

PRESS RELEASE

Novartis Cosentyx[®] receives FDA approval for pediatric patients aged 12+ with moderate to severe hidradenitis suppurativa

- *Cosentyx is the only IL-17A inhibitor approved for this population, and the first differentiated mechanism in nearly a decade¹⁻³*
- *HS often emerges around puberty, underscoring importance of early diagnosis and intervention with biologics to help reduce long-term disease burden⁴⁻⁶*
- *Approval marks fourth pediatric indication for Cosentyx, reinforcing its robust safety and efficacy profile¹*

Basel, March 13, 2026 – Novartis announced today that Cosentyx[®] (secukinumab) received US Food and Drug Administration (FDA) approval for treating pediatric patients 12 years and older with moderate to severe hidradenitis suppurativa (HS), making it the only IL-17A inhibitor for this population¹. The approval of a distinct biologic option for pediatric patients living with HS allows treatment to be tailored to the individual and establishes Cosentyx as a meaningful addition to the treatment landscape¹⁻¹³.

“Hidradenitis suppurativa (HS) often begins in adolescence and can cause irreversible scarring and disabilities,” said Alexa B. Kimball, MD, MPH, lead investigator of the SUNSHINE and SUNRISE clinical trials in adult HS patients, President and CEO of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center, Boston, and Professor of Dermatology at Harvard Medical School. “The approval of Cosentyx represents an important advancement for younger HS patients who have had limited treatment options.”

HS is a chronic, systemic inflammatory skin disease that causes recurring boil-like lesions, which can rupture into painful wounds and lead to scarring⁷. HS affects as many as 1 in 100 people worldwide and often begins around puberty⁷. More than half of patients develop symptoms during adolescence, highlighting the importance of early intervention^{5,6}.

“Hidradenitis suppurativa (HS) affects far more than skin; it impacts confidence, emotional well-being and relationships during a formative period for many pediatric patients,” said Brindley Brooks, Founder & CEO, HS Connect. “For families watching their children struggle, this FDA approval brings hope for earlier intervention.”

The distinct IL-17A mechanism provides physicians with a differentiated therapeutic option to help manage this challenging condition in younger patients, with dosing tailored to patient weight¹. The use of Cosentyx in patients aged 12+ with moderate to severe HS weighing 30 kg or more is supported by well-controlled adult studies and pharmacokinetic modeling extrapolated from adult HS and psoriasis clinical trials, as well as pediatric clinical trial data from other approved indications¹. The approval is also supported by dosing analysis, which predicted that weight-based dosing of Cosentyx in pediatric patients can provide similar exposure to adult HS patients¹.

“With more than a decade of real-world experience across multiple autoimmune diseases, Cosentyx is a well-established treatment option that many physicians trust,” said Victor Bultó, President, Novartis US. “Yet for young people living with moderate to severe hidradenitis suppurativa (HS), treatment options have remained limited for far too long. Expanding Cosentyx to this population addresses a critical gap in care and underscores our focus on advancing solutions where we can make the greatest impact on outcomes.”

About Cosentyx® (secukinumab)

Cosentyx is a fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation underlying multiple immune-mediated inflammatory diseases. It is approved for use in adults with hidradenitis suppurativa (HS), psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), and non-radiographic axial spondyloarthritis (nr-axSpA)⁸⁻¹⁰, as well as in pediatric patients with HS, PsO, enthesitis-related arthritis (ERA), and juvenile psoriatic arthritis (JPsA)^{11,12}. Cosentyx is supported by robust evidence and more than 10 years of real-world data demonstrating its long-term safety and sustained efficacy¹³⁻¹⁸. Since its launch in 2015, it has been used to treat more than 1.8 million patients worldwide and is now approved in over 100 countries¹³.

About hidradenitis suppurativa (HS)

HS is a chronic, systemic, progressive and often painful inflammatory skin disease^{6,19}. It causes recurring boil-like abscesses that can burst, creating open wounds, often in the most intimate parts of the body, which may result in irreversible scarring^{6,20}. It can take up to 10 years on average to get a correct diagnosis, and may affect approximately 1 in 100 people globally^{6,21}. HS impacts patients' quality of life more than any other skin disease, and people living with HS often experience comorbidities such as obesity, diabetes, arthritis and depression^{20,22, 23}.

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About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people’s lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at <https://www.novartis.com> and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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