BlueCross BlueShield Federal Employee Program

TAKHZYRO
(lanadelumab-flyo)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Takhzyro (lanadelumab-flyo) is a fully human monoclonal antibody that binds plasma kallikrein and inhibits its proteolytic activity. Plasma kallikrein is a protease that cleaves high-molecular-weight-kininogen (HMWK) to generate cleaved HMWK (cHMWK) and bradykinin, a potent vasodilator that increases vascular permeability resulting in swelling and pain associated with hereditary angioedema (HAE). In patients with HAE due to C1-inhibitor deficiency or dysfunction, normal regulation of plasma kallikrein activity is not present, which leads to uncontrolled increases in plasma kallikrein activity and results in angioedema attacks. Takhzyro decreases plasma kallikrein activity to control excess bradykinin generation in patients with HAE (1).

Regulatory Status

FDA-approved indication: Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older (1).

Hypersensitivity reactions may occur. In the case of a severe hypersensitivity reaction, Takhzyro should be discontinued, and appropriate treatment should be instituted (1).

The safety and effectiveness of Takhzyro in pediatric patients less than 2 years of age have not been established (1).

Summary

Takhzyro (lanadelumab-flyo) is a fully human monoclonal antibody that binds plasma kallikrein and inhibits its proteolytic activity. Plasma kallikrein is a protease that cleaves high-molecular-weight-kininogen (HMWK) to generate cleaved HMWK (cHMWK) and bradykinin, a potent vasodilator that increases vascular permeability resulting in swelling and pain associated with hereditary angioedema (HAE). In patients with HAE due to C1-inhibitor deficiency or dysfunction, normal regulation of plasma kallikrein activity is not present, which leads to uncontrolled increases in plasma kallikrein activity and results in angioedema attacks. Takhzyro decreases plasma kallikrein activity to control excess bradykinin generation in patients with HAE. The safety and effectiveness of Takhzyro in pediatric patients less than 2 years of age have not been established (1).

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

References

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; February 2023.