

Statement of Medical Necessity for Evivo®



Patient Name: _____ Date of Birth: _____

Cardholder's Name: _____ Cardholder's Birthdate: _____

Group or Group Number: _____ ID Number: _____

To whom it may concern:

I am requesting insurance coverage and reimbursement for my patient, for whom I have recommended the use of **Evivo®** (activated *B. infantis* EVC001), manufactured by Evolve BioSystems, Inc. Evivo is the first and only clinically proven Food for Special Dietary Use (FSDU), to substantially and persistently restore the infant gut microbiome.

In clinical trials, infants fed Evivo had an 80% reduction in potentially harmful bacteria such as *E. coli*, *Clostridium*, *Staphylococcus* and *Streptococcus*, a 79% increase in beneficial bacteria, 4x lower fecal endotoxin levels and a significantly lower fecal pH by ~1.5 log units.^{1,6} The abundance of potentially harmful bacteria may be a consequence of dysbiosis and may present as colic, fussiness and gas. Dysbiosis may also lead to the future development of eczema, allergies, obesity and diabetes.

Diagnosis	ICD-10 Code	Diagnosis	ICD-10 Code
<input type="checkbox"/> Newborn affected by cesarean delivery Long-term (current) use of antibiotics (Corresponding Z-Code—Z79.2)	P03.4	<input type="checkbox"/> Underweight	R63.6
<input type="checkbox"/> Newborn affected by unspecified maternal conditions	P00.9	<input type="checkbox"/> Excessive crying of infant (baby)	R68.11
<input type="checkbox"/> Meconium passage during delivery	P03.82	<input type="checkbox"/> Fussy infant (baby)	R68.12
<input type="checkbox"/> Preterm (premature), newborn (other)	P07.3	<input type="checkbox"/> Other symptoms and signs concerning food and fluid intake	R63.8
<input type="checkbox"/> Perinatal digestive system disorder, unspecified	P78.9	<input type="checkbox"/> Imbalance of constituents of food intake	E63.1
<input type="checkbox"/> Nutritional deficiency, unspecified	E63.9	<input type="checkbox"/> Sequelae of unspecified nutritional deficiency	E64.9
<input type="checkbox"/> Feeding problem of newborn, unspecified	P92.9	<input type="checkbox"/> Intestinal malabsorption, unspecified	K90.9
<input type="checkbox"/> Colic	R10.83	<input type="checkbox"/> Gastro-esophageal reflux	K21.9
<input type="checkbox"/> Feeding difficulties	R63.3	<input type="checkbox"/> Other nonspecific symptoms peculiar to infancy	R68.19
<input type="checkbox"/> Abnormal weight loss	R63.4	<input type="checkbox"/> Other general symptoms	R68.89
		<input type="checkbox"/> Other, please specify: _____	

RECOMMENDED PRODUCT

Product Description	Product Code	Product Reimbursement Code (NDC Formatted Number)
Evivo Starter Kit (28 x 0.625g)	854695008007	54695-0008-00
Evivo Powder Refill (28 x 0.625g)	854695008014	54695-0008-01



Based on my patient's current diagnosis, I am recommending **1 Sachet of Evivo (8 billion CFU) per day for _____ months.**

There is no other beneficial bacterium that has been clinically shown to substantially and persistently colonize the infant gut microbiome like Evivo (activated *B. infantis* EVC001). There is no substitution for Evivo; the benefits of probiotics are strain specific.

PROVIDER INFORMATION

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By signing below, I also acknowledge that I have obtained the legal guardian's authorization to release the above information and other medical information that may be disclosed. Approval for this request for insurance coverage and reimbursement of Evivo will make a significant impact on the health of this patient.

Provider Name: _____ Physician NPI#: _____

Contact Person: _____ Contact Phone: _____

Email: _____ Fax Number: _____

Address: _____

City: _____ State: _____ Zip: _____

Provider Signature: _____ Date: _____

References: 1. Underwood M et al. *Pediatr Res.* 2015;77:229-235. 2. Frese SA et al. *mSphere* 2017;2(6):e00501-17. 3. Tannock GW. *Int J. Epidemiol.* 2005;34:13-15. 4. Vatanen T et al. *Cell.* 2016;165(4):842-853. 5. Kalliomäki M et al. *Am. J Clin Nutr.* 2008;87(3):534-538. 6. Fujimura KE et al. *Nat Med.* 2016;22(10):1187-1191.

The list of diagnoses contained in this Statement of Medical Necessity (SMN) is not all-inclusive. It is ultimately the responsibility of the healthcare professional/persons associated with the patient's care to determine and document the appropriate diagnosis(es) and code(s) for the patient's condition. Evolve BioSystems, Inc. does not guarantee that the use of any information provided in the SMN will result in coverage or payment by any third-party payer.

