
Title: New Jersey Infant Formula Mandate
Policy #: Rx.01.60

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for infant formulas as provided under the member's prescription drug benefit.

Description:

Consideration for non-standard formula coverage is available only to infants enrolled in an AmeriHealth New Jersey plan that includes coverage for prescription drugs. In accordance with New Jersey Senate Bill 1839, specialized non-standard infant formula is covered when an infant is diagnosed as having multiple food protein intolerance that has not been responsive to trials of standard non-cow milk based formulas. Standard formulas include milk-based, soy-based, and milk-based lactose free products.

Specialized formulas for infants with metabolic disorders are not covered through the prescription drug benefit. Metabolic formulas are covered through the medical benefit.

Coverage for non-standard formulas is subject to utilization review, including periodic review, of the continued medical necessity of the specialized infant formula. Under Senate Bill 1839, "infant" is defined as birth through age 12 months.

Policy:

Non-standard formulas, including, but not limited to, Enfamil®, Pregestimil®, Neocate®, EleCare®, Portagen®, Alimentum®, Similac Expert Care Alimentum®, Similac NeoSure®, Similac® PM 60/40, Similac Special Care® are approved when all of the following inclusion criteria are met:

- a. Documentation that the infant is 12 months old or younger; and
- b. Documentation of a diagnosis of multiple food protein intolerance; and
- c. Documentation infant has not been responsive to at least one trial of a standard non-cow milk-based formula, including soybean or goat milk

APPROVAL LENGTH: Through member's age of 12 months

QUANTITY LIMIT = four cases for a 30-day supply per copay or co-insurance

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

New Jersey Senate Bill 1839, dated January 22, 2001. Available at: http://www.nileg.state.nj.us/2000/Bills/S2000/1839_S1.PDF . Accessed March 29,2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

N/A

Cross References:

Off-Label Use Rx.01.33

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| Policy Version Number: | 12.00 |
| P&T Approval Date: | March 18,2021 |
| Policy Effective Date: | July 01, 2021 |
| Next Required Review Date: | March 18, 2022 |

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

