BlueCross BlueShield Federal Employee Program

OMVOH
(mirikizumab-mrkz)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Omvoh (mirikizumab-mrkz) is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human interleukin (IL)-23 cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets, and innate immune cell subsets, which represent sources of pro-inflammatory cytokines. Research in animal models has shown that pharmacological inhibition of IL-23p19 can ameliorate intestinal inflammation. Omvoh inhibits the release of pro-inflammatory cytokines and chemokines (1).

Regulatory Status

FDA-approved indication: Omvoh is an interleukin-23 antagonist indicated for the treatment of: (1)

- moderately to severely active ulcerative colitis (UC) in adults.
- moderately to severely active Crohn's disease in adults.

Omvoh may increase the risk of infections. Omvoh should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves (1).

Evaluate patients for tuberculosis infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Omvoh. Consider anti-tuberculosis therapy prior to initiation of Omvoh in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Omvoh should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Omvoh may cause hepatotoxicity. Liver enzymes and bilirubin should be evaluated at baseline and for at least 24 weeks of treatment. Consider other treatment options in patients with evidence of liver cirrhosis (1).

The safety and effectiveness of Omvoh in pediatric patients less than 18 years of age have not

been established (1).

Summary

Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD) in adults. Omvoh has warnings regarding infections, tuberculosis, hepatotoxicity, and immunizations. The safety and effectiveness of Omvoh in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2025.