Secukinumab (COSENTYX) Subcutaneous Injection in Hidradenitis Suppurativa
National Drug Monograph
March 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. Updates will be made if new clinical data warrant additional formulary discussion. The Product Information or other resources should be consulted for detailed and most current drug information.

Abbreviations: AAE, anticipated absolute effect per 1000 cases; DB, double-blind; DD, double-dummy; DLQI-5, ≥ 5-point reduction in the Dermatology Life Quality Index; HiSCR, hidradenitis suppurativa clinical response; LOE, level of evidence; MN, multinational; PC, placebo-controlled; PRO, patient-reported outcome; RCT, randomized clinical trial; SOR, strength of recommendation

FDA APPROVAL INFORMATION

Description / MOA	Selective interleukin-17A inhibitor (IL-17Ai). Secukinumab is the second biologic and the first IL-17Ai approved for the treatment of hidradenitis suppurativa (HS).
Indication Under Review[1]	Treatment of adults with moderate to severe HS.
Dosage Regimen	300 mg SC at Weeks 0, 1, 2, 3 and 4 then every 4 weeks thereafter. If the patient has an inadequate response, a dosage increase to 300 mg SC every 2 weeks may be considered.
Dosage Forms Under Review	Injection: 300 mg/2 mL in a single-dose UnoReady pen or single-dose prefilled syringe Injection: 150 mg/mL in a single-dose Sensoready pen or single-dose prefilled syringe

EFFICACY CONSIDERATIONS

Trial	**SUNSHINE[2]**
Design	Phase 3 MN DB DD PC RCT with 16-week PC period, long-term treatment period to Week 52, and follow-up period to Week 60. Randomization was stratified by region, concomitant antibiotic use (yes / no), and body weight (< 90 / ≥ 90 kg). Placebo group was rerandomized (1:1) to secukinumab 300 mg every 2 weeks or every 4 weeks at Week 16. *Primary Efficacy Measure:* Week-16 HiSCR, defined as a decrease in abscess and inflammatory nodule count by ≥ 50% with no increase in the number of abscesses or in the number of draining fistulae vs baseline. *PROs* were exploratory and included DLQI-5.
Population	*Included:* Adults ≥ 18 y of age; moderate to severe HS (total of ≥ 5 inflammatory lesions affecting at least two distinct anatomical areas) for at least 1 year; agreed to daily use of topical OTC antiseptics on affected areas. *Excluded:* ≥ 20 fistulae *Allowed:* Prior TNFI; stable dose of selected antibiotics (tetracycline up to 500 mg twice daily, minocycline up to 100 mg twice daily, or doxycycline up to 100 mg twice daily); rescue therapy for increased disease activity (e.g., intralesional corticosteroids, incision and drainage). However, patients who used rescue therapy were considered nonresponders. *Baseline Characteristics (N = 541):* Mean age 36.1 y, 44% men, 79% White; 82% had prior antibiotic use; 24% had prior systemic biologic use.
Interventions	Secukinumab 300 mg SC at Weeks 0, 1, 2, 3, and 4 then Q2W Secukinumab 300 mg SC at Weeks 0, 1, 2, 3, and 4 then Q4W
Comparator	Placebo
Results	Efficacy measures at Week 16

Outcome	SEC Q2W	SEC Q4W	PBO
HiSCR, n/N (%)	82/181 (45)	75/180 (42)	61/180 (34)
RR (95% CI)	1.3 (1.03, 1.73)	1.2 (0.94, 1.61)	Ref
AAE (95% CI)	114 (14, 214)	78 (22, 178)	Ref
DLQI-5, n/N (%)	64/134 (48)	62/128 (48)	37/128 (29)

	RR (95% CI)	1.6 (1.19, 2.29)	1.7 (1.21, 2.32)	Ref
	AAE (95% CI)	189 (73, 304)	195 (78, 312)	Ref

Blue text indicates that 95% CI excludes 1 for RR or 0 for AAE.

Onset of clinically meaningful difference: Week 4

Duration of an adequate therapeutic trial: HiSCR improved over time to Week 52.

Post-hoc analysis of HiSCR achieved at both Week 16 and Week 52: 44/58 (76%) and 42/52 (81%) on SEC Q2W and SEC Q4W, respectively.

Trial: **SUNRISE**[2]

Design: Same as SUNSHINE trial

Population: Same Inclusion and Exclusions as in SUNSHINE trial.

Baseline Characteristics (N = 543): Mean age 36.3 y, 44% men, 76% White; 84% had prior antibiotic use; 23% had prior systemic biologic use.

Interventions: Same as in SUNSHINE trial

Comparator: Placebo

Results: Efficacy measures at Week 16

Outcome	SEC Q2W	SEC Q4W	PBO
HiSCR, n/N (%)	76/180 (42)	83/180 (46)	57/183 (31)
RR (95% CI)	1.4 (1.03, 1.78)	1.5 (1.13, 1.93)	Ref
AAE (95% CI)	111 (12, 209)	150 (51, 249)	Ref
DLQI-5, n/N (%)	54/144 (38)	67/142 (47)	46/145 (32)
RR (95% CI)	1.2 (0.86, 1.63)	1.5 (1.11, 2.00)	Ref
AAE (95% CI)	58 (–52, 167)	155 (43, 266)	Ref

Onset of clinically meaningful difference: Week 2

Duration of an adequate therapeutic trial: HiSCR improved over time to Week 52.

Post-hoc analysis of HiSCR achieved at both Week 16 and Week 52: 51/61 (84%) and 50/65 (77%) on SEC Q2W and SEC Q4W, respectively.

Effect Size and GRADE Quality of Evidence: HiSCR: Small effect (low certainty evidence; downgraded for indirectness to a clinical outcome and imprecision with wide CIs).

DLQI-5: Small effect (low certainty evidence; downgraded for inconsistency between trials and imprecision due to suboptimal information size with wide CIs).

SAFETY CONSIDERATIONS	
Boxed Warnings	None
Contraindications	Hypersensitivity
Other Warnings	Infections, hypersensitivity reactions, tuberculosis (TB), inflammatory bowel disease, eczematous eruptions, risk of hypersensitivity in latex-sensitive individuals, immunization (avoid live vaccines)
Top AEs	Nasopharyngitis, diarrhea, upper respiratory tract infection
Drug Interactions	Certain CYP450 substrates, particularly those where minimal changes in concentration may affect efficacy or safety.
AEs in HS Trials	Consistent with those in psoriasis trials. Fungal infections (19/361 [5.3%] vs 14/360 [4.2%]) were somewhat more common on secukinumab 300 mg every 2 weeks than every 4 weeks. With long-term exposure, the incidences were 14.7/100 patient-years and 10.1/100 patient-years, respectively. In the placebo-controlled trial periods, inflammatory bowel disease (IBD) occurred in 1 patient in both secukinumab treatment groups (0.3% of each group). In the open-label phase, IBD was more common on secukinumab 300 mg every 2 weeks than 300 mg every 4 weeks (5 [0.7%] and no cases, respectively).[1]

PLACE IN THERAPY	BIOLOGIC	On VANF	RESTRICTIONS	FDA	NORTH AMERICAN HS GUIDELINES (2019)[3]
	Adalimumab	Yes	PA-F, restricted to providers appropriate for prescribing TNFis	Treatment of moderate to severe HS in patients ≥ 12 years of age	2nd line after rifampin + clindamycin for moderate to severe HS; recommended to improve disease severity and quality of life. Adalimumab was the only agent given an LOE = A and an SOR = I.
	Secukinumab	No	CFU for other indications	Treatment of adults with moderate to severe HS.	FDA approved for HS in 2023.
	Infliximab-abda	Yes	PA-F, restricted to providers appropriate for prescribing TNFIs	Off-label	2nd line after rifampin + clindamycin for moderate to severe HS; however, dose-ranging studies are needed to determine optimal dosage. LOE = B; SOR = II.
	Anakinra	No	COVID-19 Emergency Use Authorization	Off-label	May be effective for HS at dosage of 100 mg daily; however, dose-ranging studies are needed to determine optimal dosage. LOE = B; SOR = II.
	Ustekinumab	No	CFU for other indications	Off-label	May be effective for HS at dosage of 45mg every 12 weeks; however, placebo-controlled dose-ranging studies are needed to determine optimal dosage. LOE = B; SOR = II.
	Golimumab	No	No	Off-label	Only 2 case reports. LOE = C; SOR = III.

LOE = A, recommendation based on consistent and good-quality patient-oriented evidence; LOE = B, recommendation based on inconsistent or limited-quality patient-oriented evidence; LOE = C, recommendation based on consensus, opinion, case studies, or disease-oriented evidence; SOR = I, good-quality patient-oriented evidence; SOR = II, limited-quality patient-oriented evidence; SOR = III, other evidence including consensus guidelines, opinion, case studies, and disease-oriented evidence

VHA PLACE IN THERAPY	
Potential Use in VHA	1. Treatment of moderate to severe HS after a trial of adalimumab / biosimilar (preferred) or infliximab / biosimilar (alternative).

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References

1 COSENTYX (secukinumab) injection for subcutaneous or intravenous use [prescribing information online]. East Hanover, NJ: Novartis Pharmaceuticals. July 2023. Available at: cosentyx.pdf (novartis.com). Accessed 3 November 2023.

2 Kimball AB, Jemec GBE, Alavi A, Reguiai Z, Gottlieb AB, Bechara FG, Paul C, Giamarellos Bourboulis EJ, Villani AP, Schwinn A, Ruëff F, Pillay Ramaya L, Reich A, Lobo I, Sinclair R, Passeron T, Martorell A, Mendes-Bastos P, Kokolakis G, Becherel PA, Wozniak MB, Martinez AL, Wei X, Uhlmann L, Passera A, Keefe D, Martin R, Field C, Chen L, Vandemeulebroecke M, Ravichandran S, Muscianisi E. Secukinumab in moderate-to-severe hidradenitis suppurativa (SUNSHINE and SUNRISE): week 16 and week 52 results of two identical, multicentre, randomised, placebo-controlled, double-blind phase 3 trials. Lancet. 2023 Mar 4;401(10378):747-761. doi: 10.1016/S0140-6736(23)00022-3. Epub 2023 Feb 3. PMID: 36746171.

3 Alikhan A, Sayed C, Alavi A, Alhusayen R, Brassard A, Burkhart C, Crowell K, Eisen DB, Gottlieb AB, Hamzavi I, Hazen PG, Jaleel T, Kimball AB, Kirby J, Lowes MA, Micheletti R, Miller A, Naik HB, Orgill D, Poulin Y. 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. J Am Acad Dermatol. 2019 Jul;81(1):91-101. doi: 10.1016/j.jaad.2019.02.068. Epub 2019 Mar 11. PMID: 30872149; PMCID: PMC9131892.