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EVIDENCE-BASED CRITERIA SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 11/01/23 LAST REVIEW DATE: 10/15/24 CURRENT EFFECTIVE DATE: 10/15/24 LAST CRITERIA REVISION DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025

PARENTERAL AND ENTERAL NUTRITION

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "<u>Description</u>" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "<u>Criteria</u>" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Parenteral Nutrition:

Parenteral nutrition is the intravenous administration of nutrition. Parenteral nutrition, also referred to as hyperalimentation, may be total parenteral nutrition (TPN) or supplemental.

- Total parenteral nutrition (TPN): Intravenous feeding that provides all of the carbohydrates, proteins, fats, water, electrolytes, vitamins, and minerals needed for the building of tissue, expenditure of energy, and other physiologic activities. Administration of the nutrients is usually performed through a central venous catheter inserted in the superior vena cava. TPN is used when medical or surgical conditions impair gastrointestinal (GI) absorption causing risk for malnutrition and/or wasting.
- Intradialytic parenteral nutrition (IDPN): Infusion of nutrients during dialysis to treat protein calorie
 malnutrition for individuals with renal failure. Intravenous administration is performed during
 hemodialysis through the dialysis tubing. In peritoneal dialysis, also referred to as intraperitoneal
 parenteral nutrition (IPPN) or intraperitoneal nutrition (IP), nutrition is infused into the peritoneal cavity.

Enteral Nutrition (EN):

Feeding provided through the gastrointestinal tract via a tube (e.g. nasogastric, gastrostomy or jejunostomy tubes), catheter, or stoma that delivers nutrients distal to the oral cavity on a continuous or intermittent schedule. EN is used for individuals with a functioning gastrointestinal (GI) tract who are at risk for malnutrition and/or wasting as the result of disorders of the pharynx, esophagus or stomach that prevent nutrients from reaching the absorbing surfaces of the small bowel.

Criteria:

Total Parenteral Nutrition:

- Initial course of TPN for <u>seven (7) days</u> is considered *medically necessary* with documentation of **ALL**¹ of the following:
 - 1. Non-functioning GI tract, impaired gastrointestinal (GI) absorption or need for bowel rest as the result of **ONE** of the following medical or surgical conditions, to include, *but not limited to*:
 - Dysphagia as a result of a central nervous system (CNS) disorder with high risk for aspiration
 - Enterocolic, enterovesical, or enterocutaneous fistulas (TPN is considered temporary until the fistula is repaired)
 - Failure to thrive due to systemic disease or secondarily to intestinal insufficiency associated with short bowel syndrome, malabsorption, or chronic idiopathic diarrhea in infants and young children
 - Gastrointestinal anomalies that are catastrophic, e.g., tracheoesophageal fistula, gastroschisis, omphalocele, or massive intestinal atresia in newborn infants



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- Hypermetabolic conditions:
 - Burns
 - Major surgery
 - Sepsis
 - Trauma
- Inflammatory bowel disease, e.g., Crohn's disease, ulcerative colitis
- Malnutrition from inadequate oral intake, severe (e.g., chemotherapy-induced nausea and vomiting)
- Motility disorder (pseudo-obstruction)
- Necrotizing pancreatitis, severe
- Neurological impairment
- Obstruction secondary to stricture or neoplasm of the esophagus or stomach
- Paralytic ileus for a prolonged period of time following a major surgical procedure or following multiple injuries
- Perioperative: NPO status (withholding of food and water) for 7 14 days before or after surgery
- Pregnancy hyperemesis and low weight gain from impaired intake or absorption
- Short bowel syndrome secondary to massive small bowel resection
- 2. Risk of wasting as documented by the following:
 - Weight is significantly less than normal body weight for an individual's height and age in comparison with pre-illness weight, and
 - Serum albumin less than 3.2gm, or
 - Protein intake less than 0.8g/kg/day
- 3. Efforts to correct malnutrition have failed, to include, but not limited to:
 - Treatment of an underlying medical, psychiatric, psychosocial and/or surgical disorder that may be impairing food intake
 - Dietary adjustments and oral supplements
 - Trial of enteral nutrition (tube feeding, G-Tube, J-Tube) has failed or is contraindicated as a result of a medical or surgical condition
- 4. Individual is unable to orally receive more than 30% of daily caloric needs



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Continuation of TPN for an additional seven (7) days is considered *medically necessary* with documentation of **ONE** of the following:

- 1. Individual remains at risk of wasting as documented by the following:
 - Weight continues to be significantly less than normal body weight for an individual's height and age in comparison with pre-illness weight, and
 - Serum albumin less than 3.2gm or

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- Protein intake less than 0.8g/kg/day
- 2. Individual continues to need bowel rest

Intradialytic Parenteral Nutrition:

- > Initial course of IDPN is considered *medically necessary* with documentation of **ALL** of the following:
 - 1. Individual is on dialysis
 - 2. Risk of wasting as documented by the following:
 - Weight is significantly less than normal body weight for an individual's height and age in comparison with pre-illness weight, and
 - Serum albumin less than 3.2qm. or
 - Protein intake less than 0.8g/kg/day
 - 3. Efforts to correct malnutrition have failed, to include, but not limited to:
 - Treatment of an underlying medical, psychiatric, psychosocial and/or surgical disorder that may be impairing food intake
 - Dietary adjustments and oral supplements
 - Trial of enteral nutrition has failed or is contraindicated as a result of a medical or surgical condition

Enteral Nutrition (EN):

- > Initial course of EN for fourteen (14) days is considered medically necessary with documentation of **ALL** of the following:
 - 1. Functional intestinal tract
 - 2. Inability to swallow as the result of **ONE** of the following medical conditions, to include, but not limited to:
 - Anatomical or structural problems or diseases/conditions of the esophagus, including severe allergic reaction, that prevents food from reaching the stomach or other intestinal structures



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 Neurological disorder resulting in chewing and/or swallowing problem(s) that create a high risk for aspiration

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- 3. EN is intended to be the sole source of nutrition²
- 4. The requested nutritional product is not over-the-counter (OTC).
- Continuation of EN in thirty (30) day increments is considered medically necessary with documentation that an individual remains unable to orally receive more than 30% of daily caloric needs.
- Continuation of EN for ninety (90) days or greater, not to exceed 365 day increments, is considered medically necessary with documentation that EN therapy is chronic and is medically necessary as the sole source of nutrition².
- Initial and continuing <u>365 day increments</u> of EN for the following indications are considered *medically necessary* and may be approved at the R.N. level of review without the 14, 30, and 90 day increments needing to be met with documentation that EN therapy is chronic and is medically necessary as the sole source of nutrition².

These indications include, but are not limited to:

- Amyotrophic Lateral Sclerosis with feeding tube due to probability of aspiration pneumonia
- Persistent aspiration pneumonia
- Enteral Nutrition prescribed as the sole source of nutrition for the treatment of inherited metabolic disorders tested under the state's newborn screening program is *eligible for coverage* under the Medical Food benefit.
- Guidelines 2 through 4 do not apply to an individual in need of **bowel rest only**.
- Sole source of nutrition is defined as inability to orally receive more than 30% of daily caloric needs.

Resources:

Literature reviewed 10/17/23. We do not include marketing materials, poster boards and non-published literature in our review.

- 1. Anderson J., Peterson K., Bourne D, Boundy E. Evidence Brief: Use of Intradialytic Parenteral Nutrition (IDPN) to Treat Malnutrition in Hemodialysis Patients. VA ESP Project #09-199. 2018. Accessed April 2, 2023. https://www.hsrd.research.va.gov/publications/esp/idpn-supplemental.pdf
- 2. Ariz Rev. Stat § 20-2327. (2023)
- 3. Ariz Rev. Stat § 36-694. (2023)



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- Beddhu S, Cho ME, Bansal S. Pathogenesis and treatment of malnutrition in patients on maintenance hemodialysis. In: Schwab SJ, ed. *UpToDate*. UpToDate; 2023. Accessed September 7, 2023. https://www.uptodate.com/contents/pathogenesis-and-treatment-of-malnutrition-in-patients-on-maintenance-hemodialysis
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- 7. Brown RO, Compher C, American Society for P, Enteral Nutrition Board of D. A.S.P.E.N. clinical guidelines: nutrition support in adult acute and chronic renal failure. *JPEN J Parenter Enteral Nutr.* Jul-Aug 2010;34(4):366-77. doi:10.1177/0148607110374577
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- 10. Department of Health and Human Services. Health Care Financing Administration. HCFA Rulings. Ruling No. 96-3. 1996. Accessed April 2, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads//hcfar963.pdf
- 11. Hiroshige K, Iwamoto M, Kabashima N, Mutoh Y, Yuu K, Ohtani A. Prolonged use of intradialysis parenteral nutrition in elderly malnourished chronic haemodialysis patients. *Nephrol Dial Transplant*. Aug 1998;13(8):2081-7. doi:10.1093/ndt/13.8.2081
- 12. Ikizler TA, Burrowes JD, Byham-Gray LD, et al. KDOQI Clinical Practice Guideline for Nutrition in CKD: 2020 Update. *Am J Kidney Dis.* Sep 2020;76 (3 Suppl 1):S1-S107. doi:10.1053/j.ajkd.2020.05.006
- 13. Joannidis M, Rauchenzauner M, Leiner B, et al. Effect of intradialytic parenteral nutrition in patients with malnutrition-inflammation complex syndrome on body weight, inflammation, serum lipids and adipocytokines: results from a pilot study. *Eur J Clin Nutr*. Jun 2008;62(6):789-95. doi:10.1038/sj.ejcn.1602777
- KDOQI Work Group. KDOQI Clinical Practice Guideline for Nutrition in Children with CKD: 2008 update. Executive summary. *Am J Kidney Dis*. Mar 2009;53(3 Suppl 2):S11-104. doi:10.1053/j.ajkd.2008.11.017



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- 17. Liu Y, Xiao X, Qin DP, et al. Comparison of Intradialytic Parenteral Nutrition with Glucose or Amino Acid Mixtures in Maintenance Hemodialysis Patients. Nutrients. Jun 2 2016;8(6)doi:10.3390/nu8060220
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B4222, B4224, B5000, B5100, B5200, B9998, B9999

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, cro@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólo díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojj' bich'j' hodíilnih 877-475-4799.

Chinese: 如果您, 或是您正在協助的對象, 有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題, 您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員, 請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة المتحدث مع مترجم اتصل ب .877-479-877



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問が ございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はか かりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 4799-475-877 _[تماس حاصل نمایید.

Assyrian:

1, نسمه، برسم فغومفة دوسودوس بمهر، نبطهومه معمودة معمدة ومعقد معمد (Blue Cross Blue Shield of Arizona) بسمه المحكومة ومعطيمه المحكمة ومعطمة و

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะใดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799