RXADVANCE
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Taltz (ixekizumab) Injection

Clinical Update

Clinical Update: FDA Approval for the Treatment of Non-Radiographic Axial Spondyloarthritis (nr-axSpA)
FDA approval date: May 29, 2020

Taltz® (ixekizumab) is a monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Taltz inhibits the release of pro-inflammatory cytokines and chemokines. It is indicated for the treatment of:

- Patients aged 6 years or older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Adults with active psoriatic arthritis.
- Adults with active ankylosing spondylitis.

Lilly's Taltz® ((ixekizumab) is the First IL-17A Antagonist to receive U.S. FDA Approval for the treatment of Non-Radiographic Axial Spondyloarthritis (nr-axSpA).

FDA Approval for the Treatment of Non-Radiographic Axial Spondyloarthritis (nr-axSpA) based on the results from the Phase 3 COAST-X trial, which evaluated improvement in signs and symptoms of nr-axSpA as measured by the proportion of patients who achieved Assessment of Spondyloarthritis International Society 40 (ASAS40) response criteria compared to placebo. ASAS40 measures disease signs and symptoms such as pain, inflammation and function.

The safety profile of Taltz in patients with nr-axSpA was consistent with previous experience with Taltz in other approved indications. Taltz should not be used in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients. Taltz may increase the risk of infection. Other warnings and precautions for Taltz include pre-treatment evaluation for tuberculosis, hypersensitivity, inflammatory bowel disease, and immunizations.