From: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *(Physician Name & Subscriber Name)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Subscriber ID Number)*

To: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Insurance Provider)*

**SUBJECT: Insurance Coverage Request for Fortini™ Infant**

Dear Sir or Madam:

I am requesting insurance coverage and reimbursement for my patient, NAME, born on D.O.B., for whom I have prescribed the use of **Fortini™ Infant**, an energy- and nutrient-dense exempt infantformula. **Based on this patient’s clinical history, I have determined that this formula is medically necessary. INCLUDE IF APPROPRIATE: Fortini™ Infant** will be his/her sole source of nutrition.

At diagnosis, my patient’s weight was WEIGHT kg/lb and length was LENGTH in/cm. My patient’s present weight is WEIGHT kg/lb and length is LENGTH in/cm. He/She will require CALORIES kcal per day or FLUID OUNCES fl oz per day of **Fortini™ Infant**. This amount may be adjusted as his/her nutritional needs change. **Fortini™ Infant** can be taken orally or through an enteral feeding tube. In this case, it will be administered orally/by tube. **INCLUDE IF APPROPRIATE:** My patient requires a fluid restriction of VOLUME mL/fl oz and will not be able to meet calorie needs from standard infant formula due to the volume of intake that would be required.

**Fortini™** **Infant** is unique among nutritional interventions available to manage growth failure, risk of growth failure, increased energy requirements and/or fluid restrictions:

* clinically shown to support catch-up growth in infants with various causes of growth failure1-3
* supported by 7 clinical studies,1-7
* provides 10.3% of energy from protein, which meets expert recommendations to support appropriate catch-up growth and achievement of appropriate body composition8 - the only formula that meets these targets
* contains 25% more protein per 100 calories than available energy-dense term infant formulas, shown to support growth and promote anabolism1,5,6,9
* at a concentration of 30 kcal/fl oz to support growth in volume-restricted infants
* clinically shown to be well-tolerated in infants with various causes of growth failure1-3
* nutritionally complete
* ready-to-feed, sterile liquid to reduce the risks of concentration errors10-12 and bacterial contamination13-15

**Fortini™ Infant** is indicated for use from birth up to 18 months of age or 19 lbs 13 oz (9 kg) in patients with or at risk of growth failure, increased energy requirements and/or fluid restrictions. At this time, **Fortini™ Infant** is the only term infant formula available in the US that provides 30 kcal/fl oz and 2.6 g protein/100 kcal. My patient has been diagnosed with one or more of the following conditions that involve growth failure, increased energy needs and/or fluid restrictions:

|  |  |
| --- | --- |
| **Diagnosis** | **ICD-10 Code[[1]](#endnote-1)** |
| [ ]  **Congenital heart disease** | Q20.0-25.9 |
| **Chronic lung disease**[ ] Bronchopulmonary dysplasia, perinatal[ ] Other perinatal chronic respiratory condition[ ] Unspecified perinatal chronic respiratory condition | P27.1P27.8 P27.9 |
| [ ] **Respiratory syncytial virus** (as cause of other disease) | B97.4 |
| **Neurological syndrome or neuro-disabilities**[ ] Down syndrome[ ]  Muscular dystrophy[ ] Cerebral palsy | Q90.0-Q90.2, Q90.9G71.00, G71.02, G71.09, G71.11G80.0-G80.4, G80.8, G80.9 |
| [ ] **Cystic fibrosis** | E84.0-E84.9 |
| **Malnutrition (undernutrition) or Failure to thrive**[ ] Non-organic failure to thrive (Under 28 days old - Newborn)[ ] Non-organic failure to thrive (Over 28 days old - Child)[ ] Short stature (Over 28 days old – Child)[ ] Abnormal weight loss[ ] Underweight - Less than 5th percentile weight[ ] Cachexia[ ] Unspecified protein-calorie malnutrition[ ] Moderate protein-calorie malnutrition[ ] Mild protein-calorie malnutrition[ ] Retarded development following protein-calorie malnutrition[ ] Newborn affected by maternal nutritional disorders | P92.6R62.51R62.52R63.4R63.6 + Z68.51R64E43 or E46E44.0E44.1E45P00.4 |
| **Feeding difficulty**[ ] Feeding problems of newborn (Under 28 days old)[ ] Disorder of muscle, unspecified (including hypotonia or hypertonia)[ ]  Congenital hypertonia[ ]  Congenital hypotonia[ ] Feeding difficulties (Over 28 days old – Child)[ ] Other symptoms and signs concerning food and fluid intake[ ] Rumination disorder of infancy[ ] Other feeding disorders of infancy and childhood | P92.1-P92.9M62.9P94.1P94.2R63.3R63.8F98.21F98.29 |
| [ ] Other (specify): |  |

PATIENT has previously been managed with LIST FORMULA(s) and/or modular nutritional additive(s) which has/have proven ineffective.

**Fortini™ Infant** is not a drug, but the FDA classifies **Fortini™ Infant** as an “Exempt Infant Formula,” and must be used under medical supervision. FDA does not require a prescription for **Fortini™ Infant**: however, many pharmacies and homecare suppliers have policies that require a prescription to purchase **Fortini™ Infant** to ensure that the appropriate product is being dispensed and the patient is receiving medical supervision. This patient’s clinical nutritional status will be monitored by a (EDIT AS APPROPRIATE) pediatrician, cardiologist, gastroenterologist, registered dietitian and feeding specialist.

Your approval of this request for assistance with medical care and reimbursement of the formula would have a significant positive impact on this patient’s health.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Title*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Title – Center/Hospital/Institution/Practice*

Enclosures: Current Growth Chart, Letter of Dictation, Reports, Prescription

**Product and Reimbursement Information for Fortini™ Infant**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Product Code** | **Packaging** | **Calories per Carton** | **Yield per Case** | **NDC-format Code[[2]](#endnote-2)** | **HCPCS Code** |
| **Fortini™ Infant** | 161212 | 30 x 4 fl oz(Net 120 fl oz) | 118 kcal | 120 fl oz(3,540 kcal) | 49735-0112-12 | B4160 |

**References:**

**1.** Clarke, et al. J Hum Nutr Diet. 2007;20:329-39. **2.** Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10. **3.** Scheeffer, et al. JPEN J Parenter Enteral Nutr. 2020;44:348-54. **4.** Nutricia North America. https://clinicaltrials.gov/ct2/show/NCT03563391. **5.** Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204. **6.** van Waardenburg, et al. Clin Nutr. 2009;28:249-55. **7.** Evans, et al. J Hum Nutr Diet. 2006;19:191-7. **8.** World Health Organization; Food and Agriculture Organization of the United Nations. Protein and amino acid requirements in human nutrition. 2007. **9.** de Betue, et al. Arch Dis Child. 2011;96:817-22. **10.** Altazan, et al. Pediatr Obes. 2019;14:e12564. **11.** Altazan, et al. Pediatr Obes. 2019;14:e12564. **12.** Renfrew, et al. Arch Dis Child. 2003;88:855-8. **13.** Fagerman. Nutr Clin Pract. 1992;7:31-6. **14.** Labiner-Wolfe, et al. Pediatrics. 2008;122 Suppl 2:S85-90. **15.** Rocha Carvalho, et al. JPEN J Parenter Enteral Nutr. 2000;24:296-303.

1. This letter is intended to be used as a template and customized by the physician for each patient. The list of diagnoses and ICD-10 codes contained in this letter is not all-inclusive. It is ultimately the responsibility of the healthcare professionals/persons associated with the patient's care to determine and document the appropriate diagnosis(es) and code(s) for the patient's condition(s). Nutricia does not guarantee that the use of any information provided in this letter will result in coverage or payment by any third-party payer. [↑](#endnote-ref-1)
2. Nutricia North America does not represent codes to be National Drug Codes (NDCs). NDC-format codes are product codes adjusted according to standard industry practice to meet the format requirements of requirements of pharmacy and health insurance systems. [↑](#endnote-ref-2)