January 11, 2017

2017 Parenteral Nutrition Lipid Injectable Emulsion Product Shortage Considerations

ASPEN has developed shortage recommendations to assist members and other clinicians in coping with parenteral nutrition (PN) shortages for their patients.

For the most up-to-date product shortage information, see these websites:

- American Society of Health-System Pharmacists (ASHP), Drug Shortages Resource Center
- U.S. FDA Drug Shortages
- ASPEN Latest News and ASPEN Product Shortage Latest News

Important Note:

These recommendations do not constitute medical or professional advice and should not be taken as such. To the extent the information published herein may be used to assist in the care of patients, this is the result of the sole professional judgment of the attending health professional whose judgment is the primary component of quality medical care. The information presented herein is not a substitute for the exercise of such judgment by the health professional.

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Approved by the ASPEN Clinical Practice Committee and the Board of Directors on December 21, 2016.

Questions regarding these recommendations should be directed to clinicalpractice@nutritioncare.org.

Considerations for Lipid Injectable Emulsion Product Shortage

During a Lipid Injectable Emulsion (ILE) (also known as IV lipid emulsion/IV fat emulsion) products shortage period, consider one or more of the following measures:

1. Assess and routinely reassess each patient as to the indication for PN and provide nutrition via the oral or enteral route when possible.
2. Purchase only as much ILE supply as needed. In the interest of fair allocation to all patients nationally, please do not stockpile.
3. During prolonged shortages of ILE products, the FDA may approve the temporary importation of alternative products. These products may have different oil emulsion components, fatty acid sources and amounts, and packaging and labeling compared to products available in the United States. The Dear Healthcare Professional Letter accompanying imported products should be carefully reviewed before implementing clinical use. Members of the healthcare team should be educated on any differences between imported ILE products and ILE products approved for use in the U.S.

4. Compound PN in a single, central location (either in a centralized pharmacy or as outsourced preparation) to decrease inventory waste. Consider a supply outreach to other facilities in your geographic location.
5. Facilities and practitioners need to continue to observe and be compliant with the product labeling (e.g., package insert), USP General Chapter<797> Pharmaceutical Compounding-Sterile Preparations, and state Boards of Pharmacy and federal rules and regulations.
6. Include PN component shortages and outages in the healthcare organization's strategies and procedures for managing medication shortages and outages. These procedures should include a process:
    - to identify and monitor patients who do not receive ILE,
    - to notify providers when a shortage situation occurs, and
    - to notify patients receiving long-term (e.g., more than 1 month) PN therapy and their caregivers when their PN formulation has been adjusted for shortages and outages of PN components.
7. Prioritize supply of soybean oil-based ILE as follows:
    - Neonatal and pediatric hospitalized patients should continue the same ILE therapy as before the shortage to minimize risk of adverse effects associated with essential fatty acid deficiency (EFAD) in this high-risk patient population. Priority for ILE during critical shortages should be given to neonates followed by pediatric patients and finally, adolescent patients.
    - Adult, mild-to-moderately malnourished hospitalized patients receiving PN less than 2 weeks may have ILE withheld during a shortage unless it is considered essential in the judgment of the healthcare professional.
    - Adult, hospitalized patients receiving PN greater than 2 weeks should receive a total of 100 g of a soybean oil-based ILE weekly for EFAD prevention,[2] which should be provided by the safest and most efficient method that minimizes waste. The remainder of non-protein energy may be provided by dextrose unless not indicated clinically, such as hyperglycemia, hypertriglyceridemia, and obesity. ILE should be provided as a component of daily energy based on current practice recommendations prior to the shortage for some specific adult hospitalized patients (e.g., patients with glucose intolerance, severely malnourished patients, patients at risk for re-feeding syndrome, during pregnancy). Patients should be monitored for EFAD. See #8 for more information on EFAD.
    - Adult, hospitalized, critically-ill patients receiving propofol should not require additional ILE for EFAD prevention since the soybean oil in the medication will supply needed essential fatty acids (EFAs).
    - Home or long-term care patients receiving PN should continue to receive the same ILE therapy as before the shortage. However, ILE should be minimized when clinically feasible. At a minimum, patients should receive a total of 100 g of a soybean oil-based ILE weekly for EFAD prevention which should be provided by the safest and most efficient method that minimizes waste. The remainder of non-protein energy should be provided by dextrose unless not indicated clinically, such as hyperglycemia, hypertriglyceridemia, and obesity. ILE should be provided as a component of daily energy based on current practice recommendations prior to the shortage for some specific adult home or long-term PN patients (e.g., patients with glucose intolerance, severely malnourished patients, patients at risk for refeeding syndrome, during pregnancy). Patients should be monitored for EFAD. See # 8 for information on EFAD.
8. Monitor closely patients receiving PN for developing EFAD when your institution is experiencing ongoing shortages. Increase awareness and assessment for signs and symptoms of EFAD. Signs

and symptoms of EFAD include but are not limited to, diffuse dry, scaly rash, alopecia, thrombocytopenia, anemia, and impaired wound healing. Biochemical evidence of EFAD is confirmed by a triene-to-tetraene ratio greater than 0.2. [1,2] Using topical oils for prevention and treatment of EFAD has produced mixed results. Safflower and sunflower seed oils had beneficial results whereas vegetable oil (corn oil) did not.[3-7]

9. Consider using an alternative ILE product such as a four-oil (soybean oil, medium chain triglycerides, olive oil and fish oil) during a soybean oil-based ILE shortage. This product is only approved for use in adults in the U.S. The doses and frequency of administration to meet EFA needs for adults may be different than soybean oil-based ILE. Consult the manufacturer for specific information on meeting EFAs needs. The healthcare team should be educated on the differences between alternative ILE products and soybean oil-based ILE products.
10. In the event of a four-oil (soybean oil, medium chain triglycerides, olive oil and fish oil) ILE shortage use standard soybean oil-based ILE dosing and frequency to meet patients' EFAs needs.
11. Report severe drug product shortage information to the FDA Drug Shortage Program (DSP).
12. Report any patient adverse events or medication hazard related to shortages to ISMP Medication Errors Reporting Program (MERP).

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Suggested Readings

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About ASPEN

The American Society for Parenteral and Enteral Nutrition (ASPEN) is dedicated to improving patient care by advancing the science and practice of nutrition support therapy and metabolism. Founded in 1976, ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With members from around the world, ASPEN is a community of dietitians, nurses, nurse practitioners, pharmacists, physicians, PAs, researchers, scientists, and students from every facet of nutrition support clinical practice, research, and education. For more information about ASPEN, please visit www.nutritioncare.org.