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A close-up photograph of a person's arm showing several red, inflamed, and pus-filled lesions characteristic of hidradenitis suppurativa. The lesions are clustered along the axillary line.

WHY HIDRADENITIS SUPPURATIVA SHOULD BE ON YOUR RADAR

Haley B. Naik, MD, MHSc

BASED ON A MEDSCAPE ONLINE ACTIVITY

Why Hidradenitis Suppurativa Should Be on Your Radar

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CME / ABIM MOC

Release Date: 12/2/24

Expiration Date: 12/2/25

Target Audience: This activity is intended for dermatologists, primary care physicians, pediatricians, physician assistants, nurse practitioners, obstetricians/gynecologists, and other clinicians who treat skin conditions or specialize in skin care.

Goal Statement: The goal of this activity is for learners to better recognize the burden associated with hidradenitis suppurativa (HS), establish

a timely diagnosis, and select appropriate management strategies to improve patient outcomes.

Learning Objectives: Upon completion of this activity, participants will:

Have increased knowledge regarding the

- Burden that HS places on patients across different domains of life
- Current evidence-based treatments for HS
- Clinical data on emerging HS therapies

Disclosures: Faculty, Editors, Medical Writer, CME/CE Reviewer/ Nurse Planner, Peer Reviewer

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Why Hidradenitis Suppurative Should Be on Your Radar

CLINICAL BURDEN OF HIDRADENITIS SUPPURATIVA

Epidemiology and Demographics

Painful comedones, nodules, draining tunnels, abscesses, and disfiguring scars—these are the prominent features of hidradenitis suppurativa (HS), a chronic, disabling inflammatory dermatosis of the hair follicle.^{1,2} Estimated global prevalence of HS is 1% to 2%; however, reported estimates range from 0.02% to 4.1%,^{3–6} with variations being attributed to differences in study design, data collection methodology, populations screened, and geographical location. As such, the true prevalence of HS may be underreported and attempts to ascertain a definitive figure are likely limited by its underdiagnosis.¹ Accordingly, HS is a medical area with high unmet clinical needs. In light of this, the Global Hidradenitis Suppurativa Atlas (GHiSA) group has developed an initiative, which in part aims to provide an accurate estimate of global HS prevalence using validated patient questionnaire data. With such information, clinicians can make efforts to improve healthcare interventions for HS across the world.^{7,8}

Causes and Impacted Populations

The underlying causes of HS are still not yet known, although several complicating factors, such as genetics, hormones, and lifestyle factors (eg, smoking, alcohol, obesity) are thought to play a role in this skin disease.^{1,2} Hidradenitis suppurativa can occur at any age and develop in any gender. Historically, it has been described to occur more commonly in women; however, men are more likely to develop severe HS. As a result, men may suffer in silence and keep their challenges hidden.^{9–13} In addition, HS has previously been described to be more prevalent among Black Americans.^{14,15} Nevertheless, it is important to emphasize that HS can and does develop in people of all ethnic and racial backgrounds, throughout childhood and adulthood, and across all genders.^{9–13,16}

Clinical Presentation

Clinicians should note that HS can occur anywhere on the skin where hair follicles exist, but most commonly impacts intertriginous areas of the body, such as the axillae and inguinal and anogenital regions,^{1,2} so it is important to be vigilant and carefully examine the patient's skin.^{17,18} Physical symptoms observed in HS include the presence of singular or multiple painful, tender, erythematous nodules and abscesses, comedones, scarring, and tunneling sinus tracts that may interconnect or coalesce and have associated malodorous drainage.^{1,2,19,20}

Diagnostic Approach to HS

Patients with HS may experience a delayed diagnosis, partly attributed to healthcare professionals' under recognition of the disease. As a result, many patients with HS experience an average delay of ~10 years from the initial presentation of symptoms to the establishment of a diagnosis.²¹ This may be of unique concern for patients with darker skin tones since the inflammatory lesions of HS can appear dark brown, violaceous, or gray in these individuals,^{22–24} further complicating the ability to make an accurate diagnosis. Therefore, clinicians should become familiar with the signs and symptoms associated with this condition across diverse skin tones to diagnose and implement adequate treatment strategies as early as possible for all patients with HS.

Currently, the clinical approach to diagnosing HS in adults is based on the identification of typical skin lesions, often found in areas where folds and creases of the body occur, such as the axillae, groin, and buttocks, and identifying a pattern of disease that shows recurrence at least every 6 months. In many pediatric patients with HS, recurrence may take longer to be observed (> 6 months).^{17,19,20,25}

Because HS may present with characteristics that overlap with other skin conditions, the disease may be mistaken for other dermatoses. Common misdiagnoses include cellulitis, inflamed epidermal cysts, furunculosis, and cutaneous abscesses, and sometimes necrotizing fasciitis. As a result, clinicians should perform a careful physical examination and a review of systems to capture any relevant signs/symptoms, such as the recurrence of lesions over a 6-month period, and comorbid conditions present in the patient's clinical presentation.^{19,20,26} Recurrent lesions that tend to appear in certain areas of the body can be a clue to help differentiate HS from similarly presenting dermatologic conditions.²

Comorbidities and Impact on Quality of Life

Hidradenitis suppurativa is associated with a high degree of morbidity. Comorbid conditions commonly reported in patients with HS include endocrine and metabolic-related disorders (eg, diabetes, dyslipidemia, polycystic ovary syndrome), cardiovascular disease and related events/conditions (eg, myocardial infarction, cerebrovascular accident, hypertension), pregnancy risks (eg, spontaneous abortion, gestational diabetes), gastrointestinal issues (eg, inflammatory bowel disease), musculoskeletal diseases (eg, arthropathies), and acute and/or chronic pain.^{1,2,19,20}

Clinicians should employ appropriate strategies to screen for common comorbidities in patients with HS, as this can be an important step toward helping these patients achieve improved overall health and reduced disease burden.^{2,19,20}

Hidradenitis suppurativa also significantly impairs numerous domains of patient quality of life (QoL) and psychosocial well-being, including mental health conditions (eg, depression, generalized anxiety disorder, suicidality), sex life and intimate relationship barriers, unemployment, socioeconomic challenges, self-esteem, stigmatization, isolation, and impaired body image.^{1,2,19,20,27} Clinicians should be aware of the myths and misconceptions surrounding HS (eg, HS is contagious, HS is caused by being overweight or smoking tobacco) when discussing aspects of patient care, as this can further impact patient QoL and mental health. The use of sensitive and appropriate language that emphasizes the patient's health can help establish a trustful relationship. This is important since it may pave the way for successful treatment, support adherence, and positive long-term outcomes.²⁷⁻³⁰

Assessing Disease Severity and Symptom Burden

Disease severity can be assessed using the Hurley staging system based on the presence and extent of lesions, scarring, and sinus tracts. Clinicians can use this staging system

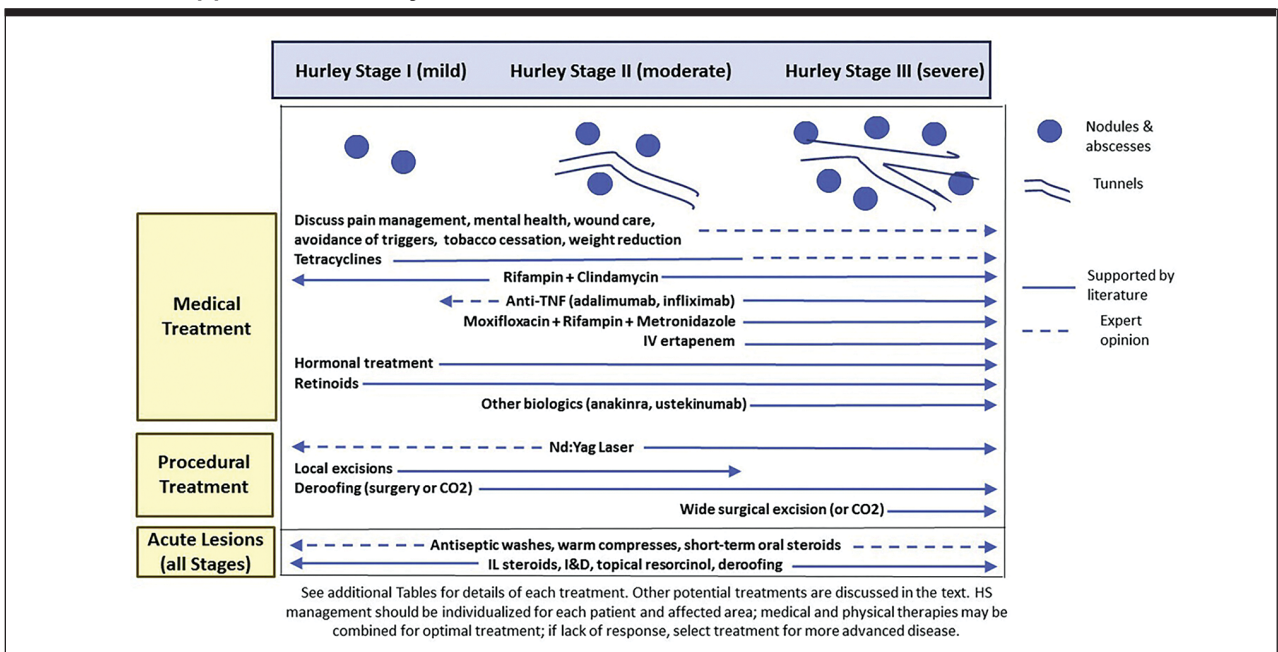
as a simple tool to help inform the individual therapeutic needs of a patient (Figure).^{19,20,32}

Several other instruments are available for researchers and clinicians to assess disease severity/symptom burden in patients with HS. However, most are based on lesion counts of inflammatory/noninflammatory nodules, sinuses/fistulas, scarring, and surface area affected and do not accurately capture the heterogeneous disease activity seen across patients with HS (eg, the extent of disease, severity of pain).^{19,20}

In addition to skin manifestations, patient-reported outcomes, such as pain, are important to assess since they have a major impact on QoL in patients with HS. Therefore, identifying and managing acute and chronic pain related to HS can help optimize patient treatment plans.^{1,2,19,20} In a global survey of patients with HS (N = 827), more than 60% of respondents rated their pain as either moderate or severe, highlighting it as a significant and prevalent QoL domain impacted by this disease. Consequently, patients should be referred or encouraged to seek pain or palliative specialty care to manage HS-related pain and develop an individualized treatment plan that meets their needs.³³

Clinicians can assess pain using several available scales, including the Pain Visual Analog Scale score and the

FIGURE. Medical Therapy Selection Based on the Hurley Classification System for Staging Hidradenitis Suppurativa Severity³²



Abbreviations: I&D, incision and drainage; IL, intralesional; IV, intravenous; Nd:YAG, neodymium-doped yttrium-aluminum-garnet; TNF, tumor necrosis factor.

J Am Acad Dermatol., 81, Ali Alikhan et al., North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management, 91-101, 2019, with permission from Elsevier.

Dermatology Life Quality Index, which are straightforward to implement in the clinical setting. However, no preferred or recommended patient-reported outcomes are available yet for evaluating HS impairment in QoL.^{1,2,19,20} Future work by dermatologists should aim to develop more specific standardized assessments for this disease, such as the Hidradenitis Suppurativa Quality of Life score, which aims to overcome the limitations of generic QoL tools by assessing distinctive symptoms of HS on QoL.¹

MANAGING HS

Goals of Therapy

Due to the complexity of the disease, the clinical management of HS typically involves a multipronged approach that combines medical and surgical treatments, especially for those with advanced disease.^{1,2,19,20} Current medical and expert guidance recommends an interprofessional approach to care (including primary care physicians, surgeons, rheumatologists, pain specialists, nutritionists, endocrinologists, and psychologists) that adequately addresses HS, its associated complications, and comorbidities.^{1,2,19,20,30,34} In line with this, the key goals clinicians should aim to achieve include reduction in symptoms (eg, pain, suppuration) and inflammatory processes; prevention of chronic lesion formation and irreversible scarring and tissue disfigurement; treatment of intercurrent/secondary infections; and improvement in patient QoL.^{1,18,19,20,35-37} Important adjunctive measures to help patients achieve treatment goals, include counseling on modifying lifestyle factors that influence the disease (eg, smoking cessation, weight loss) and providing appropriate education regarding self-care (eg, wound management).^{19,20}

Pharmacologic Strategies

The precise cause of HS and the molecular underpinnings responsible for its pathologic features remain largely unknown but appear to involve multiple cell types and immunologic pathways, with elevated levels of key proinflammatory factors such as tumor necrosis factor (TNF)- α , and several soluble mediators (eg, interleukin [IL]-1 β , IL-6, IL-17, CXCL1, CXCL8, and CXCL20) being implicated.^{1,38} This limited understanding of the pathobiology of HS has afforded a treatment landscape marked by few available therapies, leading to suboptimal management of this incapacitating disease. Despite this, new and emerging therapies targeting various immune system components implicated in HS have either been approved or are amidst various phases of clinical development.^{1,38,39}

Licensed Agents and Medical Recommendations

Medical guidelines recommend several therapies to manage early-stage (mild to moderate disease) HS, including topical agents such as skin cleansers, keratolytic agents, and topical antibiotics (eg, clindamycin), systemic antibiotics (eg, oral tetracyclines, rifampin; combination regimens), hormonal agents (eg, spironolactone, finasteride, oral contraceptive pills), and retinoids (eg, acitretin,

alitretinoin). Many of these agents may also be used concomitantly and/or adjunctively.³²

Intralesional steroids are considered for acute flares, and long-term systemic steroids may be utilized short-term for severe HS not responsive to standard therapy.³²

Advanced therapies, such as biologics (eg, anti-TNF- α inhibitors; IL-1, IL-17, and IL-12/23 inhibitors) are typically reserved for those with moderate to severe disease. Only 3 agents have been approved by the US Food and Drug Administration (FDA) and/or the European Medicines Agency (Table) for HS.^{19,20,32,40-44}

APPROVED AND EMERGING TARGETED THERAPIES

The Table^{19,20,40-44} summarizes key data from pivotal trials that have either supported the approval of available targeted therapies or currently are investigating emerging targeted agents for the management of moderate to severe HS.

New and Investigative Agents

Povorcitinib, a small molecule inhibitor of JAK1, is an investigative agent currently in the later stages of clinical development for treating moderate to severe HS.^{1,44,46,47} However, data from these 2 phase 3 povorcitinib trials (NCT05620823, NCT05620836) were not available at the time of this publication.^{1,46,47} Several other drugs are now either actively recruiting for or under various phases of clinical investigation for managing HS, including those that target the JAK/STAT pathways (eg, upadacitinib, brepocitinib), agents that block different proinflammatory cytokines (eg, MAS825, LYS006, spesolimab, lutikizumab, and sonelokimab), agents that interfere with chemokines (eg, eltrekibart), agents that inhibit BTK signaling (eg, remibrutinib), and phosphodiesterase type 4 inhibitors (eg, orismilast).^{1,38,39} Large randomized controlled trials are still needed to establish whether these agents will become an integral part of the therapeutic armamentarium for patients with HS.

Physical and Surgical Interventions

Multiple physical/surgical procedures exist to manage HS lesions by attempting to remove all or part of the affected skin areas. While incision and drainage may be employed for immediate pain relief and alleviation of discomfort, clinicians should note that it is associated with a high recurrence rate (almost 100%).^{19,48} Other common procedures used to manage HS include deroofting and wide excisions with ablative CO₂ laser local excision/evaporation.^{19,20} Currently, such procedures are recommended by American and European guidelines for HS in patients who present with HS that is uncontrolled or has failed to respond adequately to medical therapy alone.¹⁹ For those who may already be on medical therapy for HS, it is advised that therapy not be interrupted if surgery is indicated. This is supported by recent clinical data from the SHARPS study, which demonstrated that 12 weeks of perisurgical adalimumab therapy is more efficacious in conjunction with wide excision surgery compared

TABLE. Regulatory-Approved Targeted Therapies for Moderate to Severe HS^{19,20,40-44}

Class of Drug	Agent/MOA	Pivotal Phase 3 Clinical Trial Name/ Enrollment Number	Primary Efficacy Endpoint	Primary Efficacy and Safety Data Available
Biologic/mAb ^{40,41}	Adalimumab: TNF- α inhibitor	PIONEER 1, N = 307	HiSCR 50	HiSCR 50 at week 12: adalimumab, 41.8% vs placebo, 26.0%; $P = .003$
		PIONEER 2, N = 326		HiSCR 50 at week 12: adalimumab, 58.9% vs placebo, 27.6%; $P < .001$
				Rates of AEs were similar between the adalimumab and placebo study groups in both trials
Biologic/mAb ^{42,43}	Secukinumab: IL-17 inhibitor	SUNSHINE, N = 541	HiSCR 50	HiSCR 50 at week 16: secukinumab every 2 weeks 45.0% vs 34%, placebo; $P = .0070$
		SUNRISE, N = 543		HiSCR 50 at week 16: secukinumab every 2 weeks 42% vs placebo, 31%; $P = .015$
				Most common AEs with secukinumab in both trials: headache, nasopharyngitis, hidradenitis
Biologic/mAb ^{44,a}	Bimekizumab: IL-17A/IL-17F inhibitor ^{41,a}	BE HEARD I, N = 505	HiSCR 50	HiSCR 50 at week 16: bimekizumab every 2 weeks 48% vs placebo, 29%; $P = .0060$
		BE HEARD II, N = 509		HiSCR 50 at week 16: bimekizumab every 2 weeks 52% vs placebo, 32%; $P = .0032$
				Most common AEs with bimekizumab in both trials: hidradenitis, coronavirus infection, and diarrhea

Abbreviations: AE, adverse event; HiSCR 50, hidradenitis suppurativa clinical response ≥ 50 ; HS, hidradenitis suppurativa; mAb, monoclonal antibody; MOA, mechanism of action.

^aAt the time of this publication, bimekizumab was not yet FDA-approved for use in HS in the United States. However, it received marketing authorization from the European Commission for the management of moderate to severe HS in adults who have not responded well to conventional systemic HS therapies.

to placebo ($P = .049$).⁴⁹ Given the multifaceted approach to care, heterogeneity in response to treatments, and the possibility of worsening disease, early referral to dermatology is critical for those with suspected HS.^{19,20}

KEY TAKEAWAYS

Hidradenitis suppurativa is a chronic debilitating and clinically variable skin disease that significantly impacts patient QoL.^{1,2,19,20} While a diagnosis of HS can be made clinically with a high degree of accuracy (97%),⁵⁰ current treatment options are scarce, with approved targeted therapies being limited in their indications for moderate to severe disease.^{19,20,41,43,45} Fortunately, new trials are on the horizon investigating novel targeted agents that aim to alter HS disease course and expand the treatment landscape.^{1,38,39} Due to the complex nature of HS and its therapeutic options, clinicians should consider adopting a comprehensive approach to management. This can best be done by implementing an interprofessional care

model that aims to improve the physical symptoms and psychological well-being of patients with HS as early in the disease course as possible.^{1,2,19,20,30,34}

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