Transcript Details
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Navigating the Prior Authorization Process: Expert Perspective for a Postmenopausal Osteoporosis Therapy

Announcer Introduction:
Welcome to ReachMD.

This medical industry feature, titled "Navigating the Prior Authorization Process: Expert Perspective for a Postmenopausal Osteoporosis Therapy," is sponsored by Radius Health, Incorporated. This program is intended for US physicians.

See the full prescribing information, including Boxed Warning, for TYMLOS, also known as abaloparatide, at www.tymlospi.com.

Here's your host, Dr. John Russell.

Dr. Russell:
Prior authorization is a tool payers use that is designed to ensure that patients with postmenopausal osteoporosis receive appropriate therapies, requiring a physician to get preapproval for prescribing a certain drug in order for the drug to qualify for coverage. But how exactly does this process work? More details on that and how it relates to a therapy for postmenopausal osteoporosis coming up on today's program. This is ReachMD and I'm Dr. John Russell. Joining me today are Dr. Robin Dore, a rheumatologist with over 40 years of practice experience, and Ms. Wendy Simmons, a Physician Assistant specializing in osteoporosis who works within a rheumatology practice. Both are paid consultants for Radius Health. Dr. Dore, Ms. Simmons, welcome to you both.

Dr. Dore:
Thank you very much for having us. We really appreciate it.

Ms. Simmons:
Thank you.

Dr. Russell:
So, Dr. Dore, how often do you work through the process of prior authorization for a specialty pharmacy medication?

Dr. Dore:
I submit about 10 to 12 prior authorizations for specialty products each day and they only get denied about twice a year, and it's really because I've worked hard on trying to get the process down so I don't have to keep on trying over and over again to get it approved.

Dr. Russell:
And Ms. Simmons, what's your experience?

Ms. Simmons:
It feels like I've been on a roll. I would say I am also 99.8% or 99.9% successful. Once you have the experience on a daily basis, you know what's going to come at you. I probably also do about 10 prior authorizations a day, many for postmenopausal osteoporosis medications like TYMLOS.

Dr. Russell:
Before we discuss further, let's take a minute to review some important safety information about TYMLOS.

Announcer:
TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis

therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.[1]

Limitations of Use: Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.[1]

WARNING: RISK OF OSTEOSARCOMA[1]

- **Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.**
- **The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.**
- **Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.**

Dr. Russell:
So, to start us off, Dr. Dore, can you explain why some medications actually need a prior authorization?

Dr. Dore:
I think the main reason is the cost of the medicine, but also sometimes medications are complicated or used to treat rare conditions, and therefore are considered specialty because they require close patient monitoring or special handling. Especially when there's more than one medication available, the prior authorization process, are really in place to ask questions to support the provider's request.

Dr. Russell:
So, as a follow-up to that, Dr. Dore, could you briefly go over the process of submitting a prior authorization and what's your role in the process?

Dr. Dore:
When I'm in the room with the patient, I send a message through my electronic medical records to my medical assistant and she requests a prior authorization form. I use a form from the specialty local pharmacy because they've developed ones specifically for osteoporosis and there are others for the other conditions that I manage. The form is quite similar to the form for TYMLOS as offered by Radius, so you can use ones from the manufacturer as well.

Dr. Russell:
Ms. Simmons, is your process similar?

Ms. Simmons:
My process is similar. I also partner with a specialty pharmacy, to send in that form and submit that as well, and I have a trained medical assistant that helps me.

Dr. Russell:
So, Dr. Dore, what kind of information are they looking for on these forms?

Dr. Dore:
The form gathers information about their osteoporosis such as their BMD T-scores, fracture history, use of prior medications, whether they failed other medications or had side effects from those medications, and then my rationale for requesting that specific therapy.

Dr. Russell:
And Ms. Simmons, based on your experience, do you have any tricks on gathering this type of information from your patients?

Ms. Simmons:
Yes, often it can be difficult to get this information out of the patient. Sometimes I'll ask them questions – did they take prior medications, did they remember anything about the medications, did they tolerate the medications – and their answers, will be prompted and this will help fill in some details.

Dr. Russell:
So, Dr. Dore, you go through the process of filling out this form, send it to the specialty pharmacy, then what happens?

Dr. Dore:

From my experience about 95% of the first requests are denied, but I've learned to expect this, and I tell the patients that this is gonna happen. Often, the same information is asked about, but it needs to be documented either in a different way or on another form. My office will respond with that form using the exact same information and then about 80% of the time that gets approved.

Dr. Russell:
So, if it doesn't get approved, then you file an appeal, correct?

Dr. Dore:
That's correct. A specialty pharmacy might include paperwork that provides a rationale for the rejection, which helps me then focus on specifically addressing that issue.

Dr. Russell:
Now turning to you, Ms. Simmons. Could you share your experience with denials?

Ms. Simmons:
Initially, this was a very frustrating stage. I wondered, "What do I do? How do I overcome this?" But it was actually a great learning experience. I learned from the appeals to see what I needed to start putting down at the outset. I found that the most helpful thing was to be very thorough at the outset of the patient visit and have robust documentation in my notes. At first, I wasn't very good about sending an office note and now I realize that my documentation and sending my office notes can be my biggest support. I really try to build a story and build a case from that office note.

Dr. Russell:
For those just tuning in, this is ReachMD. I'm Dr. John Russell, and here with me today are Dr. Robin Dore and Physician Assistant Wendy Simmons, who are sharing their insights on the prior authorization process for therapies like TYMLOS, which is a treatment option for women with postmenopausal osteoporosis who are at high risk for fracture.

Now, for some more important safety information.

Announcer:
Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.[1]

TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.[1]

Dr. Russell:
So, Ms. Simmons, you've been working with osteoporosis patients for over 20 years. So, beyond the typical elements that are collected for a postmenopausal osteoporosis evaluation, is there anything else you consider?

Ms. Simmons:
I really feel that looking at the patient's risk factors and documenting those, to help support, to get the medication approved. I look at if the patient's petite, do they smoke, do they consume alcohol, have a family history of osteoporosis such as a first degree relative, or have fractures? This helps me assess the fracture risk, specifically using the FRAX score to generate those scores for the patients and be able to attach that FRAX score when I send in the request.[2] I also ask about GI issues, whether they've had lap band procedures, Barrett's esophagus, something that might be a reason why that patient wouldn't be suitable to take an oral bisphosphonate.

Dr. Russell:
So, Dr. Dore, when we do prior authorizations, oftentimes we're educating someone in a field that's not ours about the importance of a medicine for a patient. Are there any tools or information you share to educate people on the other end of the appeals process?

Dr. Dore:
Yes, I frequently provide articles to substantiate my appeals. One I use a lot is a paper by Ethel Siris and colleagues which explains that the clinical diagnosis of osteoporosis can go beyond the T-score definition and actually be based on a fracture history. Clinical practice guidelines may be helpful to support this as well.

Dr. Russell:
So, Ms. Simmons, do you encounter similar barriers when it comes to the clinical diagnosis of osteoporosis?

Ms. Simmons:

Yes, I absolutely do, and I agree with Dr. Dore. The bone densities can be a little tricky if your patient has a T-score better than -2.5, and I still can make the clinical diagnosis of osteoporosis based on their fracture history.

Dr. Russell:
So, coming back to you, Dr. Dore, how do you communicate with your postmenopausal patients at high risk for fracture about the choice of an anabolic medication such as TYMLOS?

Dr. Dore:
I explain that agents with an anabolic effect like TYMLOS build new bone and that anabolic agents are the only ones that are going to build bone, because while antiresorptives slow bone loss, they are not able to build new bone.[3,4]

Dr. Russell:
Let's take a moment for some more important safety information about TYMLOS.

Announcer:
TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

Dr. Russell:
So, Ms. Simmons, in your opinion, does having a conversation with the patient help with the approval process?

Ms. Simmons:
The patient can be a valuable partner in this process. One thing to share with some of our peers is if you're feeling frustrated with the steps that you're taking to get a medication for the patient, talk to the patient and ask them to be part of the process. If they share their experience with, for example, their insurance company, that can help.

Dr. Russell:
And Dr. Dore, how do you prepare them for the process leading up to receiving their prescription?

Dr. Dore:
I tell them to expect a call from the specialty pharmacy and let them know it will come from an 866 or 800 number, hopefully with a name. I receive about one fax every three days from the specialty pharmacies saying that they were unable to reach the patient. Radius actually has a resource that describes the three calls that the patients should expect from a toll-free number: the welcome call, the delivery call, and the refill call. I also make sure that the patients are prepared for the delivery, the storage, and handling of their medications, or if it needs to be refrigerated, I emphasize the refrigerator, not the freezer, that they need to be home at that time, and to inspect the product to make sure if it's supposed to be refrigerated, that it is cool to touch.

Dr. Russell:
Ms. Simmons, anything else to add about preparing your patients?

Ms. Simmons:
Yes, in addition to Dr. Dore's recommendations, with preparing her patients, I also tell them not to hang up when they see that number, show up on their phone. I also remind them to ask about the savings card so that they can get a sense of their out-of-pocket costs early and then also let them know what to expect and educate them early on as I feel that's helpful for them. Longer term, I set a three-month follow-up visit, with me in the office. If by chance the patient is struggling with compliance, then at that time I'm able to capture that and help them get back on therapy.

Dr. Russell:
So, speaking about following up with our patients, it certainly was different pre-COVID as it is in the COVID epidemic so how do you get around these constraints?

Ms. Simmons:
We have had a lot of changes with COVID-19. In North Carolina, telemedicine was not legal at the time that this started. I've found that it's helpful to split up some of the visits with the telemedicine, make it a little bit easier, talking with the patients on a first call, and then arranging for them to be able to have their labs somewhere, and then having another telemedicine visit with an osteoporosis consult to be able to review everything over the phone and make plans for therapy. It's a lot more moving parts but it's definitely manageable and it

can be done. I've realized I've had to find other things in my toolbox to educate my patients. For example, I've been directing them to the tymlos.com website for additional resources after we've decided together that TYMLOS is an appropriate therapy.

Dr. Russell:
Dr. Dore, what are some of the changes that you've noticed?

Dr. Dore:
Patients may need to advocate for themselves throughout this process that we are discussing today, and that can be difficult when they already have other, medical problems. Pre-COVID I would have someone come with them to gather the information and support them, but that's really not an easy option now.

Dr. Russell:
So, sticking with you for another moment, Dr. Dore, has COVID-19 changed the way you think about postmenopausal osteoporosis treatment options for your patients?

Dr. Dore:
Yes, I'm more aware of options of – for patients that they can self-administer at home compared to having to come to the office or go to an infusion center and be around immunocompromised individuals.

Dr. Russell:
So, Ms. Simmons, are you having a similar experience in your practice?

Ms. Simmons:
I am having similar experiences to Dr. Dore in my practice as well. We do have immunocompromised patients that are getting therapy in the office and I also have a share of my people who are not gonna leave their home as well. For my patients that are high risk for fracture, where coming into the office is an extra challenge or not a possibility, this can help support the rationale for a therapy like TYMLOS, and they are able to administer that at home.

Dr. Russell:
So, before we close, we've covered a lot. Ms. Simmons, is there any kinda wrap up thing you'd like to explain to people who aren't as familiar with this process?

Ms. Simmons:
My advice is to remember that the first time is your biggest opportunity. Coming out of the gate, give them a lot of information on the form and be confident and strong. This patient needs this medication and I want them to get this medication.

Dr. Russell:
Boy, that's great advice. Thank you, Ms. Simmons. Dr. Dore, how about you?

Dr. Dore:
Hang in there. You can almost always get the medication for a patient that they need as long as you spend the time. It took me a long time to master this process, but it's so important which is the reason I spent the time to learn how to do it. Drawing from your colleagues' experiences in the area where you practice makes a huge difference and can certainly make things easier for you. You might find something that they found useful and you can make it work for you.

Dr. Russell:
Alright, I want to thank you both for sharing your experiences with us today in navigating the fulfillment pathway for specialty osteoporosis medicine like TYMLOS. Dr. Dore, Ms. Simmons, it was great speaking with you both.

Dr. Dore:
Thank you very much for asking us to discuss this extremely important topic.

Ms. Simmons:
Thank you, I've enjoyed talking with everyone to share this important information, to be able to get our patients the medication that they need to have.

Announcer Close:
This program was sponsored by Radius Health, Incorporated. If you missed any part of this discussion visit ReachMD.com. This is ReachMD. Be part of the knowledge.

References:

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