HFS
Illinois Department of
Healthcare and Family Services

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Criteria For In-Line Digestive Enzyme (Lipase) Cartridge For Use with Enteral Tube Feedings

1. Diagnosis of a condition associated with fat malabsorption to include one of the following:
    a. Exocrine pancreatic insufficiency (EPI)
    b. Short bowel syndrome (SBS)
    c. Other diagnosis associated with chronic fat malabsorption; AND

2. With receipt of the first prior approval submission of laboratory test(s) results and diagnostic work-up confirming any of the above, or as applicable with those with SBS operative report(s) documenting what portion and how much of the bowel was resected with amount of remaining bowel, and as applicable any operative report(s) related to bowel lengthening surgical procedure(s) or intestinal transplantation; AND

3. Attainment of a chronologic age of at least 1 year; AND

4. Failure to meet nutritional needs despite oral and enteral nutritional supplementation, and/or total parenteral nutritional dependence and as applicable for those with EPI despite pancreatic enzyme replacement therapy (PERT) thereby placing the customer at nutritional risk; AND

5. Date of institution and cessation of nutritional supplementation and PERT as applicable for any entry specified in #4; AND

6. For those receiving oral and/or enteral supplementation:

    a. Name of supplement
    b. Amount administered per day by each route
    c. Route of delivery (i.e., oral, orogastric tube, nasogastric tube, gastrostomy tube, gastrojejunostomy tube)
    d. Method of delivery (i.e., syringe, gravity, pump)
    e. Rate of delivery; AND

7. Failure to meet nutritional needs for a condition noted in #1 above despite involvement of a registered dietitian knowledgeable about these needs; AND

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8. For an existing lipase cartridge user:

    a. Date use started
    b. Number of cartridges used per day
    c. Details about enteral infusion (i.e., name of supplement, delivery method via syringe, gravity, pump, volume, rate of infusion, duration of infusion, and daily schedule); AND

9. Cartridge Quantity:
    a. Maximum 6 cartridges in a 24 hour time period
    b. For continuous or bolus feedings delivered by an enteral pump, a single cartridge may be used for up to 500 mls of enteral formula
    c. For continuous feedings with an enteral pump for volumes between 500 mls up to 1,000 mls, 2 cartridges may be connected in tandem
    d. For manual bolus by enteral syringe (push or gravity), a single cartridge may be used for up to 250 mls of enteral formula; AND

10. Proposed enteral formula must not contain insoluble fiber including blenderized formulas or food particulates; AND

11. Adherence to manufacturer's instructions, warnings, cautions, and precautions concerning approved use of the lipase cartridge including but not limited to use with enteral feeding pump systems with low flow/no flow alarms, enteral syringes for manual bolus by syringe (push or gravity), approved flow rates, and maximum allowable infusion interruption times; AND

12. Longitudinal data:
    a. For those 1-20 years old: CDC growth charts that are age and sex specific for height, weight, weight against stature up to limits of chart, and body mass index (BMI) with longitudinally plotted data spanning at least as far back as onset of nutritional supplementation and PERT as applicable.
    b. For adults over age 20: Height and weight measurements to calculate BMI or BMIs spanning at least as far back as date of onset of nutritional supplementation and use of PERT as applicable
    c. Prior approval requests for ongoing use in adults require updated BMI or weight measurement (provided height is already in file to calculate BMI) or weight and height

d. Device renewal for all customers requires documentation of improved growth for the pediatric aged customer, improved weight for the adult customer, or other evidence of improved nutritional status while utilizing the device.

13. Nutritional risk for a customer with cystic fibrosis is defined as:
    a. BMI less than 50th percentile for age and sex for those less than 21 years old; OR
    b. Adult women with cystic fibrosis with a BMI less than 22; OR
    c. Adult men with cystic fibrosis with a BMI less than 23.