# Total Artificial Heart and Ventricular Assist Devices (for Indiana Only)

Policy Number: CS122IN.01
Effective Date: April 1, 2021

Instructions for Use

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Related Policy

- Clinical Trials

## Application

This Medical Policy only applies to the state of Indiana.

## Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Surgical Services Provider Reference Module.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|---|---|
| 33927 | Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy |
| 33928 | Removal and replacement of total replacement heart system (artificial heart) |
| 33975 | Insertion of ventricular assist device; extracorporeal, single ventricle |
| 33976 | Insertion of ventricular assist device; extracorporeal, biventricular |
| 33979 | Insertion of ventricular assist device, implantable intracorporeal, single ventricle |
| 33981 | Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump |
| 33982 | Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass |
| 33983 | Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass |


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| CPT Code | Description |
|---|---|
| 33995 | Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only |
| 33997 | Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion |

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# U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

## SynCardia Temporary Total Artificial Heart

The 70cc SynCardia Temporary Total Artificial Heart (formerly known as CardioWest) (SynCardia Systems, Inc.) received an Investigational Device Exemption on October 16, 1992 to study the CardioWest Total Artificial Heart under strict protocols at selected heart transplantation centers in the United States. In October 2004, the FDA granted marketing approval under the premarket approval (PMA) application process for the CardioWest TAH-T as a bridge to transplantation in cardiac transplant-eligible patients at risk of imminent death from irreversible biventricular failure. Additional information available at:

- http://www.accessdata.fda.gov/cdrh_docs/pdf3/p030011a.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

(Accessed August 25, 2020)

In a supplement to the original PMA application (P030011), the FDA granted marketing approval for the Freedom® driver system on June 26, 2014. The system is indicated for use as a bridge to transplantation in cardiac transplant candidates who have been implanted with the SynCardia device and are clinically stable.

On October 26, 2016, the FDA issued a letter to health care professionals regarding updated results from INTERMACS comparing mortality rates in patients who were initially supported with either the C2 Driver System or the CSS Console. There has continued to be a higher mortality rate for the subgroup of patients requiring pre-implant circulatory rescue interventions when using the C2 Driver System compared to those using the CSS Console. The mortality rates for patients who did not require pre-implant circulatory rescue interventions were similar for the C2 Driver System compared to the CSS Console. Additional information available at: https://www.fda.gov/medicaldevices/safety/letterstohealthcareproviders/ucm526515.htm. (Accessed August 25, 2020)

## Humanitarian Device Exemptions (HDEs) Pending FDA Approval

On April 12, 2012, SynCardia announced that the FDA approved a Humanitarian Use Device (HUD) designation for the 70cc SynCardia Total Artificial Heart to be used for destination therapy in addition to its current PMA approval as a bridge to transplant. The FDA has also approved an Investigational Device Exemption (IDE) clinical study to support FDA approval of a Humanitarian Device Exemption (HDE) application (ClinicalTrials.gov Identifier: NCT02232659).

On Jan. 15, 2013, the FDA granted a HUD designation for the 50cc SynCardia Total Artificial Heart to be used for destination therapy in adults. To be eligible, patients must be at risk of imminent death from non-reversible biventricular HF, not eligible for cardiac transplant and have a body surface area (BSA) between 1.2 and 1.79$m^2$.

On Jan. 30, 2013, the FDA granted a HUD designation for the SynCardia 50cc Total Artificial Heart to be used as a bridge to transplant for the treatment of biventricular HF in pediatric patients with a BSA that can sufficiently accommodate the device (i.e., between 1.2 and 1.7$m^2$). SynCardia is conducting an FDA-approved Investigational Device Exemption (IDE) clinical study of the 50cc Total Artificial Heart as a bridge to donor heart transplant (ClinicalTrials.gov Identifier: NCT02459054).

Humanitarian Device Exemption (HDE) is a special regulatory marketing approval that makes the device available on a limited basis provided that: (1) The device is to be used to treat or diagnose a disease or condition that affects fewer than 8,000 individuals in the United States; (2) the device would not be available to a person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of


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illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Humanitarian use devices may only be used in facilities that have established a local institutional review board (IRB) to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific rare disease.

## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 04/01/2021 | • New Medical Policy |

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.


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