



**BlueCross
BlueShield**

Federal Employee Program.

VYNDAGEL (tafamidis meglumine), VYNDAMAX (tafamidis)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process (1).

Regulatory Status

FDA-approved indication: Vyndaqel and Vyndamax are indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization (1).

Vyndaqel and Vyndamax are not substitutable on a per mg basis (1).

Vyndaqel and Vyndamax have not been studied in: New York Heart Association (NYHA) class IV, primary light chain amyloidosis, prior liver or heart transplantation, or implanted cardiac mechanical assist device (1).

The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Summary

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process. The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

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

References

1. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Inc.; October 2023.