

Reference number(s)
337-A

Initial Prior Authorization Nutritional Supplements – Infant Formulas

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Lactose Free

Brand Name
CVS Sensitivity/Iron
Enfamil Lactofree Lipil
Lactofree
Lactofree Lipil
Similac Lactose Free
Similac Lactose Free Advance - Iron
Similac Pro-sensitive
Similac Pro-sensitive/Iron
Similac Sensitive
Similac Sensitive Non-GMO
Similac Sensitive Optigro/Iron
Similac Sensitive Spit-up
Similac Sensitive Pow Early Sh
Similac Spit-up
Similac Spit-up Optigro/Iron

Allergies

Brand Name
Alfamino Infant
Alfamino Junior
Alimentum
Elecare
Elecare Jr
Elecare DHA/ARA
Enfa Nutrami Pow Prob/LGG
Enfamil AA
Enfamil Nutramigen With Enflora
Equacare Jr
Essential Care Jr
Gerber Extensive Ha
Neocate
Neocate Infant
Neocate Infant DHA/ARA
Neocate Jr
Neocate Jr Prebiotic
Neocate One
Neocate Nutra
Neocate Syneo
Neocate Syneo Pow Junior
Nutramigen AA
Nutramigen Lipil Products
Nutramigen Liq DHA/ARA
Neocate Products
Pepticate
Puramino
Puramino Jr
Puramino Pow DHA/ARA
Similac Alim Liq Exp Care
Similac Alim Liq Immune
Similac Alim Pow Iron
Similac Alim Pow Toddler

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Malabsorption/Specialized

Brand Name
Enfa Pregestimil Liq Lipil
Pregestimil

Indications

FDA-approved Indications

N/A

Coverage Criteria

Authorization may be granted for the requested product when ONE of the following criteria are met:

- The product is medically necessary due to severe food allergies and the following criteria is met:
 - The patient has tried at least two standard (cow's milk based) enteral nutrition formulas
- The product is medically necessary due to a diagnosis of lactose intolerance
- The product is medically necessary to avoid serious malnutrition
- Lack of this product would result in serious disability or death

Duration of Approval (DOA)

- 337-A: DOA: Lifetime

References

1. Mass. Gen. Laws Ch. 176B Section 4K, Coverage for nonprescription enteral formulas for home use. Available at: <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176B/Section4K>.
2. California Code of Regulations [CCR], Title 22, Section 51313.3. Available at: <https://files.medical.ca.gov/pubsdoco/Publications/masters-MTP/Part2/enteral.pdf>.
3. RI Gen L § 27-41-74 (2021) Enteral nutrition products. Available at: <https://law.justia.com/codes/rhode-island/2021/title-27/chapter-27-41/section-27-41-74/>.

Document History

Written by: UM Development (NB)

Date Written: 01/2008

Revised: UM Development (SE) 04/2009; 02/2010, 04/2012 (Added Similac Alim Liq Exp Care, removed Prosoabee, Prosoabee Lipil 02-2010 (3)), 06/2012, (SE) 04/2013, 08/2013, 01/2014, 04/2014, 08/2014, 12/2014, 03/2015 (SF) 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 12/2017, 10/2018 12/2018, 12/2019, 05/2020, 12/2020; (RP) 06/2021 (added products to target list); (RZ) 10/2021 (added products to target list), 12/2021 (no clinical changes), (VLS) 12/2022 (no clinical changes), 02/2023 (added products to target list), 12/2023 (added products to target drug list), 12/2023 (no clinical changes), 03/2024 (added products to target drug list), 07/2024 (added products to target drug list), 12/2024 (no clinical changes)

Reviewed: CDPR: 01/2008; Medical Affairs (WLF) 04/2009, (DNC) 06/2012, (KP) 04/2013, (LMS) 08/2013, (KP) 01/2014, (SES) 04/2014, (DHR) 08/2014, (DNC) 12/2014, (SES) 04/2015 (DNC) 06/2015, (LCB) 09/2015, (JG) 12/2016, (LMS) 12/2017, (EPA) 12/2018, (CHART) 01/09/2020, 06/04/2020, 01/14/2021, 07/08/2021, 11/04/2021, 12/30/2021, 12/29/2022, 02/2023, 12/13/2023, 12/21/2023, 03/28/2024, 07/18/2024, 01/16/2024

External Review: 08/2008, 08/2012

CRITERIA FOR APPROVAL			
1	Is this product medically necessary due to severe food allergies? [If Yes, then go to 2. If No, then go to 3.]	Yes	No
2	Has the patient tried at least two standard (cow's milk based) enteral nutrition formulas? [No further questions]	Yes	No
3	Is this product medically necessary due to a diagnosis of lactose intolerance? [If Yes, then no further questions. If No, then go to 4.]	Yes	No

4	Is this product medically necessary to avoid serious malnutrition? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Would lack of this product result in serious disability or death? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Go to 3	
2.	Approve, LIFETIME	Deny	Your plan only covers this drug if you have tried two cow's milk based formulas, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
3.	Approve, LIFETIME	Go to 4	
4.	Approve, LIFETIME	Go to 5	
5.	Approve, LIFETIME	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) When you have a medical need for it due to severe food allergies, B) When you have a medical need for it due to lactose intolerance, C) When you have a medical need for it to avoid serious malnutrition, and D) When lack of this product would result in serious injury or death. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet

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			<p>other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
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