

Cosentyx® (secukinumab) - New indication

- On June 17, 2020, <u>Novartis announced</u> the <u>FDA approval</u> of <u>Cosentyx (secukinumab)</u>, for the
 treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective
 signs of inflammation.
- Cosentyx is also approved for the treatment of adult patients with moderate to severe plaque psoriasis, active psoriatic arthritis, and active ankylosing spondylitis.
- The efficacy of Cosentyx was evaluated in a randomized, double-blind study of 555 adult patients
 with nr-axSpA. Patients received Cosentyx with a loading dose, Cosentyx without a loading dose or
 placebo. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis
 International Society (ASAS40) at week 52.
 - A total of 70% of patients receiving Cosentyx without a loading dose, 62% of patients receiving Cosentyx with a loading dose vs. 36% of placebo patients met the primary endpoint (treatment difference vs. placebo: Cosentyx without a load: 19% [95% CI: 10, 28] and Cosentyx with a load: 14% [95% CI: 5, 23]).
- The dose of Cosentyx for nr-axSpA is administered with or without a loading dose as a subcutaneous (SC) injection as follows:
 - With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
 - Without a loading dosage: 150 mg every 4 weeks.
 - Cosentyx is intended for use under the guidance and supervision of a physician. Patients
 may self-inject after proper training in SC injection technique using the Sensoready pen or
 prefilled syringe and when deemed appropriate.
 - The lyophilized powder for reconstitution is for healthcare provider use only.
 - Refer to the Cosentyx drug label for dosing recommendations for its other indications.



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