BlueCross BlueShield Federal Employee Program

PIASKY
(crovalimab-akkz)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Piasky (crovalimab-akkz) is a monoclonal antibody that specifically binds with high affinity to the complement protein C5, inhibiting its cleavage into C5a and C5b, preventing the formation of the membrane attack complex (MAC). Piasky inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH) (1).

Regulatory Status

FDA-approved indications: Piasky is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg (1).

Piasky includes a boxed warning citing the increased risk of serious infections caused by Neisseria meningitidis. Vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) should be completed or updated at least 2 weeks prior to the first dose of Piasky, unless the risks of delaying therapy with Piasky outweigh the risk of developing a serious infection (1).

Piasky is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Piasky REMS, prescribers must enroll in the program (1).

In addition, Piasky has warnings regarding Type III hypersensitivity reactions, other infections, and infusion- and injection-related reactions (1).

Piasky is contraindicated in patients with unresolved serious Neisseria meningitidis infection (1).

The safety and effectiveness of Piasky in pediatric patients less than 13 years of age and in those with body weight < 40 kg have not been established (1).

Summary

Piasky is a complement C5 inhibitor indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Piasky includes a boxed warning citing the risk of serious and life-threatening infections caused by Neisseria meningitidis. Piasky is available only through a

restricted program under a Risk Evaluation and Mitigation Strategy (REMS). The safety and effectiveness of Piasky in pediatric patients less than 13 years of age and in those with body weight < 40 kg have not been established (1).

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

References

1. Piasky [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.