EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE:**	**09/19/22**
SECTION: SURGERY	**LAST REVIEW DATE:**	**10/15/24**
	CURRENT EFFECTIVE DATE:	**10/15/24**
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025	**ARCHIVE DATE:**	

SMALL BOWEL/LIVER AND MULTIVISCERAL TRANSPLANT

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 "Description" 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 "Criteria" 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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SMALL BOWEL/LIVER AND MULTIVISCERAL TRANSPLANT

Description:

Solid organ transplantation offers a treatment option for individuals with different types of end-stage organ failure that can be lifesaving or provide significant improvements to an individual's quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Intestinal failure results from surgical resection, congenital defect, or disease-associated loss of absorption, and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance. Short bowel syndrome is an example of intestinal failure.

Evidence of intolerance of total parenteral nutrition (TPN) includes, but is not limited to, multiple and prolonged hospitalizations to treat TPN-related complications or the development of progressive but reversible liver failure. In the setting of progressive liver failure, small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN and would thus avoid the necessity of a multivisceral transplant.

Potential contraindications for solid organ transplant that are subject to the judgment of the transplant center include the following:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to intestinal failure
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

SMALL BOWEL/LIVER AND MULTIVISCERAL TRANSPLANT

Criteria:

Small bowel/liver and multivisceral transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

- A small bowel and liver transplant or a multivisceral transplant, for pediatric and adult individuals are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Intestinal failure characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance
  2. Management with long-term total parenteral nutrition
  3. Development of evidence of impending end-stage liver failure
  4. Adequate cardiopulmonary status
  5. Documentation of individual compliance with medical management

- A small bowel and liver retransplant and a multivisceral retransplant, after a failed primary small bowel and liver transplant or multivisceral transplant are considered ***medically necessary.***

- A small bowel and liver transplant or a multivisceral transplant for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

SMALL BOWEL/LIVER AND MULTIVISCERAL TRANSPLANT

Resources:

Literature reviewed 10/15/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 10/15/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abu-Elmagd KM, Costa G, Bond GJ, et al. Five hundred intestinal and multivisceral transplantations at a single center: major advances with new challenges. *Ann Surg*. Oct 2009;250(4):567-81. doi:10.1097/SLA.0b013e3181b67725

2. American Gastroenterological Association medical position statement: short bowel syndrome and intestinal transplantation. *Gastroenterology*. Apr 2003;124(4):1105-10. doi:10.1053/gast.2003.50139

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5. Center for Medicare & Medicaid Services. National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (260.5). 2006. Accessed June 27, 2024. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=280&ncdver=2&bc=0

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10. Florescu DF, Qiu F, Langnas AN, et al. Bloodstream infections during the first year after pediatric small bowel transplantation. *Pediatr Infect Dis J*. Jul 2012;31(7):700-4. doi:10.1097/INF.0b013e318256f9c3

11. Garcia Aroz S, Tzvetanov I, Hetterman EA, et al. Long-term outcomes of living-related small intestinal transplantation in children: A single-center experience. *Pediatr Transplant*. Jun 2017;21(4)doi:10.1111/petr.12910

12. Iyer K, DiBaise JK, Rubio-Tapia A. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. *Clin Gastroenterol Hepatol*. Oct 2022;20(10):2185-2194.e2. doi:10.1016/j.cgh.2022.05.032

13. Kaufman SS, Atkinson JB, Bianchi A, et al. Indications for pediatric intestinal transplantation: a position paper of the American Society of Transplantation. *Pediatr Transplant*. Apr 2001;5(2):80-7. doi:10.1034/j.1399-3046.2001.005002080.x

14. Lacaille F, Irtan S, Dupic L, et al. Twenty-eight years of intestinal transplantation in Paris: experience of the oldest European center. *Transpl Int*. Feb 2017;30(2):178-186. doi:10.1111/tri.12894

15. Lauro A, Zanfi C, Dazzi A, et al. Disease-related intestinal transplant in adults: results from a single center. *Transplant Proc*. Jan-Feb 2014;46(1):245-8. doi:10.1016/j.transproceed.2013.08.110

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29. Working Party of the British Transplantation Society. Kidney & Pancreas Transplantation in Patients with HIV. Second Edition (Revised). British Transplantation Society Guidelines. Macclesfield, UK: British Transplantation Society; 2017.

30. Wu G, Selvaggi G, Nishida S, et al. Graft-versus-host disease after intestinal and multivisceral transplantation. *Transplantation*. Jan 27 2011;91(2):219-24. doi:10.1097/TP.0b013e3181ff86ec

31. Wu GS, Cruz RJ, Jr., Cai JC. Acute antibody-mediated rejection after intestinal transplantation. *World J Transplant*. Dec 24 2016;6(4):719-728. doi:10.5500/wjt.v6.i4.719

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Coding:

CPT: 44120, 44121, 44132, 44133, 44715, 44720, 44721, 44799, 47133, 47135, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, 47399
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History:	**Date:**	**Activity:**
Medical Policy Panel	10/15/24	Review with revisions
Medical Directors (Dr. Raja, Dr. Sutanto)	10/03/24	Review with no revisions
Medical Policy Panel	10/03/23	Review with revisions
Medical Policy Panel	08/01/23	Review with no revisions
Medical Policy Panel	08/30/22	Approved guideline (Effective 09/19/22)

Policy Revisions:

10/15/24	Added:	"CPT copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association"
10/15/24	Updated:	Resources section
10/03/23	Added:	CPT code: 44720; "Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria bullets
10/03/23	Revised:	"Insufficient evidence to support improvement outside the investigational setting" from #3 to #5 in experimental or investigational criteria bullets
10/03/23	Updated:	Description section; Resources section

SMALL BOWEL/LIVER AND MULTIVISCERAL TRANSPLANT

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, crc@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'ídílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídílkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí koj' 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 .للتحدث مع مترجم اتصل ب 877-475-4799.

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<u>Multi-Language Interpreter Services</u>:

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 877-475-4799
.[تماس حاصل نمایید

Assyrian:

[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 877-475-4799.

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
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