PHARMACY POLICY STATEMENT

BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Galafold is an alpha-galactosidase A (alpha-Gal A) pharmacological chaperone indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. It is estimated that the amenable variants are present in 35-50% of the Fabry disease patient population. Galafold is an alternative to enzyme replacement therapy (ERT) and is taken orally. It increases activity of the deficient enzyme instead of replacing it.
Fabry disease is an X-linked lysosomal storage disorder caused by mutations in the GLA gene that cause deficiency of the alpha-galactosidase A (alpha-Gal A) lysosomal enzyme. Normally this enzyme breaks down certain lipids in lysosomes, such as globotriaosylceramide (GL-3). Without it, GL-3 accumulates in blood vessels, the kidneys, heart, nerves, and other organs.

Galafold (migalastat) will be considered for coverage when the following criteria are met: