

## **HS Connect Plain Language Summary (PLS)**

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#### **Delphi consensus: First-line use of biologics and small molecules in hidradenitis suppurativa**

##### **What should you know to understand this study?**

In hidradenitis suppurativa (HS), early treatment with an effective medication is very important. Studies of HS have shown that there may be a “point of no return,” meaning that if HS is not treated appropriately before this point, scars and tunnels can form and cannot be reversed.

Antibiotics are commonly used as first-line (meaning first choice) treatment for HS because they can reduce both bacteria and inflammation that are present in HS. However, antibiotics are sometimes not effective enough to control the disease. If effective treatment is not started in time, patients may progress to have more severe disease.

There are other treatments for HS that can be more effective than antibiotics. These include biologics and small molecules.

- Biologics are usually given as injections or IV medications. Examples include adalimumab (Humira), secukinumab (Cosentyx), and bimekizumab (Bimzelx).
- Small molecules are usually taken as pills or applied to the skin. Examples include apremilast (Otezla), ruxolitinib (Opzelura), and upadacitinib (Rinvoq).

Currently, none of the small molecules are approved by the FDA specifically for HS, but they are being studied and sometimes still used.

##### **What was the goal of the study?**

The goal of this study was to identify when biologics and small molecules should be used as the first treatment, or when a patient’s treatment should be changed to these stronger options.

##### **How was the study performed?**

This study used a method called a Delphi consensus, which is a way for experts on a condition to reach agreement about a treatment recommendation.

- 54 experts participated in this study while at the European Hidradenitis Suppurativa Foundation Conference.
- These experts voted on 16 statements about when biologics or small molecules should be used as the first treatment or when treatment should be upgraded to these stronger options when the current treatment the patient is using is not working well enough.

If at least 70% of the experts agreed, the statement was accepted as valid. If 75% or more agreed, it was called a consensus. If 90% or more agreed, it was called a strong consensus.

To understand the statements, the experts used two main systems to determine how severe a patient's HS is.

1. **IHS4 (International HS Severity Score System)** – This score is based on counting lesions: nodules are 1 point, abscesses are 2 points, and draining tunnels are 4 points.
  - a. Mild HS: 3 points or less
  - b. Moderate HS: 4 to 10 points
  - c. Severe HS: 11 points or more
2. **Hurley Staging** – This system focuses on scarring and tunnels.
  - a. Stage I: No tunnels or scarring
  - b. Stage II: Lesions with tunnels and scarring that keep coming back, but there is area between lesions that does not have HS lesions
  - c. Stage III: Connected tunnels and scarring

**What did the study find?** Below are the main findings based on the patient scenario presented, presented as a question, and what they mean for patients.

***Can the patient take antibiotics?***

- Experts strongly agreed: Use biologics or small molecules (B/SM) as first treatment for patients who cannot take antibiotics.

Takeaway: If antibiotics are not a safe option, B/SM should be started first.

***How severe is the patient's HS?***

- Experts agreed (but 10% expressed hesitation about this one!): Consider B/SM as the first treatment for patients with moderate or severe HS.
- Experts strongly agreed: Use B/SM for patients with severe HS, even if they do not have tunnels or scarring.
- Experts strongly agreed: Use B/SM as the first treatment for patients with Hurley Stage II or III, IHS4  $\geq$  4, and draining tunnels.

Takeaway: In patients with evidence of a lot of inflammation, starting stronger treatments early can help prevent irreversible changes.

***How fast is the disease changing?***

- Experts strongly agreed: Use B/SM for patients whose disease is progressing quickly (any Hurley stage increases within 3 months).

Takeaway: While everybody's HS does not change in the same way, HS that is worsening quickly needs stronger treatment.

***How many flares does the patient have, and how many areas are affected?***

- Experts strongly agreed: Use B/SM for patients with 3 or more flares in 12 weeks and moderate or severe HS.

- Experts strongly agreed: Use biologics for patients with Hurley Stage II or III, moderate or severe HS, and 3 or more affected areas.
- Experts agreed: Use biologics for patients with moderate or severe HS and 3 or more flares per year.

Takeaway: A recent study showed that people with HS are good at noticing draining tunnels and reasonably good at noticing abscesses and inflamed nodules. Frequent flares or multiple affected areas, which may not be present at your dermatology visit, mean the disease is not controlled and stronger treatment is needed.

***How is the disease affecting the patient?***

- Experts strongly agreed: Use B/SM for patients with 5 or more abscesses and nodules, or for patients with fewer lesions but if their pain is severe and/or their quality of life is greatly affected.

Takeaway: HS affects every person uniquely. Even if there are not many HS lesions present, stronger treatment is justified if HS causes significant pain or severely affects daily life.

***What does the HS look like?*** This is determined by your dermatologist.

- Experts agreed: Use biologics for patients with the following types of HS: ectopic, conglobata, frictional, or scarring folliculitis.
- Experts strongly agreed: Use biologics for the “mixed or inflammatory” types of HS if the disease is moderate or severe.
- Experts strongly agreed: Use biologics for HS affecting the following areas: inguinal (where upper thigh meets lower abdomen), anogenital (areas around the anus and the genitals, like the vulva, penis, and scrotum), or visible areas (like the face) if the disease is moderate or severe.

Takeaway: HS can appear differently in each person, and there isn’t one system currently to describe all types of HS based on what it looks like. However, some types of HS are more likely to worsen and/or some areas may be more noticeable, so stronger treatment should be started.

***Is the HS part of a syndrome?***

- Experts strongly agreed: Use B/SM for patients with HS as part of a syndrome and is moderate or severe, even if a genetic cause has not been identified.

Takeaway: A syndrome is when two or more health conditions happen together because they share a common cause. Some people with HS have a syndrome, meaning their HS occurs along with other related health conditions, often due to genetics or inflammation. Even if a genetic cause isn’t known, people with HS as part of a syndrome may benefit from starting stronger treatment early.

### ***Are there other conditions occurring alongside the HS?***

- Experts strongly agreed: Use B/SM for patients who also have other diseases caused by inflammation, such as inflammatory bowel disease (IBD) or axial spondyloarthritis.

Takeaway: In patients with multiple inflammatory conditions, early stronger treatment may better control HS and the other diseases.

### ***Is the patient affected by HS a child or adolescent?***

- Experts agreed: Use B/SM for children or adolescents with moderate or severe HS and a family history of HS.
- Experts agreed: Use B/SM for “inflammatory” type HS (what it looks like) in children or adolescents with a family history of HS and moderate or severe disease.

Takeaway: While it’s not always clear if HS starting at a younger age means the disease will be more severe, starting stronger therapy early may help slow or stop the worsening of HS over time.

### ***What should you keep in mind when reading the results of this study?***

- This study reflects the opinions of HS experts and does not replace research based on actual studies of patients. More studies are needed to confirm these recommendations.
- Some experts have conflicts of interest, which can include ties to pharmaceutical companies.
- Patients were not involved in giving input for this study. Including patients in future studies could help better understand how these recommendations affect the people who live with HS.

### ***What key points should you take-away from this study?***

- This study shows that stronger treatments, like biologics and small molecules, may need to be used earlier in many situations to better control HS and prevent long-term, irreversible skin changes.
- Patient input matters. Sharing your symptoms, pain, and how HS affects your life helps doctors make the best treatment decisions.
- While this study was done in Europe and reflects guidelines there, this may encourage similar approaches in the United States once new roadmaps/instructions for treatment (guidelines) are updated.
- If any of these scenarios apply to you, speak up! Your experiences matter and should help guide your care.

### **References:**

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