Transcript Details
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Integrating Telemedicine to Help Diagnose & Manage Severe Eosinophilic Asthma

Announcer Opening:
Welcome to ReachMD. This medical industry feature, titled "Integrating Telemedicine to Help Diagnose and Manage Severe Eosinophilic Asthma" is sponsored by AstraZeneca.

Your host is Dr Matt Birnholz.

Dr Birnholz:
With the ever-changing healthcare environment, clinicians may need different options for seeing and managing their patients. Because of this, telemedicine or telehealth has increased in need.[1] However, asthma specialists may have unique challenges in managing those with severe eosinophilic asthma during these times, which is why today, we'll focus on a biologic therapy that offers both at-home and in-office administration options.

This is ReachMD, and I'm Dr Matt Birnholz. Joining me is Dr Kevin Fussell, Medical Director of Pulmonary Care at Sentara Martha Jefferson in Charlottesville, Virginia.

Dr Fussell, welcome to the program.

Dr Fussell:
Thank you so much for having me.

Dr Birnholz:
So, Dr Fussell, why don't you start by giving us a little background refresher on the impacts of severe eosinophilic asthma?

Dr Fussell:
I'd be happy to. Asthma affects approximately 25 million people in the United States.[2] A total of 5%-10% of patients with asthma are classified as severe and up to 1.3 million of these patients have severe uncontrolled asthma.[3-5] Though this is a small proportion of Americans, severe uncontrolled asthma accounts for approximately 40% of the total costs of asthma care.[4] These patients remain uncontrolled despite correct inhaler technique, adherence to maximal optimized ICS/LABA therapy, use of other controller medications and treatment of contributory factors.[5] About 55% of patients with severe uncontrolled asthma need three or more long-term medications to control their asthma,[6] which is why our goal is to help patients with severe, uncontrolled asthma breathe better and prevent exacerbations.

Dr Birnholz:
So, when we have a patient who we suspect has severe uncontrolled asthma, what should our next steps be?

Dr Fussell:
Well it's important to be able to communicate with your patients. Telemedicine provides us an option to discuss with and manage patient treatment during times like these when a pandemic strikes. While telemedicine does *not* replace an in-office visit, it allows us to communicate with our patients in order to help diagnose and manage the disease. We can also gauge how our patients might be

feeling. Similarly, you can assess medication use such as inhaler technique and medication administration.[7,8]

If you have a patient on ICS/LABA who is still experiencing exacerbations with increasing need for oral steroids or requiring hospitalization, it's this point I begin to suspect severe eosinophilic asthma.[5,9,10] That's a patient you should consider getting a CBC with differential because in a US study, two-thirds of adult patients with severe asthma had eosinophilic asthma.[*,11,12]

** Data from the US CHRONICLE Study, an observational study of subspecialist-treated adults with severe asthma that evaluated 1168 eligible and 659 enrolled patients between February 27, 2018 and December 1, 2018.*
Although not defined by clinical guidelines, for this analysis, eosinophilic asthma was defined as treatment with anti-IL5/IL5R therapy (estimated 28% of eligible patients) or blood eosinophil counts >150 cells/µL in patients not receiving anti-IL5/IL5R therapy (estimated 41% of eligible patients). Estimates for patients not receiving anti-IL5/IL5R therapy were derived from enrolled patients with available blood eosinophil counts (n=213) and projected to the full eligible population.[12]

Dr Birnholz:
And as I understand it, part of the challenge here in trying to diagnose and manage severe uncontrolled asthma is that we're dealing with different phenotypes, including eosinophilic asthma. So, can you provide us more information on eosinophilic asthma?

Dr Fussell:
Eosinophils are one variety of white blood cell, common in the immune system, as we know. For patients with severe asthma, too many eosinophils can be problematic.[9] Eosinophils have been associated with increased asthma severity, exacerbations, and reduced lung function.[10,13,14] Some clinical features of eosinophilic asthma include frequent exacerbations, low lung function, oral corticosteroid responsiveness, and chronic rhinosinusitis with nasal polyps.[9,10]

Dr Birnholz:
So, if we focus on these patients with severe eosinophilic asthma, what treatment options do they have?

Dr Fussell:
For patients who are maximized on their asthma regimen, specifically an ICS/LABA, with two or more exacerbations in the previous year and who have blood eosinophil levels greater than or equal to 150 cells per microliter, †[,5,9,10,15-17] I would consider adding a targeted treatment.[18] FASENRA® (benralizumab) may be an option to consider.[19] FASENRA, or benralizumab, is an anti-eosinophil biologic medication indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years or older, and with an eosinophilic phenotype.[1 9] FASENRA is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.[19] It's given subcutaneously at a recommended dose of 30 milligrams administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter and has both in-office and at-home administration options.[19] FASENRA is the only respiratory biologic with Q8W maintenance dosing.[19]

†Although not defined by clinical guidelines, one characterization of eosinophilic asthma can be a blood eosinophil count of ≥150 cells/µL.[16,17]

Dr Birnholz:
Now as we know, many patients may feel anxious about going into an office during these challenging times—and may not be going in at all. So how can we ensure that our severe eosinophilic asthmatic patients continue on their treatment?

Dr Fussell:
Yeah, this is so important because it's absolutely critical these patients get the care they need in a manner that works best for them. If FASENRA is appropriate for your severe eosinophilic asthma patients, remember, it is the *only* respiratory biologic that combines Q8W dosing with at-home and in-office administration options.[19] This convenient dosing schedule can allow for patients to continue treatment during these challenging times while minimizing exposure in-office. Talk to your patients to see if FASENRA is an appropriate treatment option for them.

Dr Birnholz:
So, given that information, what has the research shown about treating severe eosinophilic asthma?

Dr Fussell:
So in two Phase three clinical trials, called SIROCCO and CALIMA, researchers compared the effect of treatment with FASENRA against placebo on the annual exacerbation rates in patients with severe asthma and elevated blood eosinophil levels. SIROCCO and

CALIMA were randomized, double-blind, placebo-controlled trials, involving a total of 2,510 patients. The primary endpoint was annual exacerbation rates in patients with baseline blood eosinophil levels greater than or equal to 300 cells per microliter, who were taking high-dose ICS/LABAs.[20,21]

The researchers found that in both trials, patients treated with FASENRA plus standard of care had significant reductions in annual exacerbation rates compared with placebo plus standard of care.[20,21] A recent phase 3 trial showed consistent asthma exacerbation rate data in patients with baseline blood eosinophil counts greater than or equal to 150 cells per microliter treated with FASENRA plus standard of care.[22]

As a secondary endpoint, FEV_1 was also improved after the first dose,[23] and this pulmonary function improvement was sustained for the duration of the trials.[20-22] Statistical significance for FEV_1 improvement was established at the end of treatment for the SIROCCO and CALIMA trials.[20,21]

Dr Birnholz:
And can you walk us through the Phase 3 extension trial assessing long-term safety?

Dr Fussell:
Absolutely. Patients from the previously mentioned SIROCCO and CALIMA trials were invited to continue into BORA, a long-term Phase 3 extension study, to assess the safety and tolerability of FASENRA plus standard of care. The length of treatment was an additional 56 weeks for adults. Patients from the original trials were either continued on their FASENRA dosing or, if they were previously taking placebo, were re-randomized to receive FASENRA every four weeks or every eight weeks after the first three doses every four weeks.[24]

Dr Birnholz:
And what were the results of this Phase 3 safety extension trial?

Dr Fussell:
With regards to safety and tolerability, BORA continued to show a similar adverse event profile to SIROCCO and CALIMA. Additionally, in terms of asthma exacerbation data, in patients continuing on the dosing regimen of every 8 weeks and with baseline blood eosinophil levels greater than or equal to 300 cells per microliter, 74% of patients had zero exacerbations during the long-term safety extension trial.[24] The analysis of this endpoint was not multiplicity protected and results are descriptive only.

Dr Birnholz:
That's great. So Dr Fussell, with all of this mind, I'd like to come back to *your* experience and hear how this information impacts your own approach to treating a patient with severe eosinophilic asthma. Do you have a hypothetical case you can share?

Dr Fussell:
I do, let's consider Joseph, who will be our representative patient. He is a 48-year-old African-American male with adult-onset asthma who is currently taking a high-dose ICS/LABA. He's also taking a short-acting $beta_2$-agonist, as needed, for his symptoms. Over the past year he's had two exacerbations, which were treated with oral corticosteroid bursts. Joseph reports that his asthma continues to worsen despite his current treatment regimen. Based on Joseph's still-worsening asthma and history of exacerbations while still using daily ICS/LABA, he has clinical characteristics of severe asthma.

Dr Birnholz:
What is your approach to this patient?

Dr Fussell:
Well a recent US study has shown that approximately two-thirds of adult patients with severe asthma had eosinophilic asthma,[*,12] so I'm putting this phenotype high on my differential to start.

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After Joseph had a telemedicine visit, I had his blood work done and I reviewed his last pulmonary function test, which had been

performed in the previous December, before the pandemic. His forced vital capacity was 60% predicted with a 17% increase after bronchodilator therapy.

Additionally, he had a blood eosinophil count of 182 cells per microliter. This may point toward a diagnosis of severe asthma with an eosinophilic phenotype.†[16,17]

†Although not defined by clinical guidelines, one characterization of eosinophilic asthma can be a blood eosinophil count of ≥150 cells/µL.[16,17]

Once we get to a point where my patients have persistent symptoms, exacerbations, and/or occasional OCS use, it's time to evaluate their current plan and consider additional treatment options. FASENRA is one to consider. It offers proven efficacy in reducing annual asthma exacerbation rates, improvements in lung function, and has a dosing regimen that seems to work well for my patients.[19-22] It's important to note that individual results may vary.

Dr Birnholz:
Well with these important takeaways in mind, I very much want to thank Dr Fussell for joining me to talk about the diagnostic and treatment considerations for severe asthma with an eosinophilic phenotype. I'd also like to share with you important safety information for FASENRA.

Dr Fussell, it was great having you on the program. Thanks so much.

Dr Fussell:
It was my pleasure being here. Thank you so much.

Announcer:
FASENRA® (benralizumab) is contraindicated in patients with a known hypersensitivity to benralizumab or its excipients. Reactions (for example, anaphylaxis, angioedema, urticaria, and rash) have occurred after administration of FASENRA.These generally occur within hours of administration, but can have a delayed onset.[19]
Do not abruptly discontinue corticosteroids. Dose reductions, if appropriate, should be gradual and may be associated with withdrawal symptoms and/or unmask previously controlled conditions.[19]

Treat patients with pre-existing helminth infections before starting FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helminth treatment, discontinue FASENRA until infection resolves. FASENRA is not a rescue medicine. Most common adverse reactions include headache and pharyngitis.[19] Please see the full Prescribing Information including patient information and instructions for use at FASENRAHCP.com for complete details.

You've been listening to ReachMD. This medical industry feature has been sponsored by AstraZeneca. To view the full US prescribing information for FASENRA, visit www.FASENRAHCP.com. This is ReachMD. Be part of the knowledge.

You can read the full Prescribing Information by clicking here.

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