



## Total Artificial Heart

<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial  <input checked="" type="checkbox"/> Medicare  <input checked="" type="checkbox"/> Medicaid	<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:  <input type="checkbox"/> Oregon
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## Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

## Background

The Total Artificial Heart (TAH) is a mechanical circulatory support device used as a bridge to heart transplantation in individuals with irreversible biventricular heart failure (HF).

An FDA approved TAH system, such as SynCardia, is an implantable, pulsatile biventricular device that serves as a total replacement for both ventricles and all four native valves. The device consists of an internal pump and a pneumatic driver housed in an external console.

## Criteria

### Commercial

#### Prior authorization is required.

- A. PacificSource considers a Food and Drug Administration (FDA) approved Total Artificial Heart (TAH) medically necessary when ALL of the following criteria have been met at the time of implant request:
1. Functional Class IV per New York Heart Association (NYHA)
  2. No other reasonable medical or surgical treatment options available to treat heart failure

### 3. TAH will be used as a bridge to transplant (BTT) for biventricular failure

#### Medicaid

PacificSource Community Solutions follows Excluded Services Guideline E2 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services and the general coverage requirements, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200 to determine coverage of a Total Artificial Heart.

PCS follows the “*Unlisted, Unspecified, and Not Otherwise Specified Procedure Codes*” policy for requests for unlisted codes.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) coverage requirements in OAR 410-151-0000 through 410-151-0003 for EPSDT beneficiaries. Relevant coverage guidance, including but not limited to Excluded Services Guideline Note E2, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) policy for details.

#### Medicare

PacificSource Medicare follows National Coverage Determination NCD 20.9.1 for review of medical necessity.

#### Experimental/Investigational/Unproven

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PacificSource considers Total Artificial Heart (TAH) to be experimental, investigational, or unproven for use as a destination therapy (permanent replacement of the failing heart).

#### Coding Information

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The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

33927 Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy

33928 Removal and replacement of total replacement heart system (artificial heart

33929 Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)

33999 Unlisted procedure, cardiac surgery

L8698 Miscellaneous component, supply, or accessory for use with total artificial heart system

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

## Definitions

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**NYHA Functional Classification** (Class – Patient Symptoms) per New York Heart Association:

- I – No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)
- II – Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath)
- III – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea
- IV – Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases

## Related Policies

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Clinical Criteria Used in UM Decisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Unlisted, Unspecified, and Not Otherwise Specified Procedure Codes

## References

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Arabía, F. A., & Murray, C. F. (2023). The total artificial heart: Where have we been, where are we now, and where are we going? *Indian Journal of Thoracic and Cardiovascular Surgery*, 39, 198–205. <https://doi.org/10.1007/s12055-023-01559-8>

Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., Deswal, A., Drazner, M. H., Dunlay, S. M., Evers, L. R., Fang, J. C., Fonarow, G. C., Hayek, S. S., Hernandez, A. F., Khazanie, P., Kittleson, M. M., Lee, C. S., Link, M. S., Milano, C. A., ... Yancy, C. W. (2022). 2022 AHA/ACC/HFSA guideline for the management of heart failure. *Journal of the American College of Cardiology*, 79(17), e263–e421. <https://doi.org/10.1016/j.jacc.2021.12.012>

Hulman, M., Artemiou, P., Hudec, V., Olejarova, I., & Goncalvesova, E. (2019). SynCardia, total artificial heart, as a bridge to transplant. *Bratislavske lekarske listy*, 120(5), 325–330. Accessed 08/18/2020, 01/12/2022. <https://www.ncbi.nlm.nih.gov/pubmed/31113193>

MCG Heart Transplant ORG: S-535 (ISC).

Malas, J., Chen, Q., Akhmerov, A., Chikwe, J., Arabia, F. A., & Esmailian, F. (2023). *Experience with the SynCardia total artificial heart as a bridge to transplantation in 100 patients*. **The Annals of Thoracic Surgery**, 115(3), 725–732. <https://doi.org/10.1016/j.athoracsur.2022.11.034>

Masarone, D., Gravino, R., Falco, L., Catapano, D., Valente, F., Amarelli, C., Kittleson, M., & di Lorenzo, E. (2025). The total artificial heart: A historical perspective. *Journal of Clinical Medicine*, 14(17), 6290. <https://doi.org/10.3390/jcm14176290>

National Institute for Health and Care Excellence (NICE). (December 2017). Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure, <https://www.nice.org.uk/guidance/IPG602/chapter/1-Recommendations>

Nguyen, A., Pellerin, M., Perrault, L. P., White, M., Ducharme, A., Racine, N., & Carrier, M. (2017). Experience with the SynCardia total artificial heart in a Canadian centre. *Canadian journal of surgery. Journal canadien de chirurgie*, 60(6), 375–379. <https://www.ncbi.nlm.nih.gov/pubmed/28930049>

Oregon Health Authority. Oregon Administrative Rules (OARs). Health Systems: Medical Assistance Programs – Chapter 410.

<https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87>

Oregon Health Plan. The Health Evidence Review Commission (HERC) Prioritized List of Health Services <https://www.oregon.gov/oha/HSD/OHP/Pages/Prioritized-List.aspx>

Razumov, A., Burri, M., Lauenroth, V., Rojas, S. V., Gummert, J., Deutsch, M.-A., & Morshuis, M. (2024). *Outcomes after SynCardia® temporary total artificial heart implantation: A 20-year single-center experience in 196 patients*. *Artificial Organs*.

<https://doi.org/10.1111/aor.14860>

SynCardia Temporary Total Artificial Heart (TAH-T). (2022). SynCardia Systems, LLC.

<https://syncardia.com/>

Torregrossa, G., Morshuis, M., Varghese, R., Hosseinian, L., Vida, V., Tarzia, V., Loforte, A., Duveau, D., Arabia, F., Leprince, P., Kasirajan, V., Beyersdorf, F., Musumeci, F., Hetzer, R., Krabatsch, T., Gummert, J., Copeland, J., & Gerosa, G. (2014). Results with SynCardia total artificial heart beyond 1 year. *ASAIO journal (American Society for Artificial Internal Organs: 1992)*, 60(6), 626–634.

<https://www.ncbi.nlm.nih.gov/pubmed/25158888>

Washington State Health Technology Reviews, 2022. <https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-reviews>

## Appendix

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**Policy Number:**

**Effective:** 8/1/2020

**Next review:** 5/1/2027

**Policy type:** Enterprise

**Author(s):**

**Depts.:** Health Services

**Applicable regulation(s):** 42 CFR § 422.101(b-c), OARs 410-120-1200, 410-141-3820, 410-141-3825, 410-151-0001, 410-151-0002, 410-151-0003.

**OPs Approval:** 3/2026