August 19, 2022

Re: Update and Consideration for Reprieve of Enteral Formula Authorization Requirements and Limited Formularies

To Whom it May Concern,

The American Association for Homecare (AAHomecare) is writing to provide you information about recent changes in the enteral formula market due to (1) the current COVID-19 public health emergency (PHE), (2) the recall of a major manufacturer’s enteral formulas, and (3) the well-documented supply chain challenges. As is the case with most health care providers during the current pandemic, providers of enteral formulas have experienced significantly increased costs of doing business. More notable is the drastic impact to the life-sustaining enteral formula market due to the lack of product availability and the need for patients to switch to different enteral formulas which may be different than the originally prescribed formula.

AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures that the families and individuals you cover receive cost effective, safe, and reliable homecare products and services. Our members supply home nutrition products (including tube feedings and primary or exclusive sources of nutrition), oxygen therapy, positive airway pressure devices, ventilator services, complex rehabilitation technology (CRT) and many other medically necessary home medical equipment (HME) items and services that allow patients to be discharged from hospitals, nursing homes and other health care facilities to continue their care in the home setting.

The changes in availability of enteral nutrition formulas, combined with increased cost of goods, labor, and shipping continue to impact patient access to care in the home. **Payer requirements for** **authorization when formulas are changed and restrictive formularies in some cases are no longer sustainable in today’s market environment.** The added delay to provide necessary product and expense of pursuing oftentimes redundant authorizations combined with other external market factors is contributing to widespread enteral formula access concerns. Requiring authorization for enteral nutrition formulas may reduce patient access, increase delays to patient care, and reduce patient satisfaction. On behalf of our members who are providing enteral formula to patients, we are requesting:

1. A waiver of prior authorization requirements for enteral nutrition formulas.
2. Fast-track product additions to approved product lists or formularies if necessary.
3. That all waivers apply to all enteral products, not just specialty infant formulas.
4. Consider adjusting reimbursement to accommodate inflation, added costs of multiple shipments for a bulky heavy liquid nutrition product, and other supply chain cost increases.

As has been the case for other parts of the health care sector, the PHE has contributed to the substantial cost increases HME suppliers have incurred. Enteral equipment, formula, and supply acquisition costs have risen dramatically due to reduced product availability. In addition, supply chain disruptions now require additional deliveries and shipping to provide patients with 30-day supply. The cost for personal protective equipment (PPE), vital to protecting patients and employees while providing services in a home-based setting, has also increased significantly. A tight job market has increased staffing costs; many suppliers have had to employ contract staffing and pay retention bonuses to keep existing employees, including Clinical Dietitians and Technicians who may provide direct patient care in the home.

In February 2022, a major formula manufacturer announced a voluntary recall and subsequently ceased production of formula in one of their plants in Michigan. The major manufacturer produced a range of formulas, notably formulas used for infants and children with severe allergies, renal failure, intestinal failure, and various metabolic disorders. According to *The American Journal of Clinical Nutrition*, many of these formulas had limited alternatives or a limited supply, which was rapidly depleted following a surge in demand.1 This impacted the already strained supply chain and exacerbated shortages in the market.

Increased costs are impacting access to these products due to limited availability for raw materials and ingredients that manufacturers require to produce these formulas, along with product containers. The COVID-19 pandemic has also affected manufacturers’ workforces and their ability to sustain unexpected increases in production due to a major enteral nutrition manufacturer’s extended plant closure.2 Unfortunately, many other industries use the same ingredients to manufacture their products. While other industries can pass along those added costs to the end user/consumer, enteral nutrition suppliers are limited to receiving fixed payment rates set by insurance companies.

Without some relaxation of authorization and prescription requirements for enteral formula changes and restrictive formularies in some cases, it may become extremely difficult for suppliers to continue providing life-sustaining enteral nutrition and supplies to those who need them to safely manage their medical conditions. A disruption in access could lead to adverse health outcomes and increase overall costs of care. **To mitigate enteral nutrition access issues, we ask that insurance companies and Medicaid agencies waive, for a limited period of time, any authorization requirements for enteral formulas and relax any restrictive product lists that may exist.** The current enteral nutrition market environment is severely strained due to the impacts of the PHE, the major recall of formulas, and the global supply chain challenges.

AAHomecare and our HME supplier members share your goal of providing quality and timely products and services to the individuals you cover and improving patient outcomes while lowering overall health care expenses. Our members are happy to work with you to help determine optimal solutions for patients and HME providers alike. Please let us know if you would like further information about the current HME market situation. We are available to discuss and provide additional details as needed.

Cordially,

American Association for Homecare

1. “Infant and child formula shortages: now is the time to prevent recurrences” – *American Journal of Clinical Nutrition* – May 17, 2022 – <https://academic.oup.com/ajcn/advance-article/doi/10.1093/ajcn/nqac149/6587046>
2. “A break in the baby formula supply chain” – *Georgia Tech* – May, 27, 2022 <https://news.gatech.edu/news/2022/05/27/break-baby-formula-supply-chain>