Elelyso™ (taliglucerase alfa)
(Intravenous)

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Medical Guideline Disclaimer

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LENGTH OF AUTHORIZATION

Coverage will be provided for 12 months and may be renewed.

DOSSING LIMITS

Max Units (per dose and over time) [Medical Benefit]:

- 700 billable units every 14 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

Type 1 Gaucher’s Disease †

- Patient at least 4 years of age; **AND**

- Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by reduced glucocerebrosidase activity in peripheral leukocytes; **AND**

- **Adults only criteria (patient at least 18 years or older):** Patient’s disease results in one or more of the following:
  - Anemia [hemoglobin less than or equal to 11 g/dL (women) or 12 g/dL (men) ]; **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
• Skeletal disease (e.g. lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.); OR

• Symptomatic disease (e.g. bone pain, fatigue dyspnea, angina, abdominal distension, diminished quality of life, etc.); OR

• Thrombocytopenia (platelet count less than or equal to 120,000/mm³); AND

• Must be used as a single agent

† FDA Approved Indication(s)

II. RENEWAL CRITERIA

• Patient continues to meet the criteria in Section I; AND

• Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  o Improvement in symptoms (e.g. bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.)
  o Reduction in size of liver or spleen
  o Improvement in hemoglobin/anemia
  o Improvement in skeletal disease
  o Improvement in platelet counts; AND

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, etc.

Limitations/Exclusions
Elelyso is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

| J3060 | Injection, taliglucerase alfa, 10 units; 1 billable unit = 10 units |

Applicable NDCs

| 00069-0106-xx | Elelyso 200 unit powder for injection |

Applicable Diagnosis Codes

| E75.22 | Gaucher Disease |

Revision History

N/A
References