Biologics Webinar FAQ

Introduction to biologics

What is a biologic?

Instead of a “chemical” drug, biologics are made out of proteins produced by living cells. Most are antibodies that mimic how our immune system recognizes viruses and other infections. Early biologics often partially contained non-human proteins, but most now use human-only proteins.

How are biologics different from other treatments?

Biologics are molecularly much larger than chemical drugs and don’t typically interact with them. They can pass through the body like our own antibodies. Since they are made of proteins, stomach acids break them down – as such, they are usually given by home injection or infusion instead of taken by mouth.

Who are biologics for?

There are many uses for biologics for different conditions, so it depends on the condition being treated.

Adalimumab, and most other drugs indicated for HS, have been studied in patients with “moderate-to-severe” HS. However, some biologics aren’t right for everyone – for example, TNF-inhibitors like adalimumab are avoided in patients with heart failure and some other conditions, and IL-17 inhibitors should not be used in patients with history of inflammatory bowel disease.

What is the time to improvement when using a biologic?

Response rates may vary by each particular medication and condition being treated. Time to see improvement may be a quick as two weeks or as long as three-to-six months.

What are the risks vs. benefits of biologics?

Benefits include controlling and preventing the worsening of HS, improving symptoms, preventing the need for surgery and future complications, and side effects that are generally reversible (that is, not permanent). However, risk factors include side effects, administration via an injection, affordability, and the need to consider other existing conditions.

What are some common side effects of biologics?

Though side effects vary with different medications, common side effects include:

- Injection site reaction/pain
- Infection risk
- Tuberculosis activation
- For TNF inhibitors, there’s a boxed warning for risk of lymphoma
- Factors influencing side effects include: history of cancer, inflammatory bowel disease, congestive heart failure

Can biologics lose their effectiveness over time?

Some patients who are treated with biologics, and who have a very good response to treatment at first, may lose some, or all, of that response over time. We don't have a good explanation for why this happens in some patients. It is possible that some patients who lose their response over time may develop antibodies or immunity to the biologic. In other patients, it is possible that their HS changes over time, so that it is no longer as responsive to the biologic the patient is receiving.

What is the right time to use a biologic? Is there a "window of opportunity" during which it is most beneficial to use a biologic?

When patients have flares of disease activity, it may result in permanent damage to their skin (for example, scars). This damage may also result in permanent effects on quality of life (for example, if there is a lot of scarring under the armpit, it may limit how much someone can raise their arm). The idea behind the "window of opportunity" is that it is valuable to start effective treatment *before* damage occurs, so that permanent effects on quality of life are prevented.

Is the name of the drug Biologics? How should I ask the doctor for this?

'Biologics' is not the name of a specific drug, but refers to drugs that are manufactured in or extracted from biological sources. The word 'biologics' should be familiar to your healthcare provider. If you are interested in asking about them, you can simply ask your healthcare provider about biologics. Alternatively, you could ask about generic names of biologics (for example, adalimumab, infliximab, or secukinumab) or brand names (for example, HUMIRA®, REMICADE®, COSENTYX®).

Selecting a biologic

What is the difference between COSENTYX® and HUMIRA®?

Both biologics target cytokines, which are signals that our bodies use to communicate. Specifically, they target cytokines that tell the body to increase inflammation. COSENTYX® targets a cytokine called IL-17 and HUMIRA® targets a cytokine called TNF alpha (tumor necrosis factor).

I'm on a biologic and still having issues. What other biologics might help? My quality of life is not good right now.

Trying another biologic indicated for the treatment of HS could be an option. Another important thing in HS is that you can take multiple medications together. If one treatment doesn't bring you control, we usually add another medication to your regimen. We can keep adding medications to help you get under control. Surgical procedures are also best for some issues, so it will depend on exactly what issues you're having.

How do healthcare providers determine which biologic is best for each patient? Why don't doctors often run a cytokine panel?

While we do look at cytokine panels, they unfortunately don't help us make treatment decisions. Typically, cytokine levels are high in patients with HS and we don't yet know which ones are the most important in driving the disease. One biologic may work well for one person, and another may work better for someone else. Research is underway to try to find other things, possibly genes, that will help predict which treatment is best for each patient, but we don't have that information yet.

Concurrent use of biologics, treatments, and/or surgeries

What about the use of multiple biologics at the same time?

We commonly treat HS with multiple biologic medicines, as we consider it a disease with a "medicines" deficiency. However, getting insurance companies to cover multiple biologics is often a challenge, as it is nearly impossible to get them to cover two expensive medicines.

Can you share more about surgery and biologics used in tandem?

Biologics should be continued through surgery after consultation with your healthcare provider and surgeon. There is plenty of evidence showing that infection rates are similar in patients who maintain control with biologics while undergoing surgery, and those who stop biologics prior to surgery. It is also very clear that stopping biologics before surgery results in severe worsening of disease.

What are the most common non-biologic treatments that you combine with the biologics?

Almost anything is fair game as there are few drug-drug interactions between the medicines we commonly use. Oral antibiotics, metformin, spironolactone, colchicine, and others are all good choices.

Population-specific Information

Which biologics are safe to take while pregnant or while trying to conceive?

Depending on the mechanism of action of the biologic it will have a different safety profile for pregnancy or conception. However, there is currently a lack of information regarding the impact of biologic medications on pregnancy. While pregnant, most biologics have the potential to cross the placenta and reach the fetus. certolizumab is a biologic with minimal placental and breast milk transfer, with the best safety data for pregnancy.

Have you found that biologics can clear up multiple conditions at once (e.g., psoriasis, arthritis and HS)?

Because biologics work at a cellular level, they can treat multiple diseases that have similar underlying mechanisms. HS patients have an increased risk for other conditions including inflammatory bowel disease, rheumatoid arthritis, psoriasis, and other spondyloarthropathies. In these cases, one medication can treat multiple conditions in the same patient.

Is it safe to breast feed while taking a biologic?

There is limited data on the safety of biologics and breastfeeding, except for the medication certolizumab. However, biologic medications are typically made up of very large proteins. Even if these proteins are present in the breastmilk, the biologic should be broken down into the digestive system of the infant without harm. However, the expression and impact of inactive ingredients on infants is unknown. It is important to discuss with your doctor the safety evidence on breastfeeding with the specific biologic medicine you are taking.

Side effects, getting off biologics, and switching biologics

How long does it take for biologics like HUMIRA® or COSENTYX® to clear out from your body? What are the side effects of trying to taper off a biologic medication and how long do the side effects last?

It takes approximately 8 weeks for HUMIRA®, and approximately 16 weeks for COSENTYX®, to clear out from your body. Tapering off biologic medication is generally not recommended. If you decide to stop the medicine, it is generally stopped without tapering. If you are experiencing side effects due to a biologic, the side effects may persist as long as it takes for the medicine to clear out of your body. However, it is reasonable to expect that these types of side effects would become less severe over time, as the levels of the medication in your body decrease.

Is fatigue a side effect of biologics injections?

It depends on the biologic. Based on available data, FDA does not think that HUMIRA® or COSENTYX® causes the side effect of fatigue.