Clinical Policy Title: Bloodless heart transplant

Clinical Policy Number: 05.03.05

Effective Date: July 1, 2017
Initial Review Date: June 22, 2017
Most Recent Review Date: July 20, 2017
Next Review Date: July 2018

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state and federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers bloodless heart transplant to be clinically unproven, and therefore, investigational/experimental.

Cases in which need for a heart transplant is clinically documented, and the patient refuses external blood transfusions for religious reasons (and provides documentation for such refusal), are considered medically necessary.

Limitations:

None.

Alternative covered services:

None.

Background
Bloodless surgery, defined as operative procedures that use no allogenic blood, has been performed for about a century. Procedures can be performed using lasers or minimally invasive surgical techniques, or by using medicines post-operatively to augment blood cell mass. Potential benefits of bloodless surgery include lower risk of post-operative infections and reduced costs of blood acquisition and storage.

The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists issued a guideline in 2004 that listed numerous pre-operative and peri-operative means of blood conservation used in cardiovascular surgery (Ferraris, 2004).

Over time, surgery that used no blood infusions from other persons became increasingly common in more involved procedures. A 1977 article reported that 542 cardiovascular surgeries at the Texas Heart Institute in Houston had been performed without blood transfusions; nearly all were coronary bypass or valve replacement procedures, but several were heart transplants (Ott, 1977).

Heart surgery on Jehovah’s Witnesses, who refuse transplantation of blood from other humans on religious grounds, has been performed since the mid-1960s (Burnett, 1990). At first, less invasive procedures were done, but by the 1980s, heart transplants (which had been successfully performed using blood transfusions for two decades) were offered without blood as a treatment option at certain specialty centers.

One recent bloodless heart transplantation reported using fibrinogen concentrate and other blood-conservation methods. With a multidisciplinary team and the use of preoperative erythropoietin-stimulating drugs, normovolemic hemodilution, cell salvage, and pharmacotherapy to prevent and treat coagulopathy, it is possible to maintain hemoglobin levels greater than 11 g/dL without the need for blood transfusion (Dallas, 2015).

In December 2010, Nationwide Children’s Hospital in Columbus, Ohio, performed a bloodless heart transplant on a 6-year-old boy from a family of Jehovah’s Witnesses. The case is believed to be the youngest person to receive a heart transplant without the use of transfusions (Children’s Nationwide, 2011).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on May 5, 2017. Search terms were: “bloodless”, “heart transplant” and “Jehovah’s Witness.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

While there are no professional guidelines governing bloodless heart transplants, the International Society for Minimally Invasive Cardiothoracic Surgery has prepared recommendations for drugs, devices, technologies, and techniques for blood management (Menkis, 2012).

No systematic reviews or meta-analyses specifically addressing bloodless heart transplants exist in the professional literature. One meta-analysis of six studies compared cardiac surgery outcomes for 564 Jehovah’s Witnesses with no transfusions with 903 patients given transfusions for the same procedures. Jehovah’s Witnesses had significantly higher postoperative levels of hemoglobin and significantly less postoperative blood loss. The bloodless surgery group also had non-significantly lower rates of early mortality, reoperation for bleeding, atrial fibrillation, stroke, myocardial infarction, and length of stay in the intensive care unit (Vasques, 2016).

A review of 322 Jehovah’s Witnesses who underwent cardiac surgery from the Cleveland Clinic from 1983 to 2011 were compared with 48,986 cardiac surgery patients with transfusions. The Jehovah’s Witnesses group had fewer acute complications and shorter length of stay in matched patients, along with fewer myocardial infarctions, additional operations for bleeding, prolonged ventilation, intensive care unit stays, and hospital stays, along with higher one-year survival. Twenty-year survival rates were similar for each group (Pattakos, 2012).

French researchers presented data on 250 Jehovah’s Witness cardiac patients operated upon between 1991 and 2003, and compared to 250 patients treated from 2003 to 2012 (group B). The 30-day mortality rate declined from 3 percent to 1 percent from the earlier to the later periods, despite a higher severity, suggesting improvement in care. Several factors contributed to the lower rates, i.e., preoperative erythropoietin to attain a minimal hemoglobin value of 14 g/dl, warm blood cardioplegia, the implementation of the Cornell University protocol and fast track extubation (Vaislic, 2012).
Although there is considerable evidence that bloodless cardiovascular surgery can be efficacious, little is published specifically on results of bloodless heart transplants. Aside from reports from famed Houston heart surgeon Denton Cooley, the first heart transplant successfully performed without blood products was described in 1986, in a 45-year-old Jehovah’s Witness (Corno, 1986). The second occurred at the Texas Heart Institute in Houston, in a 46-year-old Jehovah’s Witness with congestive cardiomyopathy (Lammermeier, 1988). Soon after, a peer-reviewed article assessing bloodless heart transplants on five Jehovah’s Witnesses raised the issue of this approach becoming accepted practice in the future. No perioperative deaths occurred, and the five patients did not have higher graft rejection rates due to a lack of a pre-operative transfusion (Burnett, 1990).

Other articles in the medical literature mention bloodless heart transplants. The Texas Heart Institute reported a 57-year-old male Jehovah’s Witness, who had received a heart transplant 14 years earlier, who underwent coronary artery bypass grafting and transmyocardial laser revascularization for left main, left anterior descending, and circumflex coronary artery disease (Gregoric, 2005). At the University of Chicago Medical Center, a 29-year-old male Jehovah’s Witness underwent a second orthotopic heart transplant 20 years after his first, and discharged home – the first known bloodless re-transplant (Russo, 2013).

Duke University Medical Center researchers described the case of a 53-year-old female Jehovah’s Witness with non-ischemic cardiomyopathy who successfully underwent a bloodless heart transplant using fibrinogen concentrate and other blood-conservation methods. Authors conclude that orthotopic heart transplants may be performed successfully in select patients using standard and novel blood conservation methods (Dallas, 2015).

University of Ottawa Heart Institute researchers reviewed 29 papers and identified successful heart transplants in seven Jehovah’s Witnesses without mortality, re-exploration or blood transfusion. The group concluded that absent large studies, a multidisciplinary team approach to such surgery can make bloodless heart transplants technically feasible without an increased mortality risk in suitable candidates (Elmistekawy, 2012).

Policy updates:
None.

Summary of clinical evidence:

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<th>Content, Methods, Recommendations</th>
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References
Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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