BlueCross BlueShield Federal Employee Program

BIMZELX
(bimekizumab-bkzx)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Bimzelx (bimekizumab-bkzx) is subcutaneous injectable treatment that helps regulate inflammation in patients with moderate to severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA), active ankylosing spondylitis (AS), and moderate to severe hidradenitis suppurativa (HS). Bimzelx is a humanized immunoglobulin IgG1/κ monoclonal antibody with two identical antigen binding regions that selectively bind to interleukin 17A (IL-17A), interleukin 17F (IL-17F), and interleukin 17-AF cytokines, and inhibits their interaction with the IL-17 receptor complex. IL-17A and IL-17F are naturally occurring cytokines that are involved in normal inflammatory and immune responses. Bimzelx inhibits the release of proinflammatory cytokines and chemokines (1).

Regulatory Status

FDA-approved indications: Bimzelx is a humanized IL-17A and IL-17F antagonist indicated for the treatment of: (1)

- Moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- Adults with active psoriatic arthritis (PsA).
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
- Adults with active ankylosing spondylitis (AS).
- Adults with moderate to severe hidradenitis suppurativa (HS).

Bimzelx may increase the risk of suicidal ideation and behavior. Patients with new or worsening symptoms of depression, suicidal ideation, or other mood changes should be referred to a mental health professional, as appropriate. Prescribers should also weigh the risks and benefits of treatment with Bimzelx in patients with a history of severe depression and/or suicidal ideation or behavior (1).

Bimzelx may increase the risk of infection. Patients should seek medical advice if signs and symptoms of clinically important infection occurs. Patients should also be evaluated for tuberculosis (TB) infection prior to initiating treatment. Do not administer to patients with active TB

infection. Initiate treatment for latent TB prior to administering Bimzelx (1).

Elevations in serum transaminases can occur with Bimzelx use. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management (1).

Inflammatory bowel disease (IBD) has been reported with IL-17 inhibitors. Use of Bimzelx should be avoided in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening signs and symptoms occur (1).

The safety and effectiveness of Bimzelx have not been evaluated in pediatric patients (1).

Summary

Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA), active ankylosing spondylitis (AS) and moderate to severe hidradenitis suppurativa (HS). It is administered as an injection under the skin. Bimzelx has been associated with an increased risk of suicidal ideation and behavior, increased risk of infection, elevated serum transaminases, and inflammatory bowel disease (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bimzelx while maintaining optimal therapeutic outcomes.

References

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024