

Understanding Parenteral Nutrition Component Supply Interruptions and Shortages

Assessing the availability of parenteral nutrition (PN) components and navigating the supply chain can seem complex. This practice tool is intended to complement ASPEN's [PN product-specific shortage recommendations](#) by outlining basic steps clinicians can use when a PN component is unavailable. It explains how PN components are typically purchased, how to identify where a supply interruption or shortage may be occurring, and what procurement and clinical options may be considered.

Understanding the source and scope of the interruption or shortage can help organizations obtain the PN component promptly or determine whether alternative products or conservation measures are necessary.



How are PN Components Obtained?

PN components are typically ordered by an organization's pharmacy, procurement, and/or central supply departments through a distributor/wholesaler. Some components may also be purchased directly from a manufacturer.

- **Manufacturer:** Produces and releases the PN components.
- **Distributor/wholesaler:** Supplies PN components from manufacturers to healthcare organizations and pharmacies. Although their roles may differ in some respects, this practice tool uses the combined term "distributor/wholesaler" for simplicity.

Typical PN Component Supply Chain



Organizations will typically have a primary distributor/wholesaler, and most of their regularly purchased PN components will come from this primary source.

» **Determine which primary distributor/wholesaler your organization uses**

PN components and administration supplies may be ordered through different purchasing departments within a single organization (e.g., lipid injectable emulsions (ILEs) may be ordered through the pharmacy department, and filters may be ordered through the central supply department).

» **Determine the department(s) in which PN components and administration supplies are ordered within your organization**

What Should You Do When a PN Component is Unavailable?

- 1 Gather a team of relevant stakeholders.** Establish an interprofessional team to evaluate the interruption, coordinate the response, and communicate changes. Ideally, this team and its communication process should be established before a shortage occurs.
- 2 Investigate the source of supply and scope of the interruption or shortage.** Work with pharmacy, procurement, and/or central supply personnel to identify the source of the supply chain interruption. A **backorder** is an order that was placed but cannot currently be filled, but is expected to become available at a later date. A backorder does not, by itself, confirm a national shortage. However, it is often the first indication to an organization that a problem may exist.
 - **Organizational interruption:** The problem originates within the organization and is not a widespread issue. Examples include unexpectedly high use, insufficient inventory, an ordering issue, or an internal distribution or delivery problem.
 - **Distributor/wholesaler interruption:** The organization's usual distributor/wholesaler cannot supply the product, but the manufacturer may still be producing and releasing it. The interruption may affect only certain organizations or geographic regions.
 - **Widespread or national shortage:** The manufacturer is unable to produce, release, or supply enough product to meet demand. The cause may involve manufacturing, raw materials, product quality, production delays, product release, or widespread increased demand.

Questions to ask the stakeholder team:

- Where is the PN component normally purchased (e.g., distributor/wholesaler or manufacturer)?
- Could an internal inventory, ordering, or delivery issue explain why the product is unavailable?
- Has the primary distributor/wholesaler explained why it cannot supply the product?
- Are other organizations or geographic regions experiencing the same problem?
- Has the manufacturer confirmed a shortage (customer letter, website communication)?
 - Check both the [American Society of Health-System Pharmacists \(ASHP\)](#) and [U.S. Food & Drug Administration \(FDA\)](#) drug-shortage websites for posted information. Note that published shortage information may not always reflect real-time product availability.

» ***If a suspected widespread PN component shortage is not listed, report it to both [ASHP](#) and the [FDA](#).***

Suggested Stakeholder Team

- Pharmacy operations, including sterile compounding personnel
- Pharmacists, dietitians, prescribers, and other clinical experts
- Nursing
- Procurement or supply-chain personnel
- Medical or organizational leadership
- Information technology personnel
- Medication safety experts
- Home infusion pharmacies, when applicable
- Additional team members as indicated by the impact of a specific shortage (e.g., NICU)

- 3 Concurrently assess supply and utilization.** While investigating the source of the interruption, determine whether the organization has enough product to meet anticipated needs until additional supply becomes available.

Regardless of the cause, it is essential to assess whether there is adequate product to cover the interruption or shortage.

Questions to ask the stakeholder team:

- How much product is currently available (consider expiration dates)?
- How long is the interruption expected to last?
- What is the organization's average daily use?
- Based on current inventory and use, how many days of supply remain (may also be referred to as 'days on hand')?
- Are there open orders, and when are they expected to arrive?
- Is the component subject to an allocation or other purchasing restriction?
- If allocated, how much product may the organization purchase, and who established the allocation — the manufacturer or distributor/wholesaler?
- Will the available inventory and anticipated deliveries cover the expected interruption?

An **allocation** is a purchasing limit denoted as a percentage, typically based on an organization's historical purchase of the product, used to promote fair distribution of the component and prevent stockpiling (ie, purchasing more than is typically needed). They may be established separately by a manufacturer or distributor/wholesaler and may vary by organization or geographic region (e.g., organizations with large neonatal units or pediatric populations may receive a higher allocation due to the prioritized populations they serve).

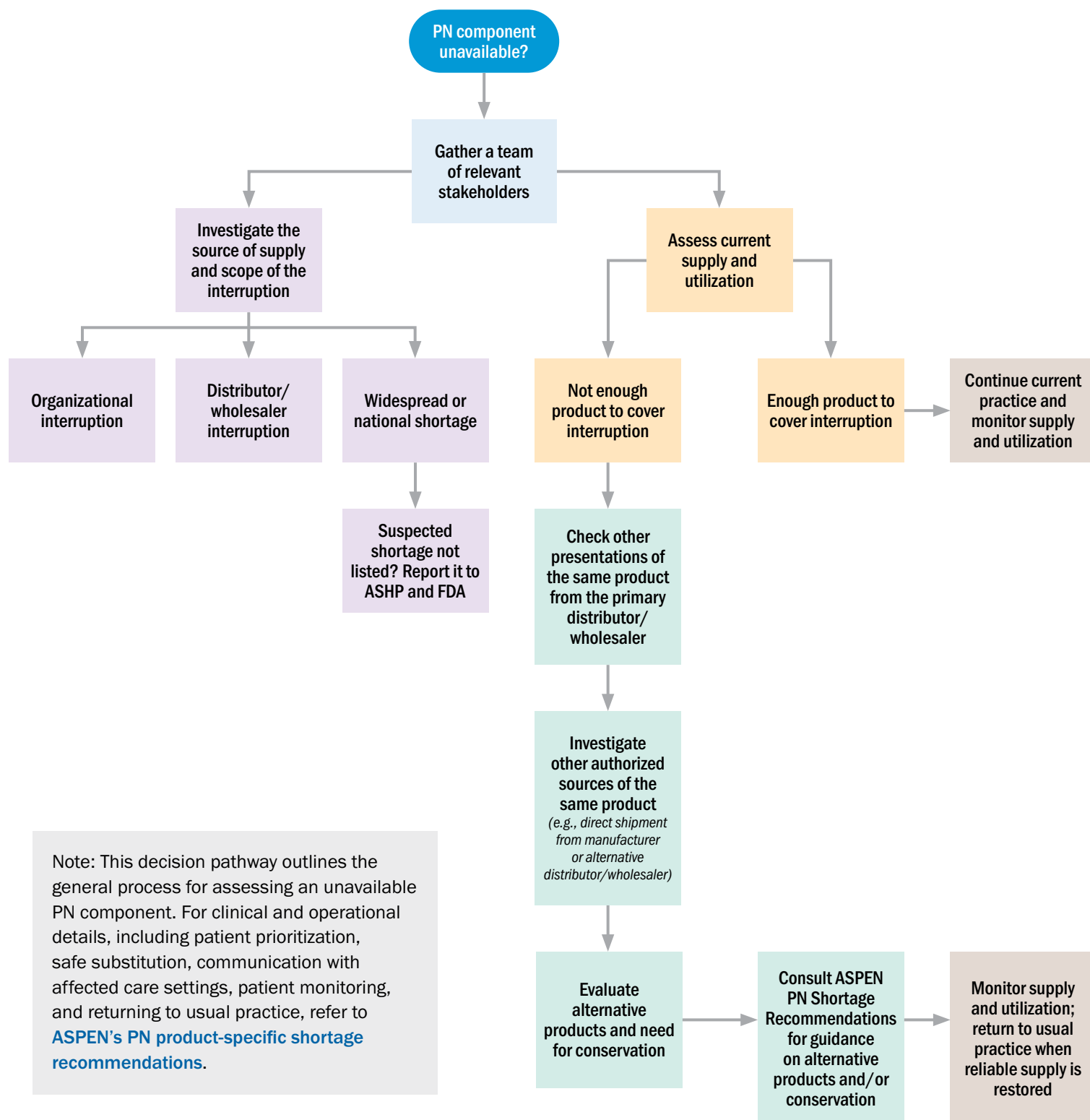
Examples:

- A **restrictive allocation** is an allocation amount that is less than 100% of typical usage (e.g., a 50% allocation limits the organization to purchasing 50% of its usual amount during the same timeframe).
 - A **protective allocation** is an allocation amount that is 100% or greater than typical usage, allowing for excess purchasing to cover normal variations in utilization, but preventing stockpiling (e.g., a 110% allocation limits the organization to purchasing 110% of its usual amount during the same timeframe).
- » ***Do not stockpile PN components. Stockpiling by one organization reduces availability for patients at other organizations and can worsen a shortage.***

- 4** If the available supply may not cover the interruption or shortage, work with the stakeholder team to:
 - a. Check other presentations of the same product.** An interruption or shortage may affect only certain container sizes, package types, or concentrations. For example, there may be a shortage of an ILE product in a 250 mL container, but an adequate supply of the same ILE product in a 500 mL container. Another presentation of the component may remain available, **but any effects on compounding, stability/compatibility, storage, and workflow should be thoroughly discussed with the stakeholder team and evaluated before use.**
 - b. Investigate other authorized sources.** If there are issues obtaining product from an organization's primary distributor/wholesaler, check with the procurement department to see if the manufacturer can directly ship the product (bypassing the distributor/wholesaler), or reach out to other distributors/wholesalers.
 - c. Evaluate alternative products and the need for conservation measures.** If the usual component cannot be obtained, consult [ASPEN's PN product-specific shortage recommendations](#) for potential alternatives and conservation strategies and [ASPEN's Recommendations on Appropriate Parenteral Nutrition Dosing](#) for dosing guidance. **Seek alternative sources of products and alternative products before conservation strategies.** Assess the safety and operational implications of any change before implementation.
- 5** **Monitor supply and utilization, and return to usual practice as soon as feasible.** Together with the stakeholder team, continue monitoring inventory, utilization, anticipated deliveries, and supplier communications throughout the interruption or shortage. When a reliable supply has been restored, discontinue shortage-related substitutions or conservation measures and return to usual dosing and operational practices as soon as clinically and operationally appropriate.

Decision pathway for assessing an unavailable PN component

Colors in this pathway correspond to Steps 1-5 described on pages 2-4.



Resources

PN Shortages:

- [ASPEN Shortage Recommendations: PN Products](#)
- [American Society of Health-System Pharmacists \(ASHP\) Drug Shortages Resource Center](#)
- [US Food & Drug Administration \(FDA\) Drug Shortages website](#)

PN Indications:

- [When is Parenteral Nutrition Appropriate?](#)

PN Dosing and Safe Practices:

- [Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations](#)
- [ASPEN Clinical Guidelines: Parenteral Nutrition Ordering, Order Review, Compounding, Labeling, and Dispensing](#)
- [ASPEN Parenteral Nutrition Safety Consensus Recommendations](#)

PN Compatibility and Stability:

- [Parenteral Nutrition Compatibility and Stability: A Comprehensive Review](#)
- [Parenteral Nutrition Compatibility and Stability: Practical Considerations](#)

Multi-Chamber Bag Parenteral Nutrition (MCB-PN):

- [ISMP/ASPEN Multi-Chamber Bag Parenteral Nutrition Consensus Statements](#)

References

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