

SENTARA HEALTH PLANS

PHARMACY Pancreatic Enzyme Utilization Criteria for Cystic Fibrosis

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to **1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization may be delayed.

Drug Requested: PHARMACY Pancreatic Enzyme Utilization Criteria for Cystic Fibrosis

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

Current Weight in kg: _____ Tube Feed: Yes No

Requested medication: _____ Total # caps / day: _____

Current Dosing Schedule: _____

Additional information: _____

Pharmacy Name: _____ Pharmacy Tel #: _____

CLINCIAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

(Continued on next page)

The dose of lipase that you are requesting for your patient may put them at an increased risk of developing adverse drug reactions.

- Pancreatic enzyme replacement is often necessary when the lack of digestive enzymes impairs the ability to digest foods effectively, leading to malabsorption. However, adverse effects of enzyme replacement, in particular high-dose therapy, include diarrhea, flatulence, hyperuricosuria, fibrosing colonopathy, and strictures.^{1,2,3}
- Currently, there are no studies outlining the safety, efficacy, or superiority of lipase doses exceeding current guidelines for infants through young adults with cystic fibrosis. For these reasons, Optima Health supports the Cystic Fibrosis Foundation Consensus Conference Guidelines for pancreatic enzyme replacement. Dosing should not exceed the recommended maximum dosages as noted below.

Infants (up to 12 months)

- Infants may be given 2,000 to 4,000 lipase units per 120ml of formula or per breast feeding.

Children Older than 12 months and Younger than 4 Years

- Begin with 1,000 lipase units per kg of body weight per meal to a maximum of 2,500 lipase units per kg of body weight per meal (or less than or equal to 10,000 lipase units per kg of body weight per day), or less than 4,000 lipase units per gram of fat ingested per day.

Children 4 Years and Older

- Begin with 500 lipase units per kg of body weight per meal for those older than 4 years to a maximum of 2,500 lipase units per kg of body weight per meal (or less than or equal to 10,000 lipase units per kg of body weight per day), or less than 4,000 lipase units per gram of fat ingested per day.

¹ Pharmacotherapy 2007; 27(6): 910-920.

² N Engl J Med 1997; 336: 1283-1289

³ The Lancet 1994; 343(8889):85-6.

****Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****