Total Artificial Heart

<table>
<thead>
<tr>
<th>State(s):</th>
<th>LOB(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idaho</td>
<td>Commercial</td>
</tr>
<tr>
<td>Montana</td>
<td>Medicare</td>
</tr>
<tr>
<td>Oregon</td>
<td>Medicaid</td>
</tr>
<tr>
<td>Washington</td>
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</tbody>
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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).
    - III – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
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

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**References**

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703693/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703693/)


Hayes Medical Technology Director. Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device. (2015, May, Annual review 2018, May) Hayes, a Division of TractManager.

MCG Heart Transplant ORG:S-535 (ISC). MCG Health Inpatient & Surgical Care 25th Edition. MCG Health LLC

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


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


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