

Biologics Webinar: All Questions

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 as 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®).

Additional questions (not covered in FAQ):

Why is a TB test required when getting approved for a biologic?

Patients who have active TB or latent TB (TB bacteria are in the body but it is like they are “sleeping”) and who receive treatment with biologics that are TNF blockers (for example, adalimumab or infliximab) are at increased risk of worsening their TB infection. To prevent this from occurring, a TB test is required when getting approved for TNF blockers.

If the test is negative, that means you have no evidence of active TB or latent TB. In that case, you can receive a TNF blocker without concern about TB infection becoming worse.

If the test is positive, that means you may have active TB or latent TB. It may be appropriate for you to be checked out by an infectious disease doctor. It may be appropriate to delay treatment with a TNF blocker until the active TB or latent TB is under control, or to choose a different treatment that does not risk worsening TB.

Do we need to drain HS flares before starting a biologic for more effective results?

There is no proof that draining HS flares before starting a biologic is necessary. However, each patient is different. It is possible that some patients may benefit from drainage before starting a biologic.

This is a decision that needs to be made on an individual basis, between you and your healthcare provider.

I'm going back and forth with my insurance. We are trying to double the dose of my biologic. Have you seen increased dosage resulting in better efficacy?

Some patients may benefit from an increased dosage.

Unfortunately, the only way at this time to find out if you might benefit from an increased dosage is to try it and see. This is a decision that should be made between you and your healthcare provider.

Will my healthcare provider be able to request a biologic for me without trying prior treatment?

That is something that will probably never occur due to the United States' health insurance system.

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.

Additional questions (not covered in FAQ):

What is the best biologic for severe HS?

We still don't have an answer to that question. One biologic may work well for one person, while someone might respond better to a different one. Research is underway to try to find ways to predict which treatments will work best for which patients.

What is the biologic treatment ladder after someone that failed adalimumab?

COSENTYX® could be an option. Infliximab is another option, although it's not FDA approved for the treatment of HS. 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.

Are TNF alpha and anti-IL17 good enough? Or is there a need for additional biologics?

Researchers are currently studying many biologics and other medications with many different targets. As we learn more, we're discovering new things in the immune system, and that is helping us find new targets that may be involved in the HS disease process. It's an exciting time since there will be more treatments with similar and different targets in the near future.

You mention HUMIRA®, what about AMGEVITA®?

AMGEVITA® and HUMIRA® are both adalimumab, just made by different companies and given different brand names.

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.

Additional questions (not covered in FAQ):

Can you combine biologics with clindamycin and doxycycline? What other antibiotics do you use?

Yes, combining biologics and oral antibiotics are common combination treatments. BACTRIM®, AUGMENTIN®, and others are all good choices. All treatment choices should be made with treating physician.

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.

Additional questions (not covered in FAQ):

If someone takes a biologic for several years and then switches to another biologic, can a third biologic be tried immediately or does a certain amount of time need to pass before beginning a third?

It is not necessary for a certain amount of time to pass between stopping one biologic and beginning another biologic.

Is the Covid vaccine safe to take while on HUMIRA®?

Yes. There is no evidence that patients taking HUMIRA® are at increased risk from taking a Covid vaccine compared to patients not taking a Covid vaccine. In fact, except for live vaccines (for example, flu vaccine administered in your nose), there is no evidence that patients taking HUMIRA® are at increased risk from taking any vaccine.

General HS information (not covered in FAQ)

What are the different stages of HS?

The HS staging system is based on the types of HS lesions you have and whether you have lots of scarring. It is important to know that people with stage one (I) HS can still have significant symptoms and be very impacted by HS.

- Stage I: Individual nodules and abscesses (sometimes called boils) that come and go in common areas like armpits, groin, breasts, and buttock. There isn't usually much scarring.
- Stage II: Areas of the body have multiple abscesses that come back over and over. There are also tunnels/sinus tracts and scarring. There is still some normal skin within the affected areas.
- Stage III: Whole areas of the body have many tunnels/sinus tracts that connect. For example, the whole armpit area, the whole groin, etc.

Good resources about the stages of HS include:

- <https://dermnetnz.org/topics/hidradenitis-suppurativa-severity-assessment>
- <https://www.hs-foundation.org/hs-symptoms> (the photos of mild, moderate, and severe are good examples of stage I, stage II, and stage III)

At what age (how young) can someone start developing this disease?

Hidradenitis suppurativa is typically thought to have an average age of onset of 23 years old, but up to 50% of patients show symptoms between 10 to 21 years old. Women tend to have an earlier age of symptom onset than men. Symptom onset can coincide with hormonal changes in puberty, particularly in young women, but can occur at any age, including pre-puberty or even peri-menopause.

I was told that once women go through menopause, their symptoms with HS will decrease or go into remission. Is this accurate information?

The area of menopause and HS is currently understudied. A 2020 patient survey ([Fernandez et al. Menses, pregnancy, delivery, and menopause in hidradenitis suppurativa: A patient survey](#)) found that of 279 female respondents, only 16.3% reported an improvement in symptoms, and 39.5% reported a worsening of symptoms with menopause. The changes that some patients experience during menopause are likely due to shifts in hormones.

My HS was triggered during my second trimester of pregnancy. Is there any chance my HS may resolve post-delivery? Does breastfeeding trigger HS?

During pregnancy there are changes in hormonal levels, as well as pro- and anti-inflammatory pathways, making it difficult to predict changes in the disease after giving birth. There is currently limited research on how HS changes during pregnancy and breastfeeding. Weight gain associated with pregnancy can increase friction, which is associated with worsening HS. While breastfeeding is not contraindicated in patients with HS, if there are open lesions on the breast, patients may experience pain or worsening of HS lesions during breastfeeding. Active lesions may result in difficulties with lactation and milk-fistula formation. On the other hand, due to the lowered immune function of the mother to protect the fetus, HS symptoms could improve. The mother's body's immune function is lowered during this time to avoid rejecting the fetus as it could be identified as foreign material due to the genetic makeup of the father.

Do we know yet if genetics play a role in HS?

Genetics plays a role in many people. Around 3 or 4 out of every 10 people with HS have family with HS. We are learning more about why this is with research.

For more information, a paper on the subject was published in [2020 in the Journal of the American Academy of Dermatology](#).

Samantha R. Goldberg BA, Bruce E. Strober MD, PhD, Michael J. Payette MD, MBA. Hidradenitis suppurativa: Epidemiology, clinical presentation, and pathogenesis. Journal of the American Academy of Dermatology. 82(5) May 2020. 1045-1058.

I heard a reference to “complex” dermatology. Is there a specialty dermatologist for HS?

There are dermatologists who specialize in HS. These are usually dermatologists who see many HS patients and HS patients with more severe or complicated HS. Many of them do HS research to help us better understand and treat HS. Not all cities or states have HS specialists. While all dermatologists can treat HS, people with more severe HS or who don't get better with a few different treatments/medications may want to see a specialist or a dermatologist who has more HS patients. In some places, other specialists like surgeons or rheumatologists also help to treat HS.

Any updates about what triggers HS flares?

A 2021 study asked patients what their own triggers were. The triggers that people had the most were stress, sugary/high carbohydrate foods, exercise, gaining weight, smoking, and hormones/menstrual cycle (periods). Like many conditions, not everyone has the same triggers. Tight clothing or friction seems to make pain worse in some people.

For more information, a paper on the subject was published in [2021 in the British Journal of Dermatology](#).

Identifying triggers for hidradenitis suppurativa flare: a patient survey. A.M. Thompson, J.M. Fernandez, J. Rick, A.J. Hendricks, M. Maarouf, E.M. Mata, E.K. Collier, T.R. Grogan, J.L. Hsiao, V.Y. Shi. British Journal of Dermatology, Volume 185, Issue 1, 1 July 2021, Pages 225–226, <https://doi.org/10.1111/bjd.19926>

What is the best way to treat HS pain?

Pain can be a huge part of HS and can make people's quality of life worse. There are many choices to help treat HS pain. It is important to work with healthcare providers to find the right treatment (or treatments). Helping your HS get better with treatment can help pain get better. For flares, injecting lesions with a steroid, draining lesions, or warm or cold compresses can all help with pain. Some people do well with spot treating lesions with numbing creams. Over the counter pain medications like acetaminophen and ibuprofen can help for some. There are also prescription medications that help with different types and triggers of pain including medications like gabapentin or duloxetine. Opiate pain medications are sometimes used for very severe pain.

Does consuming sugar make HS worse?

Some small research studies have shown that eating and drinking fewer "simple sugars" can help HS symptoms. This is called a low glycemic index diet. Eating fewer simple sugars and drinking fewer sugary drinks like juice and soda can also be good for your health overall. Talk to a healthcare provider before making diet changes to make sure you are doing these safely.

For more information, papers on the subject were published in [2019 in the International Journal of Dermatology](#), and [2023 in the American Journal of Clinical Dermatology](#).

Annika Silfvast-Kaiser, Ronnie Youssef, So Yeon Paek. Diet in hidradenitis suppurativa: a review of published and lay literature. Int J Dermatol. 2019 Nov;58(11):1225-1230. doi: 10.1111/ijd.14465. Epub 2019 Apr 21.

Isaac Weber, Josie Giefer, Kari L Martin. Effects of Exercise and Dietary Modifications on Hidradenitis Suppurativa: A Systematic Review. Am J Clin Dermatol. 2023 May;24(3):343-357. doi: 10.1007/s40257-023-00756-w. Epub 2023 Feb 9.