ALPHA1-PROTEINASE INHIBITORS
Aralast NP, Glassia, Prolastin-C, Zemaira

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 Alpha₁-PI, also known as alpha₁-antitrypsin (AAT) deficiency. These medications increase antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha₁-PI (1-5).

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 alpha₁-PI (1-4).

The safety of Alpha₁-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 Alpha₁-Proteinase Inhibitors in patients with moderate to severe hepatic impairment has not been studied (1-4).

The safety and effectiveness of Alpha₁-Proteinase Inhibitors in pediatric patients have not been 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 Alpha₁-PI, also known as alpha₁-antitrypsin (AAT) deficiency. The safety of Alpha₁-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 Alpha₁-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