to think about, and thanks for tuning in.

**Announcer:**

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