

WAINUA (eplontersen)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Wainua (eplontersen) is an antisense oligonucletodie-Ga1NAc conjugate that causes degradation of mutant and wild-type TTR mRNA through binding to the TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues (1).

Regulatory Status

FDA-approved indication: Wainua is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults (1).

The recommended dosage of Wainua if 45 mg administered by subcutaneous injection once monthly (1).

Wainua treatment leads to a decrease in serum vitamin A levels. Supplementation at the recommended daily allowance of vitamin A is advised for patients taking Wainua. Higher doses than recommended daily allowance of vitamin A should not be given to try to achieve normal serum vitamin A levels during treatment with Wainua, as serum vitamin A levels do not reflect the total vitamin A in the body. Patients should be referred to an ophthalmologist if they develop ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) (1).

The safety and effectiveness of Wainua in pediatric patients have not been established (1).

Summary

Wainua is an antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. It is recommended that patients treated with Wainua be supplemented with the recommended daily allowance of vitamin A. The safety and effectiveness of Wainua in pediatric patients have not been established (1).

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



Federal Employee Program.

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References

1.	. Wainua [package inser	t]. Wilmington,	, DE: AstraZeneca	Pharmaceuticals	LP; September
	2024.				