PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Lamzede (velmanase alfa -tycv)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Lamzede, approved by the FDA in 2023, is recombinant human lysosomal alpha-mannosidase indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients. Alpha-mannosidosis (AM) is a rare, progressive lysosomal storage disorder caused by pathogenic variants in the MAN2B1 gene, resulting in accumulation of mannose-rich oligosaccharides.
Lamzede is an enzyme replacement therapy intended to provide alpha-mannosidase, the enzyme that is deficient in AM. It is the first approved treatment for AM but does not cross the blood brain barrier and therefore it not expected to benefit the neurological aspects of the disease. In a Phase 3 clinical trial, 3-minute stair climbing test (3MSCT), 6-minute walking test (6MWT) and forced vital capacity (FVC) numerically favored the Lamzede group and results were supported by a reduction in serum oligosaccharide concentration.

Lamzede (velmanase alfa-tycv) will be considered for coverage when the following criteria are met:

Alpha-Mannosidosis

[redacted]