BlueCross BlueShield
Federal Employee Program

ALPHA1-PROTEINASE INHIBITORS

Aralast NP, Glassia, **Prolastin-C**, Zemaira

Preferred Alpha1-Proteinase Inhibitor: Prolastin-C

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Aralast NP, Glassia, Prolastin-C, and Zemaira are intravenous infusions indicated for individuals with clinically evident emphysema due to severe deficiency of $Alpha_1$-PI, also known as $alpha_1$-antitrypsin (AAT) deficiency. These medications increase antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of $Alpha_1$-PI. Intravenous administration of purified preparations of pooled donor-derived human AAT has been shown to augment levels of AAT and the AAT-related anti-elastase capacity of serum and lung epithelial lining fluid. The current U.S. Food and Drug Administration (FDA)-approved intravenous augmentation therapy dose for chronic administration is 60 mg/kg body weight, administered weekly (1-6).

Regulatory Status

FDA-approved indications: Aralast NP, Glassia, Prolastin-C, and Zemaira are indicated for chronic augmentation therapy in individuals with clinically evident emphysema due to severe congenital deficiency of $alpha_1$-PI (1-4).

The safety of $Alpha_1$-Proteinase Inhibitors in patients with severe renal impairment (creatinine clearance (CrCl) less than 30 mL/min) or end-stage renal disease has not been studied. The safety of $Alpha_1$-Proteinase Inhibitors in patients with moderate to severe hepatic impairment has not been studied (1-4).

Intravenous augmentation therapy is recommended for individuals with AATD and an FEV1 in the range of 30%-65% predicted (strong recommendation, high quality evidence) (6).

High value is placed on the potential to prolong survival in this group, the finding that intravenous augmentation therapy is associated with lower levels of elastin degradation products in individuals with AATD, and lower rates of loss of CT lung density in individuals with AATD-COPD receiving augmentation therapy. Low value is placed on the cost of this therapy (6).

The safety and effectiveness of $Alpha_1$-Proteinase Inhibitors in pediatric patients have not been

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established (1-4).

Summary

Aralast NP, Glassia, Prolastin-C, and Zemaira are intravenous infusions indicated for individuals with clinically evident emphysema due to severe deficiency of $Alpha_1$-PI, also known as $alpha_1$-antitrypsin (AAT) deficiency. The safety of $Alpha_1$-Proteinase Inhibitors in patients with severe renal impairment (creatinine clearance less than 30 mL/min), end-stage renal disease or moderate to severe hepatic impairment has not been studied. The safety and effectiveness of $Alpha_1$-Proteinase Inhibitors in pediatric patients have not been established (1-4).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Aralast NP, Glassia, Prolastin-C, and Zemaira while maintaining optimal therapeutic outcomes.

References

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3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; May 2020.
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6. Sandhaus R, Turino G, et al. The Diagnosis and Management of Alpha-1 Antitrypsin Deficiency in the Adult. Journal of the COPD Foundation. Volume 3 Number 3 2016.