Clinical Oversight Review Board (CORB) Criteria for Prescribing

Alglucosidase alfa (Lumizyme)

Non-Formulary **alglucosidase alfa (Lumizyme)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

<u>Initiation (new start) criteria</u>: Non-formulary <u>alglucosidase alfa (Lumizyme)</u> will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

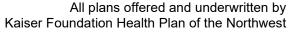
- Prescriber is metabolic specialist or geneticist.
- Patient has a diagnosis of Pompe disease (Acid alpha-glucosidase (GAA) deficiency)
- Diagnosis has been confirmed by one of the following:
 - Deficiency of acid alpha-glucosidase (GAA) enzyme activity; OR
 - Detection of biallelic pathogenic variants in the GAA gene by molecular genetic testing.
- Documented baseline values for one or more of the following:
 - <u>Infantile-onset disease</u>: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), or 6 minute walk test (6MWT)
 - <u>Late-onset (non-infantile) disease</u>: FVC or 6MWT.
- Will not be used in combination with other enzyme replacement therapies (i.e., avalglucosidase alfa-ngpt)

<u>Criteria for new members entering Kaiser Permanente already taking the</u>
<u>medication who have not been reviewed previously</u>: Non-formulary alglucosidase
alfa (Lumizyme) will be covered on the prescription drug benefit when the following
criteria are met:

- Prescriber is metabolic specialist or geneticist.
- Patient has a diagnosis of Pompe disease (Acid alpha-glucosidase (GAA) deficiency)
- Will not be used in combination with other enzyme replacement therapies (i.e., avalglucosidase alfa-ngpt)

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Revised: 09/08/22 Effective: 11/17/22





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Alglucosidase alfa (Lumizyme)

<u>Continued use criteria (12 months after initiation)</u>: Non-formulary alglucosidase alfa (Lumizyme) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
 - Infantile-onset disease: stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, and/or 6MWT
 - <u>Late-onset (non-infantile) disease</u>: stabilization or improvement in FVC and/or 6MWT

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