Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

ELELYSO™ (taliglucerase alfa)

GPI CODING:

82700080102120

DESCRIPTION:

Elelyso is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type 1 Gaucher disease. Elelyso is a recombinant active form of the lysosomal enzyme, β-glucocerebrosidase. Elelyso is produced by recombinant DNA technology using plant cell culture (carrot). β-glucocerebrosidase catalyzes the hydrolysis of the glycolipid glucocerebroside to glucose and ceramide. Gaucher disease is a genetic disorder that leads to a deficiency of β-glucocerebrosidase. This deficiency results in accumulation of the substrate, glucocerebroside, in tissue macrophages typically found in the liver, spleen and bone marrow. Complications of Gaucher disease include anemia, thrombocytopenia, hepatosplenomegaly, and skeletal problems such as osteonecrosis and osteopenia.

APPROVAL DURATION:

Approval duration: 24 months

CRITERIA FOR ELELYSO

I. Member has a diagnosis of type 1 Gaucher disease, **AND**
II. Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of β-glucocerebrosidase enzyme activity **AND**
III. Member is ≥ 18 years of age **AND**
IV. Member has at least 1 of the following complication of Gaucher disease
   A. Anemia
   B. Thrombocytopenia
   C. Bone disease (e.g., bone pain, bone crises, fractures, osteonecrosis, subchondral joint collapse)
   D. Hepatomegaly or splenomegaly

AND

V. Elelyso will not be used in combination with Zavesca (miglustat)