Total Artificial Heart

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

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

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; and

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

Medicaid

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

Medicare

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

Experimental/Investigational/Unproven

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

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

Definitions

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.

References

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Appendix

Policy Number:

Effective: 8/1/2020 **Next review:** 3/1/2025

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): National Coverage Determination (NCD) 20.9.1, Guideline Note 173 of the Oregon Health Plan (OHP) Prioritized List of Health Services

Commercial Ops: 3/2024

Government Ops: 2/2024