Total Artificial Heart

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

Enterprise Policy

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 determination 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.

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:

- New York Heart Association (NYHA) Functional Class IV:
  - NYHA Functional Classification (Class – Patient Symptoms)
    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.

- No other reasonable medical or surgical treatment options available to treat heart failure.
- TAH will be used as a bridge to transplant (BTT) for biventricular failure.

Medicaid

PacificSource Community Solutions follows Guideline Note 173 of the OHP Prioritized List of Health Services and considers Total Artificial Heart unproven treatment.

Medicare

PacificSource Medicare follows National Coverage Determination (NCD) 20.9 for review of medical necessity.

Experimental/Investigational or Unproven

PacificSource considers Total Artificial Heart (TAH) as experimental/investigational for use as a destination therapy (permanent replacement of the failing heart).

Coding Information

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
33999 Unlisted procedure, cardiac surgery

References

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

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Shah NR et al SynCardia Portable Freedom Driver: a single-Center experience with 11 patients. Innovations (Phila). May-Jun;10(3):188-94 2015 https://www.ncbi.nlm.nih.gov/pubmed/26181585

SynCardia Temporary Total Artificial Heart. SynCardia, systems LLC. 2020 https://syncardia.com/

Torregrossa G et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. 2014 Nov-Dec;60(6):626-34 https://www.ncbi.nlm.nih.gov/pubmed/25158888

U.S. Food and Drug Administration. SynCardia Temporary Cardio West Total Artificial Heart, October, 2004 https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030011a.pdf

Washington State Health Technology Reviews, 2020 https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-reviews

Appendix

Policy Number: [Policy Number]

Effective: 8/1/2020 **Next review:** 6/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): [Applicable Regulations(s)]

Commercial Ops: 5/2021

Government Ops: 5/2021