

# OPTIMA HEALTH COMMUNITY CARE

## 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 1-800-319-5003. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete forms will delay the authorization process.

**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.<sup>1,2,3</sup>
- 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.

Current Weight in kg: \_\_\_\_\_ Tube Feed:  Yes  No  
Requested medication: \_\_\_\_\_ Total # caps / day: \_\_\_\_\_  
Current Dosing Schedule: \_\_\_\_\_

***\*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.\***

Patient Name: \_\_\_\_\_

Member Optima #: \_\_\_\_\_ Member Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

Additional information: \_\_\_\_\_

Pharmacy Name: \_\_\_\_\_ Pharmacy Tel #: \_\_\_\_\_

REVISED/UPDATED: 6/29/2017.

<sup>1</sup> Pharmacotherapy 2007; 27(6): 910-920.

<sup>2</sup> N Engl J Med 1997; 336: 1283-1289

<sup>3</sup> The Lancet 1994; 343(8889):85-6.