

Severe Asthma Monograph Cases Audio Clips

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CASE 1a

A 9-year old male patient, Johnny, has persistent asthma that is currently uncontrolled despite high dose ICS/LABA (fluticasone propionate/salmeterol 500/50 mcg 1 puff twice daily) and montelukast 5 mg once daily at bedtime.

Johnny was sent to an asthma specialist who wants to order tests to help assess his asthma phenotype. Johnny is terrified of getting any type of lab work done and the provider would like you to help put him and his parents at ease.

CASE QUESTION

How would you best educate Johnny (and his parents) on the use of biomarkers to help assess his asthma phenotype?

PAUSE AND REFLECT: Assess case based on content thus far, then listen to and/or read the faculty commentary.

AUDIO CLIP: Case 1a question answered by the faculty.

TRANSCRIPT

Pharmacist: Hi, thanks for coming in to meet with me today. I'm Sue, the pharmacist. I understand you've got some questions about some upcoming tests your doctor would like you to get. How can I help?"

Parent: Yes, we're concerned about extra testing that may not be needed. Johnny hates getting bloodwork done.

Pharmacist: I totally get it! No one likes to be poked and prodded, right buddy? These tests may be pretty important though for us to better help figure out what medicines to keep you on or start you on for your asthma. Wouldn't it be awesome if you didn't have to use as much Advair! The tests Doctor would like to get are called biomarkers. They are things in our body that we can use to figure out if you have a lot of inflammation, or "swelling" going on.

Several are available with a simple blood draw (like eosinophils, periostin, IgE). I bet if you got a piece of candy and looked away, you'd barely know the nurse was getting any blood from you!

Some are simple breath tests – where you can actually just exhale into a device and we'll try to capture the amount of your breath (FENO) and rarely, we're able to get a sputum sample to check for a tiny cell like (eosinophils) that also tell us if a lot of airway swelling is happening down in your lungs.

Parent: Well, I guess that doesn't sound so bad – but why does he need this?

Pharmacist: The use of biomarker results will help us tailor his therapy and figure out a couple of things; one would be if he's a candidate for an injectable biologic agent which may help his severe asthma and

the other is figure out which one may be best to choose (there are 5 options currently available and they're all pretty similar) Let me review the order – it's likely, he'll only be getting a few of these today; not all 5.

Parents: Okay - point us to the lab and we'll see if we can grab a Snickers bar on the way!

CASE 1b

Johnny, our patient from before, (9-year-old male; 50 kg) is to be initiated on a biologic for his asthma.

His biomarker results are as follows:

Blood IgE: 280 units/ml

Sputum eosinophils: Not obtained

Blood eosinophils: 290 cells/ μ l

Periostin: 45 ng/ml

FeNO: 30 ppb

His parents deny concomitant nasal polyps. Current medications include: fluticasone propionate/salmeterol 500/50 and montelukast.

CASE QUESTION

Which of the following is the most appropriate biologic to initiate for Johnny?

- a. Omalizumab
- b. Reslizumab
- c. Benralizumab
- d. Dupilumab

PAUSE AND REFLECT: Assess case based on content thus far, then listen to and/or read the faculty commentary.

AUDIO CLIP: Case 1b question answered by the faculty.

TRANSCRIPT

The correct answer is a, omalizumab. Given that Johnny is only 9 years old, omalizumab is only one of 2 biologics FDA-approved for use in pediatrics as young as 6 years of age; the other is mepolizumab which isn't a choice.

Also, Johnny's IgE level falls within the dosing range for his weight – and would be 300 mcg every 4 weeks. Similarly, we have reason to believe he will respond to omalizumab as indicated by asthma onset during childhood, blood eosinophils >260 cells/ μ l, and FeNO ≥ 20 ppb.

CASE 1c

How would your selection change if your patient was an **adult**? Harry, a 35-year-old male is to be initiated on a biologic for his asthma due to repeated exacerbations.

His biomarker results are as follows:

Blood IgE: not obtained

Sputum eosinophils: Not obtained

Blood eosinophils: 500 cells/ μ l

Periostin: 45 ng/ml

FeNO: 50 ppb

Medications include: fluticasone propionate/salmeterol 500/50 and montelukast 10 mg, and prednisone 10 mg every other day.

CASE QUESTION

Which of the following is the most appropriate biologic to initiate for Harry?

- a. Omalizumab
- b. Reslizumab
- c. Benralizumab
- d. Dupilumab

PAUSE AND REFLECT: Assess case based on content thus far, then listen to and/or read the faculty commentary.

AUDIO CLIP: Case 1c question answered by the faculty.

TRANSCRIPT

The correct answer is d, dupilumab. Given that Harry is over 18 years of age, any of the biologics are FDA-approved. Further investigating his specific clinical picture is important. He has repeated exacerbations and is on oral corticosteroids. Likely a goal of a biologic would be to reduce exacerbations and hopefully to reduce oral steroid dose or eliminate it all together. This makes dupilumab the best choice. Other rationales for predicting a good response with dupilumab predicting a good response is his high blood eosinophil count and high FeNO.

No IgE was drawn making it impossible to dose omalizumab, and reslizumab and benralizumab could be beneficial; however, data with dupilumab and oral steroid dosing is stronger, making it a better option at this time. These would be potential options in the future.

CASE 2

Sheila is a 22-year-old female with persistent asthma. She has questions for the pharmacist related to how long she'll be on her mepolizumab, which was initiated 2 years ago. She says she doesn't mind giving herself her monthly injection, but is worried that when she switches off her parent's insurance next month that her mepolizumab won't be covered by whatever insurance she'll be able to purchase on the marketplace. She states she has seen a major reduction in exacerbation rates – from 3 per year to none since starting her therapy 2 years ago with mepolizumab – and was able to reduce her Dulera (mometasone/formoterol) from 200/5 1 puff b.i.d. to just mometasone 220 mcg 1 puff b.i.d. and has been able to stop her Spiriva (tiotropium) RespiMat altogether.

CASE QUESTION

How would you educate Sheila regarding the duration of her mepolizumab?

PAUSE AND REFLECT: Assess case based on content thus far, then listen to and/or read the faculty commentary.

AUDIO CLIP: Case 2 question answered by the faculty.

TRANSCRIPT

Pharmacist: Sure, let's talk about your mepolizumab and how long patients typically remain on those types of agents. The good news is that it sounds like you had a really positive response to the drug – no more asthma exacerbations, you got off your tiotropium, and you were able to reduce your ICS/LABA to just ICS which is great! That's the goal – using the biologic to hopefully reduce the dose or eliminate other asthma treatments. Providers generally want to assess how it is going with a biologic after the first 4 months of use, then regularly re-evaluate your therapy once on a biologic every 3-6 months. Since you've been on yours for over a year, and had a positive response, I would say a trial off your mepolizumab at this point would be appropriate.

Sheila: Oh, you think it'll be okay?

Pharmacist. I do; we'll want to make sure we closely monitor you for symptoms and worsening exacerbation rates, but it is really unclear how long patients should remain on these drugs. Now that it has been at least a year, we can trial off of it. Also, other encouraging news is that in one trial where patients were withdrawn from their biologic (in this case omalizumab) the patients still derived benefit for years (4 years in 60% of patients; n=49)

CASE 3

Melissa, an adult patient, calls the pharmacy asking for advice about how to inject her benralizumab which was recently delivered by her specialty pharmacy to her door. Melissa states it has been stored in the refrigerator since she got it and is ready to give herself the shot today.

CASE QUESTIONS

How would you educate Melissa on the benralizumab injection?

PAUSE AND REFLECT: Assess case based on content thus far, then listen to and/or read the faculty commentary.

AUDIO CLIP: Case 3 question answered by the faculty.

TRANSCRIPT

Pharmacist: Sure, we can discuss your Fasena Pen injection. Why don't you get it out and I'll walk you through it.

Melissa: Great – I've got it right here in my purse.

Pharmacist: You're going to want to start by taking the pen out of the refrigerator (which you've done) and let it warm up to room temperature. This will make the injection sting less if it's not cold. While it's

warming up – I recommend you prepare your supplies. Grab some alcohol swabs, maybe a band-aid, and a sharps container if you've got one. Make sure you wash your hands with soap and water. Injection sites are going to be either your lower stomach (but not 2 inches around your belly button) or the front part of your thigh. Generally, you want to find an "inch to pinch" ... this means you're going into the subcutaneous part of your skin.

1. Remove the cap from the pen
2. Line the Fasenra pen up at a 90-degree angle with the injection site. Press down firmly and hold.
3. You will hear a click – this indicates the injection has begun. There is a green plunger – it will start to fill the viewing window. Hold the pen in place for 15 seconds and try not to move the pen at all.
4. You will hear a second click that signals the injection is complete.
5. The green plunger should have the viewing window filled.
6. Lift the pen straight up – the needle guard will slide down and lock into place. If blood is seen, gently apply a little pressure with a cotton ball. Do not rub the injection site. If you need it – use a band-aid.
7. Dispose in a sharps container.

Melissa: Okay – that doesn't sound so hard, kind of like my Mom when she gives herself insulin?

Pharmacist: Yes. It's very similar. Just to make sure I didn't leave anything out, can you repeat back to me how you're going to inject the Fasenra?

Melissa: Sure, I can go back over that for you.