

NEWS, VIEWS, AND REVIEWS

Biologics for Pediatric Hidradenitis Suppurativa: An Update on the Evolving Therapeutic Landscape

Nikkia Zarabian BS,[a] Mina Farah BA,[a] Anastasia Chajecki BS,[b] Olive Osuoji MD,[a] Adam Friedman MD FAAD[a]

[a]The George Washington University School of Medicine and Health Sciences, Department of Dermatology, Washington, DC
[b]Division of Dermatology, Children's National Hospital, Washington, DC

INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by recurrent nodules, abscesses, and sinus tracts that primarily affect intertriginous regions.[1] HS is a multifactorial disorder driven by follicular occlusion and rupture, resulting in a dysregulated immune response characterized by activation of Th1/Th17 pathways, increased expression of proinflammatory cytokines, including interleukin (IL)-1, IL-17, and tumor necrosis factor (TNF)-α, and infiltration of neutrophils, monocytes, and mast cells.[1] These processes may promote chronic inflammation, sinus tract formation, fibrosis, and scarring.[1]

HS demonstrates a bimodal age distribution, with incidence peaks in late adolescence and the mid-40s.[1] Notably, nearly half of adults with HS report disease onset between 10 and 21 years of age.[1] Although the prevalence of pediatric HS is likely underestimated, it is reported to affect approximately 0.03% of children and adolescents in the United States (US).[1] Management of pediatric HS is typically multimodal, incorporating topical, systemic, and surgical therapies.[2] Biologic therapies are increasingly used for moderate-to-severe disease; however, pediatric patients have historically been underrepresented in HS clinical trials and real-world studies, resulting in limited evidence to guide treatment in this population.[2,3] Much of the current evidence supporting biologic use in children and adolescents is extrapolated from adult clinical trials, pediatric studies in other inflammatory diseases, and limited case series. Given the evolving therapeutic landscape and limited pediatric-specific evidence, this review provides an overview of important current and emerging biologic therapies for pediatric HS, integrating available pediatric data with adult clinical trial findings that may guide management in children and adolescents.

Adolescent FDA-Approved Treatments

Currently, adalimumab and secukinumab are the only biologic therapies approved by the US Food and Drug Administration (FDA) for the treatment of moderate-to-severe HS in pediatric patients.

Adalimumab

Adalimumab, a recombinant monoclonal antibody targeting TNF-α, was the first biologic to be FDA-approved for HS in adults in 2015, at a maintenance dose of 40 mg every week (EW) or 80 mg every other week (EOW).[3,4] In 2018, approval was expanded to adolescents aged 12 years and older weighing ≥30 kg, with recommended dosing of 40 mg EOW.[5] This indication was based on pharmacokinetic and efficacy data from pediatric populations with psoriasis, Crohn's disease, and juvenile idiopathic arthritis (JIA), as well as extrapolation from the phase III PIONEER I and II trials in adults with HS.[5]

A 2025 multicenter retrospective case series evaluated 65 pediatric patients (10-19 years old) with HS who initiated adalimumab and completed at least 6 months of therapy.[3] At 6 months, 76.9% achieved Hidradenitis Suppurativa Clinical Response 50 (HiSCR50), defined as a reduction of at least 50% in total inflammatory nodule and abscess count and no observed increase in draining fistula or abscess count from baseline.[3] Initial dosing was 80 mg EOW in 49.2% of patients, 40 mg EOW in 26.2%, and 40 mg weekly in 24.6%.[3] Patients receiving the FDA-approved adolescent regimen (40 mg EOW) were significantly more likely to require dose escalation to maintain response than those initiated on adult dosing regimens (40 mg EW/80 mg EOW), independent of age at treatment initiation.[3] These findings suggest that adult dosing may provide more durable disease control in select pediatric patients.[3] Adverse events occurred in 7 patients (10.8%) and led to treatment discontinuation in 3 (4.6%).[3] Respiratory tract infections were the most common adverse event (n=3), followed by isolated cases of paradoxical psoriasis, dizziness/nausea, injection-site pain, and worsening atopic dermatitis.[3] Most adverse events occurred in patients receiving 80 mg EOW.[3]

Secukinumab

Secukinumab, a monoclonal antibody targeting IL-17A, is the second biologic approved for the treatment of moderate-to-severe HS.[6,7] It received FDA approval for adults in 2023, with approval expanded to adolescents aged ≥12 years in 2026 at a maintenance dose of 150 mg every 4 weeks (≥30 kg and <90 kg) or 300 mg every 4 weeks (≥90 kg).[6,7] Although no clinical trials have evaluated secukinumab specifically in pediatric patients with HS, its approval for adolescents is supported by efficacy and safety data from adult HS trials and pediatric studies in other approved indications, including plaque psoriasis and JIA.[8] The phase III SUNSHINE and SUNRISE trials were multicenter, randomized, double-blind, placebo-controlled studies that enrolled 1,084 adults with moderate-to-severe HS from 219 sites across 40 countries.[8] Participants received secukinumab 300 mg every 2 weeks, every 4 weeks, or placebo.[8] In both trials, the every 2 week regimen achieved the primary endpoint, with significantly more patients attaining HiSCR50 at week 16 compared with placebo; responses were observed as early as weeks 2–4 and were sustained through week 52.[8] The every 4 week regimen met the primary endpoint in SUNRISE but not SUNSHINE.[8] Secukinumab also improved pain, lesion counts, and quality of life (QoL) measures, with a safety profile consistent with previous studies.[8] The most commonly reported adverse events were headache, nasopharyngitis, and worsening HS, with no new safety signals identified through 52 weeks.[8]

Adult-Only FDA-Approved Treatments

Bimekizumab

Bimekizumab is a monoclonal antibody that selectively inhibits IL-17A and IL-17F and was approved in 2024 for the treatment of adults with moderate-to-severe HS at a dose of 320 mg every 4 weeks after initiation.[9] Approval was primarily based on the phase III BE HEARD I (n=505) and BE HEARD II (n=509) trials, two identical 48-week, randomized, double-blind, multicenter studies evaluating adults with moderate-to-severe HS.[9]

While bimekizumab is not currently FDA-approved for pediatric HS, a case report described a 15-year-old male with a two-year history of severe HS refractory to multiple courses of systemic antibiotics and adalimumab successfully treated with off-label bimekizumab.[10] At baseline, the patient had extensive inflammatory lesions involving the axillary, inguinal, pubic, and perineal regions, as well as psychological impairment (International Hidradenitis Suppurativa Severity Score System (IHS4): 150, Skindex-16: 93, Hospital Anxiety and Depression Scale (HADS): Anxiety 12, Depression 16).[10] Treatment was initiated with bimekizumab 320 mg subcutaneously (two 160 mg injections) at week 0, 4, 8, 12, and 16, followed by maintenance dosing every 6 weeks thereafter.[10] After 2 months of treatment, the patient demonstrated notable clinical and QoL improvement (IHS4: 80, Skindex-16: 62, HADS/Anxiety: 11, HADS/Depression: 6).[10] At 6 months, disease severity and psychosocial burden had further improved (IHS4: 20, Skindex-16: 33, HADS/Anxiety: 3, HADS/Depression: 4).[10] Clinical improvement was maintained at 1-year follow-up.[10]

Furthermore, a phase III, multicenter, open-label study (NCT06921850) is actively recruiting to evaluate the pharmacokinetics and safety of bimekizumab in pubertal children and adolescents with moderate-to-severe HS.[11] The study plans to enroll approximately 40 participants aged 9 to <18 years who have reached Tanner stage II or higher, with primary outcomes focused on pharmacokinetic parameters and safety through week 16.[11]

Off-Label Treatment

Infliximab

Infliximab is an anti-TNF-α monoclonal antibody used off-label for moderate-to-severe refractory HS.[12,13] Although not FDA-approved for HS, studies support infliximab's efficacy in adult and pediatric patients, particularly at higher weight-based dosing and frequency.[12,13] In a prospective cohort of 42 patients initiated on 7.5 mg/kg every 4 weeks after induction, 70.80% of patients achieved clinical response defined as HS-Physician Global Assessment (PGA) 0-2 and ≥2 score improvement from baseline at 12 weeks.[12] Patients who did not achieve adequate clinical response after induction, defined as HS-PGA ≥3, were escalated to 10 mg/kg dosing every 4 weeks with 50% of this cohort achieving the desired clinical response.[12] In an earlier randomized, placebo-controlled, double-blind trial of infliximab 5 mg/kg every 8 weeks post-induction, approximately 27% of patients achieved a ≥50% reduction in HS Severity Index (HSSI) at week 8, suggesting that the standard 5 mg/kg dosing used in psoriasis may be inadequate to achieve optimal disease control.[13] Notably, a larger proportion of patients demonstrated partial clinical response, with improvements observed in pain, QoL, and inflammatory markers.[13] While infliximab has a well-established safety profile in pediatric Crohn's disease, pediatric-specific efficacy and dosing data in HS remain limited, highlighting the importance of further age-stratified studies.[13]

Future Directions

Sonelokimab

Sonelokimab is a trivalent nanobody fusion protein that targets IL-17A, IL-17F, and the IL-17A/F heterodimer.[14] It is not currently approved in the US; however, it is being evaluated in clinical trials for moderate-to-severe HS in adult and pediatric populations.[14] In a 28-week, randomized, double-blind Phase II trial including 234 participants, a higher proportion of patients treated with sonelokimab 120 mg and 240 mg achieved HiSCR75 compared with placebo at week 12 (43.3% and 34.8% vs 14.7%), with similar response maintained through week 24 and a safety profile consistent with other IL-17 pathway inhibitors.[14] Phase III trials (VELA-1 and VELA-2) further evaluated the efficacy and safety of sonelokimab in adults with HS.[14] VELA-TEEN is a current pediatric study assessing sonelokimab in adolescents aged 12 to 17 with moderate-to-severe HS, including evaluation of efficacy, safety, and pharmacokinetics.[15]

CONCLUSION

The therapeutic landscape for HS continues to expand, offering new treatment options for pediatric patients with moderate-to-severe HS. Emerging pediatric data suggest that treatment response, optimal dosing strategies, and medication utilization may differ from those observed in adults, as demonstrated by the frequent need for adalimumab dose escalation in adolescents. However, much of the current evidence supporting biologic use in pediatric HS is extrapolated from adult clinical trials, pediatric studies in other inflammatory diseases, and limited case studies and case series. Further pediatric-specific studies are needed to better define efficacy, safety, and optimal dosing of biologic therapies in children and adolescents with HS. Such data will also be critical for supporting insurance coverage decisions and improving access to effective treatments for this patient population.

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AUTHOR CORRESPONDENCE

Adam Friedman MD FAAD

E-mail:..... ajfriedman@mfa.gwu.edu