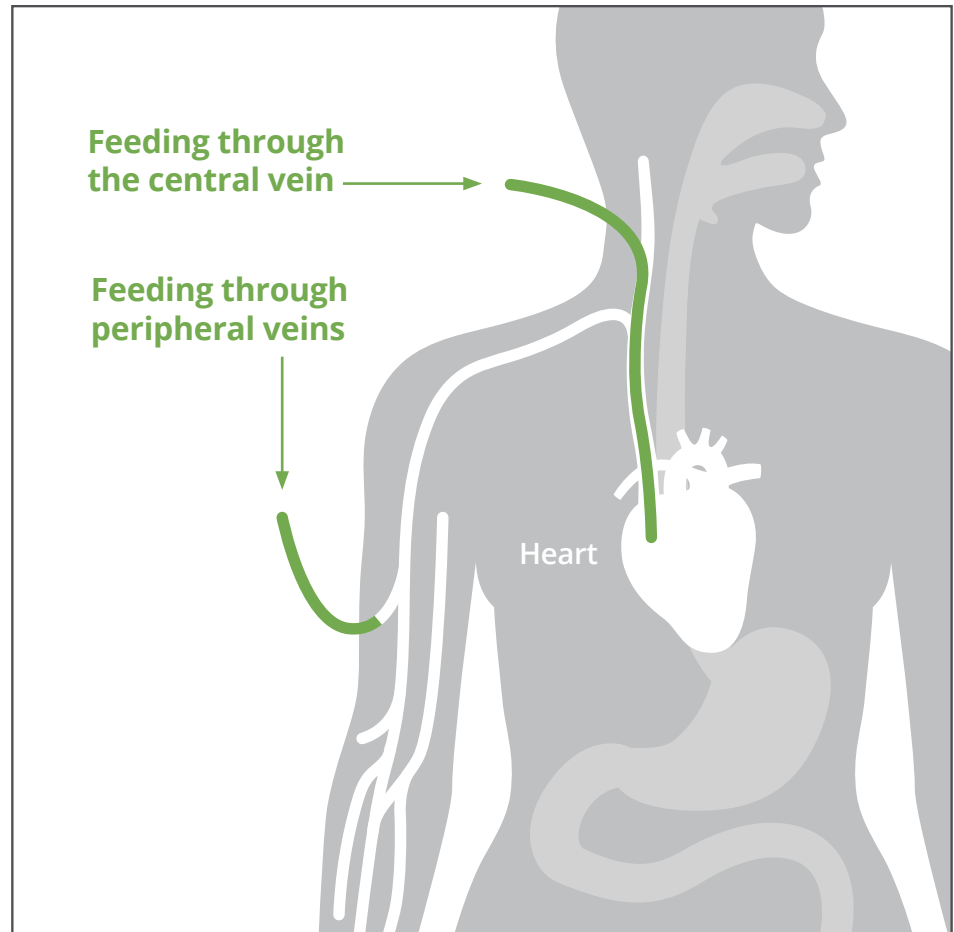




Parenteral Nutrition: Access and Coverage

Feeding intravenously, bypassing the usual process of eating and digestion.

- Parenteral nutrition (PN) products are medically necessary for sole source or complementary nutrition in order to maintain health, quality of life, and prevent malnutrition.
- PN products are not normally covered in Medicare Part B in situations involving temporary impairments and must be deemed by a physician's written order or prescription and sufficient medical documentation that these therapies are medically necessary.
- Access to PN has become increasingly difficult due to a variety of challenges within the healthcare system. This includes restrictive and Medicare coverage guidelines despite attempts to update the criteria with new clinical references.
- PN products fall under the prosthetic device benefit under Medicare Part B. Medicare coverage is restricted to beneficiaries that have a permanent impairment of the small intestine and those who have very specific and sufficient medical documentation to support the medical necessity. Individuals are assessed on a case-by-case basis at periodic intervals of no more than three months by Medicare Administrative Contractor (A/B MAC (B)) medical consultant or specially trained staff.
- PN coverage is available under Medicare Part D, but coverage for



these products is limited to the ingredients that meet the definition of a Part D drug. The beneficiary is then financially responsible for the non-covered PN ingredients and supplies. Under Medicare Part B, however, the ability of PN patients to meet this strict criteria can be challenging, especially for patients who have the ability to transition to enteral or oral feeding in less than three months.

- In addition to the complexities with PN Medicare reimbursement that restrict patient access to PN, there is a consistent shortage of elements (amino acids, dextrose, vitamins, electrolytes such as potassium and calcium salts, zinc, etc.) needed to optimally provide parenteral nutrition. The shortage stems from the small number of manufacturers



of PN solutions in the U.S. that can provide for the U.S. market. As many of the primary PN manufacturers are based outside of the U.S., they are faced with stringent regulations from U.S. Agencies when attempting to import solutions. The current product shortages issues continue to be exacerbated by the natural

disasters that occurred in 2017. PN components are treated under the same regulations as drugs. The U.S. Food Administration drug approval process requires manufacturers to submit new drug applications for nutrition products that have administered to patients around the world safely for many years. There are mandates for clinical trials that

need to be conducted on U.S. soil, despite a product that has been on the market for decades, and Agencies are constantly attempting to filter through their backlog of drug/nutrient approvals. A process needs to be developed for the timely approval and importation of foreign nutrition products.

References

- 1 [Centers for Medicare & Medicaid Services. National Coverage Determination \(NCD\) for Enteral and Parenteral Nutritional Therapy \(180.2\). \(1984\).](#)
- 2 Ibid.
- 3 [American Society for Parenteral and Enteral Nutrition. Parenteral Nutrition Component Shortages Update. \(2019\).](#)
- 4 [Centers for Medicare & Medicaid Services. National Coverage Determination \(NCD\) for Enteral and Parenteral Nutritional Therapy \(180.2\). \(1984\).](#)
- 5 [Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit Manual. \(2010\).](#)
- 6 [American Society for Parenteral and Enteral Nutrition. Parenteral Nutrition Component Shortages Update. \(2019\).](#)
- 7 Ibid.