Transcript Details

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Focus on the New Menopause Management Horizon: Improving Outcomes Through Managed Care

Announcer:
Welcome to CME on ReachMD. This activity, entitled "Focus on the New Menopause Management Horizon: Improving Outcomes Through Managed Care" is provided by Omnia Education.

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Dr. Dunn:
Hello. We just wrapped up an exciting satellite symposium here at AMCP in exciting but cold and wet Chicago, where we presented the latest data on the impact of menopause and cutting-edge information on evolving treatment and management strategies. Now we'd like to break down some of that information for you.

This is CME on ReachMD. My name is Dr. Jeff Dunn.

Dr. Owens:
And I'm Dr. Gary Owens.

Dr. Nelson:
And I'm Dr. Anita Nelson.

Dr. Dunn:
Dr. Owens, we'll start with you. Can you get us started by telling us about the important health economics and outcomes research on menopause?

Dr. Owens:
First of all, women go through menopause at age 50, plus or minus a couple of years, in general. And, you know, they're productive members of the workforce during that time. And there was a good study that showed that, on average, for each woman with symptoms of menopause, that their employers lost about $700 per year in productive time. And, well, $700 is not a big number. When you multiply that times the number of women in the workforce in that age, and the fact that every year there are about 1.3 million new women who start menopause and then the fact that that can last for years, it's a very big number. So when you do the math, it's significant. I think the other thing, and the other point I want to make on the economics, is women in menopause have a lot of other comorbid conditions: cardiovascular disease, hypertension, osteoporosis, diabetes, metabolic syndrome, obesity. And if you look at the cost of that cohort of women with these comorbidities, it's about $18 billion per year, so a significant cost both on the societal side in the workplace and on medical and societal in those comorbid patients. You have a lot of decreasing quality of life, easy fatiguability, poor sleep patterns, hot flashes themselves, maybe depression. All of those things go into that mix of causing that impact on women's productive years.

Dr. Nelson:
And when you're debilitated or tired or fatigued, then certainly that can play out in all kinds of other things we see, that women who

suffer those also have mood disorders. The loss of estrogen can affect libido. Women are smart. If it hurts to have sex, they're not going to want to have sex. Other things: you're not the sharpest little crayon in the box if you haven't had a good night's sleep. So I think there are a lot of things that can be attributed to those very profound changes that women have in sex hormones in their menopausal years.

Dr. Owens:
So, Dr. Nelson, what can you highlight to us as the most important aspects of that pathophysiology?

Dr. Nelson:
You stop and think, how many thousands and thousands of years did women have hot flashes and they had no idea what was going on, right? It was labeled as that that's time of year, you know, go to a room, maybe she'll sort out. And then to realize today that we've got a little bit of an inkling. We understand that it's a loss of the estrogen.

When her follicles run out, she loses estrogen. And what happens in the brain is that that little zone of thermoregulatory, we call it, that every day we have little fluctuations in our temperature. And we tolerate that pretty well, but if you reduce that range in which she can fluctuate, then she's going to have excursions outside that and become symptomatic. Now, add to that not only the little fluctuations, but next door to that zone in the hypothalamus is that trigger that tries to scream at the ovary to make more estrogen and can't. So it's screaming louder and louder, and it's impacting and making it worse. So that GnRH pulse generator there is affecting the thermoregulatory zone, and it's now narrowed because she has estrogen, and these women become very symptomatic.

And that insight that this existed gave us clues. How is it that estrogen is working? It turns out estrogen broadens that so that she can bounce around, and she can get hit by a GnRH pulse and maybe be able to sustain it. And the SSRIs [selective serotonin reuptake inhibitors] also broaden that, so we now have a little bit more understanding – not complete, but this gave us a target.

Other things that we've learned about is what is kicking the GnRH off is this KNDy [kisspeptin/neurokinin B/dynorphin] – I love that term, don't you? – neurokinin, right, all of those issues. They're the guys kicking the GnRH pulse and making it trigger this whole cascade. And now we have a new target, that maybe we don't have to give hormones or other things that play with this, but maybe if we shut down that trigger for the GnRH pulse generator, that we may be able to alleviate the symptoms. And I also think of other things that we can use them for, yes? When you don't want to have estrogen, with endometriosis, there's just a lot of other applications that we have a new trigger and the insight into how this whole system works. Pretty cool.

Dr. Owens:
Wow. Fascinating, and from a payer's perspective, really the treatment of menopausal symptoms has really not been something in the forefront. It's a generic marketplace; it's mostly about estrogens. We don't even know, for things like the SSRIs, when women are being treated for menopausal symptoms because, you know, we don't manage that aspect of it. And, you know, the one thing about a prescription, there's no diagnosis with it, so you often aren't capturing that. So, you know, from a payer's perspective, it's been a very silent area. Fast-forward. If we're going to have new MOAs [mechanisms of action], possibly new targets, you know, suddenly I think we're going to have to educate payers, in addition to clinicians, that times are changing and that it may not be just about these drugs that we've used for the last 30 years, 50 years, even, so that it's going to have to rekindle payer knowledge and interest.

Dr. Nelson:
And we've certainly had a lot more information that has emerged from following those women who were in the WHI [Women's Health Initiative] and gave us a whole new insight into the safety and new appreciation for that. But who's listening? Right? We have to get people out of the ground to start talking about menopause issues.

Dr. Owens:
And as a follow-up to that, you just mentioned the WHI, and Dr. Dunn, you know, talked extensively about that. And, you know, what are your thoughts about the risks and benefits of hormone therapy?

Dr. Dunn:
So there is going to need to be a reeducation of a lot of people in this space, and it's something we should be proactively asking patients about when we're seeing them because it is such an issue.

But the WHI trial, yeah, right. It was published 20 years ago. It did scare a lot of people off, but it was the seminal study in this area. And what we learned from that is that the most common reason that women go and seek treatment is the vasomotor symptoms, right? In that study, there were 3 arms. There was the combination estrogen/progestin. The second arm was estrogen unopposed, and then the third arm was placebo. And we see that the combination therapy is the most effective at reducing the vasomotor symptoms. So, again, what patients care about. But the risks that come with using the combination therapy, specifically the progestin, is that it increases the risk for breast cancer and cardiovascular disease. So the point of that is we do need to involve the patient. We need to ask them what they care about, what their tolerability is for this risk/reward, and we need to weigh the benefits of the efficacy versus the risks and find the right

drug at the right time and at the right dose and for the right duration of time.

Dr. Nelson:
You know, you made a very good point in your talk. And that was that those risks for heart attacks and for breast cancer really depended on the age of the woman and what her underlying issue was. And you pointed out there was no increase in cardiovascular disease if you started the hormones in the first 10 years after menopause. Right? And who's having the hot flashes? Those women. A lot of those issues came from the women we were studying in their 70s starting down. Starting a 70-year-old on hormones, we wouldn't even think of that today. But it did color the rest of the perceptions, I think.

Dr. Dunn:
And to further complicate it, there are some other benefits to these therapies, including prevention of osteoporosis and fractures. It potentially improves sleep and also sexual function. So again, it really is this conundrum of, you know, risk/reward and what our risk tolerability is.

Dr. Owens:
Precisely a time for informed decision-making, and really something we, as payers, have promoted for a while.

Dr. Dunn:
This last question is for you, Dr. Nelson. Can you provide some insight into the latest nonhormonal treatments with a focus on the NK3 receptor antagonist?

Dr. Nelson:
Well, I think that before we get to the newest and best and shiniest new thing, we do want to review that women can do things for themselves, right? They can layer their clothing, they can adjust their bedding, they adjust humidity and temperature. All of those things can be helpful. We can turn to nonhormonal therapies, right? All of those can be very helpful in understanding how to play with the thermoregulatory zone. We can certainly do the estrogen, and we have the new estrogen components with a SERM [selective estrogen receptor modulator] together. But all of that together needs to have a focus on it, and I think what may bring menopause back as a topic for people to talk about is the new insight, and that would be, just as you talked about, the NK3R antagonist, where we're beginning to understand that we don't have to play with hormonal feedback. We don't need to expand this thermoregulatory zone. What we can do is go upstairs and shut off the on button, right, by putting in antagonists to the NK3 receptor. We can shut down the stimulus to the GnRH, which is causing the disruption in the thermoregulatory zone and precipitating that whole cascade. So by not working through the middle man, but going straight to the top, we may have a different mechanism of action. It doesn't rely on hormones, right, and rapidly reversible. If she is stopping having hot flashes, we don't need to have prolonged therapies for it.

So this is a very exciting time when we can look at the whole array of therapies that we have, and having a new option together may get that conversation going that you were saying is so impactful for women, but payers aren't paying attention.

Dr. Dunn:
And your point, it can be a trigger to having these conversations, that we might not have had these conversations before.

I appreciate you being here today and sharing your insights. As we wrap up, I would like to ask each of you if you have one final closing comment. And Dr. Nelson, we'll start with you.

Dr. Nelson:
I think this is just an exciting time to be talking about menopause, because people are talking about it. And maybe women won't sit there and suffer silently.

We are having a lot of women issues that every day, crossing over, becoming symptomatic, and having really severe impacts on their quality of life. And to bring it out and start integrating it into everyday medicine, it is certainly something that we want to talk about, and then one of these "stay tuned" moments for us as we're understanding more and developing newer therapies. I think by itself, that may get people talking about it again.

Dr. Owens:
This has not necessarily been something that payers have had in the forefront. But if you look at some of the economic data that I presented, our customers – the employers who buy most of the commercial coverage – should be interested in more effective management, shouldn't they? If they're losing $700, $1,000 per woman of productivity, that should concern them. And likewise, I think we're going to have to rekindle payer interest in this subject because, again, we're moving into a new era and maybe, you know, a whole new set of ways to approach this, not only with new drugs, but maybe as you say, Dr. Nelson, looking at it holistically. And this really, literally, has not been the topic of conversation of payers in many years.

Dr. Dunn:
That's right. Most of us have probably heard of WHI, but it's been a long time –

Dr. Owens:
Forgot about it.

Dr. Dunn:
– since we actually looked at it. So I think my comment would be I think it's not debatable that there is a huge unmet need in this space in terms of both efficacy and safety. The challenge for payers is going to be just that, again, all of these are over the counter or generic. They're really inexpensive, so as we get new medications that come out that are incrementally better and safer but much more expensive, given the prevalence, how do we manage those things, right? So we're going to have to reeducate ourselves about this, and it really needs to be about the patient and, you know, balancing that risk/reward.

This was a great conversation. I would like to thank the audience for listening to this, and hopefully you found this informative. Thank you.

Dr. Nelson:
Bye.

Dr. Owens:
Thank you.

Announcer:
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