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February 29, 2008

BY ELECTRONIC DELIVERY (CAGinquiries@cms.hhs.gov)

Steve Phurrough, MD, MPA, Director
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on Proposed Coverage Decision Memorandum for Artificial Hearts (CAG-00322N)

Dear Dr. Phurrough:

SynCardia Systems ("SynCardia") appreciates the opportunity to comment on the proposed coverage decision memorandum concerning artificial hearts issued by the Centers for Medicare and Medicaid Services ("CMS") on February 1, 2008 ("Proposed Decision"). While we are very pleased that CMS recognizes that use of an artificial heart such as the CardioWest™ temporary Total Artificial Heart ("TAH-t") can help beneficiaries with no other treatment options and thus proposes to reverse the current national noncoverage policy, we believe that the evidence is sufficient to cover the TAH-t as a bridge to transplant without the requirement of a clinical study. SynCardia agrees that there should be conditions for coverage, but those conditions should relate to the condition of the patient, not the conduct of a clinical trial.

As explained below, we request that CMS' final decision authorize coverage of the TAH-t when used as a bridge to transplant when certain conditions (identified in Section II below) exist. We recognize that the Proposed Decision also addresses an artificial heart that is used for a different purpose (destination therapy) and a different patient population (patients not candidates for a heart transplant), but just as CMS has considered the evidence for the devices separately, so too may CMS issue different coverage policies for artificial hearts when used as a bridge to transplant and when used as destination therapy.[1] Since the TAH-t is only indicated as a bridge to transplant, our comments address only coverage of artificial hearts when used as such, and we offer no opinion on coverage of artificial hearts as destination therapy.

[1] Indeed, the agency has done this for another type of mechanical circulatory device, ventricular assist devices. For these devices, there have been separate national coverage analyses when used as a bridge to transplant versus when used as destination therapy.

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DISCUSSION

I. The Evidence Demonstrates that the TAH-t Improves Health Outcomes in Patients with Severe End-Stage Biventricular Heart Failure

In requesting a reconsideration of the national noncoverage policy for artificial hearts, SynCardia provided extensive evidence demonstrating that the TAH-t, when used as a bridge to transplant for patients at risk of imminent death of biventricular failure, improves health outcomes compared to existing treatments. It is important to emphasize that our request and the evidence presented focused on a narrow set of patients – those at risk of imminent death due to biventricular failure. As to this population, SynCardia agrees with the CMS Administrator that the TAH-t can "help patients that otherwise have no treatment options available to them."[2] Indeed, as we explained in our reconsideration request, there is virtually no alternative treatment option for this patient population, as the use of a single ventricular assist device ("VAD") commonly creates additional clinical problems and the use of a bi-ventricular assist device likewise does not improve health outcomes for patients at imminent risk of death from biventricular failure.

Treatment with VADs in this patient population contrasts with the use of the TAH-t, which has shown significantly greater likelihood of being able to successfully bridge the patient to a heart transplant, while providing improved hemodynamics that make the patient a better candidate for a heart transplant. Rather than again discussing the evidence presented earlier, we address the concerns that CMS raised about the evidence. For the reasons discussed below, we do not believe these concerns are sufficient to undermine a conclusion that the use of the TAH-t as a bridge to transplant for patients at risk of imminent death due to biventricular failure is reasonable and necessary.

A. The Age of the Data

As explained in our reconsideration request, SynCardia conducted a prospective, historically controlled trial of 81 patients in five centers, and the results of that study – treatment success at about 70% - were published in an article in the New England Journal of Medicine in 2004. Patient enrollment occurred over a nine year period, which is not surprising given the narrow patient population that the TAH-t was being investigated for and which is now the current indication. CMS indicates that a major weakness of the study is the long period of time over which the implants were done, stating that the

[2] CMS Press Release entitled "Medicare Proposes Coverage With Evidence Development For Artificial Heart Devices" (Feb. 1, 2008) (quoting the CMS Acting Administrator), available at http://www.cms.hhs.gov/apps/media/press/release.asp?.

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"medical management of patients in biventricular failure has certainly improved in the 14 years since the first study patient was successfully bridged to transplant by this device." The agency offers no foundation for this statement, likely because the management of patients at imminent risk of death due to biventricular failure has not improved much at all since that time. That is borne out by the statements of a number of the prominent physicians and directors of cardiac programs who submitted comments when this national coverage analysis was first opened (and in response to the Proposed Decision).

Below are some of the pertinent statements from commenters on this issue:

- Rohinton Morris, Surgical Director, Heart Transplantation and Mechanical Assist Programs at the University of Pennsylvania Health Systems, said that "[k]nowing that LVADs have had a long history of success as bridge-to-transplant, I laud the scientific development and testing that occurred with [the TAH-t]. Both in the literature and in our experience, when a patient experienced biventricular failure, the best survival statistics indicated only a 40-50% survival. When the [New England Journal of Medicine] report came out with a 79% survival in patients with biventricular failure, we were amazed." (comment dated August 21, 2007)

- According to the Clinical Director of the Artificial Heart Program and the University of Rochester Medical Center, without an artificial heart, "patients requiring bi-ventricular replacement may be left with marginally safe discharge options, longer hospitalizations and inadequate circulatory support." (comment dated August 10, 2007)

- The Chief of Cardiothoracic Surgery at the University of Arizona Sarver Heart Center, Dr. Jack Copeland, wrote that "I would say that the area of mechanical circulatory support is 'not healthy.'" He noted that problems have surfaced with some devices and that there have been "desperate attempts on the part of many centers to use small spinning devices which produce low outputs and can only be used on the left side to save patients who are not as sick as those who require biventricular support" and that patients are dying as a result. (comment dated August 15, 2007)

- Dr. Robert Kormos at the University of Pittsburgh Medical Center stated that "patients will always present with terminal biventricular failure, and although a large number can be supported with an LVAD alone, the compromises made due to right heart dysfunction result in a

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higher than expected mortality and a reduced quality of life." (comment dated August 31, 2007)

- Dr. Nicholas Smedira from the Heart & Vascular Institute at the Cleveland Clinic, stated, "[t]he real value of this device is it fills a void in the mechanical circulatory support armamentarium – a device that can effectively treat severe biventricular failure especially in large patients." (comment dated August 24, 2007)

There is nothing in the information before the agency that is suggestive of improvements in the management of patients with biventricular failure. The above experience of some of this country's foremost transplant surgeons and program directors indicates that for patients at risk of imminent death due to biventricular failure, until the TAH-t has become available, there had been no advances in the medical management of these patients. Thus, CMS' concern about the age of the data in light of changes in medicine is misplaced.

B. Paucity of Data in Recent Years

In the Proposed Decision, CMS also expressed concern about the "paucity of data in recent years," noting that from mid-2002 until mid-2006, all implants were done at a single institution. In selectively focusing on this period of time, CMS ignores the evidence provided by SynCardia and by commenters about the most recently available data. These data show that a number of different institutions have performed numerous TAH-t implants since 2006. For instance, the Chief Executive Officer of the Medical College of Virginia Hospitals, VCU Health Systems, John Duval, recently commented that, since April 2006, his institution has implanted 8 TAH-t devices, with <u>all</u> of the patients being successfully bridged to transplant.[3] In addition, the Mayo Clinic in Arizona has implanted the TAH-t in five patients in the past year, and all five patients were successfully bridged to transplant. Just in these two institutions, the most recent success rate is 13 of 13 patients successfully bridged to transplant. We are very troubled by the agency's selective consideration of the TAH-t outcomes experience since the end of the pivotal study, as the most recent experience shows a tremendous level of success.[4]

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[3] We note that Dr. Michael Hess, the Medical Director of the CHF and Heart Transplantation at the same institution submitted a comment in August of 2007, when this national coverage analysis was first opened, indicating that the institution had done seven TAH-t transplants since April of 2006 – six of which were successful and one patient who remained on the TAH-t awaiting transplant. As such, this information was available to CMS prior to the issuance of the Proposed Decision, but was not included in the discussion of the post study period.

[4] Attached is a chart showing the status of patients that have received the TAH-t since January 1, 2007, which shows that 17 of 30 patients were successfully bridged to transplant and 4 patients remain

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With 30 patients having received the TAH-t since January 1, 2007, the recent experience with the device averages about 24 implants per year. This exceeds the average number of implants per year during the study period (nine), which the agency does not seem to view as a paucity of data. It should be noted also that, since Food and Drug Administration ("FDA") approval in 2004, the TAH-t has been burdened by a Medicare national noncoverage decision which many insurers may follow. Certainly, an inability to obtain widespread insurance coverage contributes to a diminished number of cases in which the TAH-t has been used. The recent comments by Mr. Duval confirm this conclusion. As the Chief Executive Officer for an institution that has implanted the TAH-t, he stated that 4 patients were denied access to the device in the past year because of insurance issues. Moreover, there simply are not many patients who would be appropriate candidates for the TAH-t because of the narrow patient selection criteria.[5] Given the noncoverage policy the TAH-t confronts and the narrow patient population for its indicated use, we believe that the above information on usage since the middle of 2006 represents anything but a "paucity" of data for this technology.

C. Data from Other Institutions

In the Proposed Decision, CMS notes that a majority of the implants in the pivotal trial were done at one institution and thus seems to be concerned about the transferability of success at different institutions. Again, the recent experiences of the Mayo Clinic in Arizona and the Virginia Commonwealth University demonstrate that there is transferability of successful outcomes with the TAH-t. These institutions successfully completed SynCardia's training program, which was described in detail in our reconsideration request. Any institution utilizing the TAH-t likewise would have to undergo that training program. Given that the key to achieving positive health outcomes with the use of the TAH-t is proper patient selection, we believe that issue can best be addressed by conditioning coverage on meeting specific criteria, as opposed to clinical study participation. We have identified appropriate patient criteria below.

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supported by the TAH-t while awaiting a transplant. Of these 30 patients, eight patients were 60 years or over, three were successfully bridged to transplant and one remains on the TAH-t while waiting for a donor heart.

[5] In comments on the commencement of this national coverage analysis, the Administrative Director of The Johns Hopkins Comprehensive Transplant Center indicated that he thought that of the 2,500 heart failure patients they treat annually, the TAH-t would assist about 5 per year.

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II. CMS Should Cover the TAH-t When Used as a Bridge to Transplantation With Conditions Related to Patient Selection and Rather Than Clinical Study Participation

For the reasons discussed in the prior section, we believe that, notwithstanding the concerns expressed in the Proposed Decision, the evidence regarding the TAH-t demonstrates that the device improves health outcomes for patients at risk of imminent death due to biventricular failure. As such, the TAH-t, when used as a bridge to transplant, should be covered without a study requirement. At the same time, however, SynCardia is not suggesting that there should be no conditions on coverage of the TAH-t as a bridge to transplant. Instead, we believe that coverage should be conditioned on the following patient criteria:

- At imminent risk of death due to biventricular failure;
- Eligible for heart transplantation;
- Body surface area of $\geq 1.7 m^2$; or who have a distance between the sternum and the 10th anterior vertebral body measured by computed tomography imaging (CT scan) $\geq$ 10 cm, and

- Presence of hemodynamic insufficiency as demonstrated by A and/or B below:

  A: Cardiac index $\leq 2 L/min/m^2$ and one of the following
  - systolic arterial pressure $\leq$ 90 mm HG
  - central venous pressure $\geq$ 18 mm HG

  B: Two of the following
  - dopamine $\geq 10 \mu g/kg/min$
  - dobutamine $\geq 10 \mu g/kg/min$
  - epinephrine $\geq 2 \mu g/kg/min$
  - isoproterenol $\geq 2 \mu g/kg/min$
  - amrinone $\geq 10 \mu g/kg/min$
  - other cardioactive drugs at maximal doses
  - intra-aortic balloon pump
  - failure to wean from cardiopulmonary bypass.

III. If Coverage of the TAH-t is Tied to Clinical Studies, CMS Should Revise or Clarify the Criteria to Qualify for Coverage

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While SynCardia firmly believes that coverage of the TAH-t should be conditioned only on the conditions listed in Section II above, should the agency reach a final decision that conditions coverage on patients being in a clinical trial, we believe that the agency needs to make changes to the criteria that a study would have to meet and clarify who would decide whether a question is addressed and the criteria are met.

A. Criteria that a Study Must Meet

In the Proposed Decision, CMS identified 14 criteria that a clinical study involving artificial hearts must meet for the use of the device to be covered by Medicare. As we have explained, SynCardia has one ongoing clinical study involving the TAH-t that has already been approved by FDA (the Post Market Surveillance Study), and is developing a protocol for another clinical study involving the TAH-t that will be approved by the FDA before it commences (the IDE Trial).[6] In assessing the ability of both of these studies to satisfy the criteria in the Proposed Decision, we have identified areas in which we recommend that the criteria be modified.

1. The Criteria Must Accommodate Studies that Have Been Approved by the FDA

There are a number of criteria that, functionally, would impose retroactive obligations in order for a study to meet the criteria in the Proposed Decision. For instance, one criterion in the Proposed Decision is that the clinical study must be registered on the ClinicTrials.gov website prior to the enrollment of the first study subject. This would be an impossible criterion for us to meet with regard to the FDA approved Post Market Surveillance Study, which has already enrolled patients. While SynCardia has no objection to registering on this website (and has done so for the Post Market Surveillance Study), we believe that CMS must modify this proposed criterion to simply require registration. We note that CMS' guidance document on coverage with evidence development includes this requirement without a mandate that registration occur before enrollment of the first study subject.[7] That would be a more appropriate criterion.

Similarly, the Proposed Decision contains criteria that require the study protocol to include certain discussions - of subpopulations

[6] The Post Market Surveillance study appears as Appendix III-D to our reconsideration request and the IDE Trial is described in Section II(F) of that document.

[7] *See* https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8.

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affected by the treatment under investigation, of how the results are or are not expected to be generalizable to the Medicare population, and of the timing and method of public release of all prespecified outcomes to be measured. Here also, with respect to the Post Market Surveillance Study, SynCardia has an already established protocol that has been approved by the FDA, but that does not contain such a discussion of these issues. At the time of drafting the protocol, there was no way of knowing that either discussion would be necessary. As such, it would be inappropriate for the failure to meet any of these criteria to be what prevents the use of the TAH-t in this study from qualifying for coverage. CMS must modify these criteria so that there is flexibility to accommodate protocols that have already been written and approved through the required regulatory channels.

2. Clarifications Needed

In addition, to the above changes to certain criteria, SynCardia believes that there is a lack of clarity to some of the other criteria that should be rectified. For example, the third listed bullet indicates that the study should be "well supported by available scientific and medical information" or be "intended to clarify or establish the health outcomes of interventions already in common clinical use." It is not clear what CMS means by "well supported by" or what the agency means by "common clinical use." Without a better understanding of what the agency means by these phrases, it is difficult to understand how one would determine whether a study meets the criterion.

With respect to the criterion in the Proposed Decision that requires the protocol to specify the method and timing of public release of outcomes, the agency says that if a report is planned to be published in a peer reviewed journal, the initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors ("ICMJE"). The agency should clarify whether these are the only requirements that would suffice, or if the reference to ICMJE was just illustrative.

B. Determining Whether the Questions are Addressed and the Criteria Are Met

The Proposed Decision does not provide any indication as to what entity would be responsible for determining that a study meets the requisite criteria and addresses one of the questions. It would seem administratively burdensome and potentially redundant if a study sponsor had to approach every pertinent Medicare contractor to obtain a determination as to whether a study would meet the requirements for coverage. In our view, CMS should

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work with sponsors such as SynCardia and investigators to make this determination so that there is a uniform nationwide decision. Should CMS decide to issue a final decision that links coverage of the TAH-t to participation in a clinical study that includes requirements for a study to qualify for coverage, it should explain how satisfaction of the requirements would be assessed.

CONCLUSION

Again, SynCardia believes that the agency's Proposed Decision reflects a step in the right direction in that it would provide Medicare coverage for the TAH-t, reversing the existing national noncoverage policy. However, we disagree with the need to have coverage conditioned on patients being involved in a clinical trial. Rather, we believe that the evidence is sufficient to support coverage of the TAH-t with conditions, identified earlier, that are tied to the selection of the appropriate candidates for the TAH-t.

If you have questions concerning this letter, please do not hesitate to contact me at (520) 547-7467. Thank you for your consideration.

Respectfully,

Carole E. Marcot
Vice President
Regulatory Affairs and Quality

Attachment

TAH-t PATIENT STATUS - January 1, 2007 through February 26, 2008

U.S. Centers	Patient Count	Implant Year	Age	Status Code	Duration
Aurora St. Luke's Medical Center	1	2007	60	DEC	155
Barnes-Jewish Hospital	1	2007	54	DEC	11
Cleveland Clinic Foundation	1	2007	37	DEC	120
	1	2007	59	TRA	68
Hospital University of Pennsylvania (HUP)	1	2007	46	TRA	27
	1	2007	64	TRA	55
	1	2007	60	DEC	19
Mayo Clinic - AZ	1	2007	56	TRA	13
	1	2007	58	TRA	61
	1	2007	51	TRA	68
	1	2007	45	TRA	85
	1	2007	58	TRA	63
MCV-VCU	1	2007	54	TRA	25
	1	2007	41	TRA	2
	1	2007	33	TRA	60
	1	2007	35	TRA	29
Penn State Milton S. Hershey	1	2007	60	TRA	62
UMC - AZ	1	2007	66	TRA	76
	1	2007	70	DEC	7
	1	2007	51	TRA	33
	1	2007	35	DEC	9
	1	2007	27	TRA	106
	1	2007	19	DEC	14
	1	2008	51	IHOS	58
	1	2008	45	IHOS	20
	1	2008	42	IHOS	9
University of Maryland Medical	1	2007	24	DEC	62
	1	2007	61	DEC	33
	1	2008	64	IHOS	7
University of Michigan Health	1	2007	33	TRA	27
TOTALS:	**30**				

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February 29, 2008

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Re: Proposed Decision Memo for Artificial Hearts (CAG-00322N).

Dear Dr. Phurrough:

The American College of Cardiology (ACC; the College) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Decision Memorandum for Artificial Hearts (CAG-00322N).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. Our goal is to assist CMS in making appropriate coverage decisions based on scientific evidence.

The ACC commends CMS' proposed decision memorandum providing for Coverage with Evidence Development (CED), and supports the agency's efforts to promote clinical research in these promising technologies. The College also believes that the research questions posed by the CED for qualifying clinical studies to address are appropriate criteria for coverage. It is our sincere hope as well that this research will lead to additional breakthroughs in these and future treatment options for those heart failure patients left without other current clinical alternatives.

We appreciate your attention to this letter, and remain eager to assist you and your staff as it finalizes this NCD. If you have any questions, please contact Sergio A. Santiviago, Senior Specialist, Regulatory Affairs at 202.375.6392, or by e-mail at ssantivi@acc.org.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President

cc: Jack Lewin, M.D., C.E.O.

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February 29, 2008

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Dear Dr. Phurrough:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed national coverage decision (NCD), *Artificial Hearts* (CAG-00322N). America's Health Insurance Plans (AHIP) is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. We are pleased to submit these comments on behalf of our members.

General Comments

We support CMS's intent to ensure that all patients receive the most effective and appropriate treatments as indicated by sufficient levels of clinical evidence. We concur with CMS's assessment that the current body of evidence is inadequate to support coverage of unrestricted use of artificial hearts. Further evidence will be necessary to clarify which patients would benefit from these devices.

Currently, many of our member health insurance plans do provide coverage for SynCardia Systems, Inc., CardioWest temporary Total Artificial Heart (TAH-t) as a bridge to heart transplantation. However, most health plans have considered the AbioCor® implantable replacement heart to be experimental and investigational; some plans provide coverage only when all the criteria of the Food and Drug Administration's (FDA's) Humanitarian Device Exemption (HDE) requirements are met.

Our members generally agree with CMS's proposed decision to provide access to these devices through Coverage with Evidence Development (CED). Two key issues about this approach, however, should be highlighted:

1) The CED process could be further improved. There are growing concerns that the evidence may not be collected and reported in a manner which will provide new, useful information for patients, clinicians, and insurers. CMS should work with the FDA to assure that the key evidentiary questions highlighted in the NCD are clearly addressed by

the post-approval studies deemed suitable to merit coverage. Further evidence, once gathered, should be made available in a timely manner to improve patient outcomes.

2) When CMS chooses to provide restricted coverage through CED, health insurance plans may continue to deem these technologies experimental and investigational. Until sufficient evidence is developed, health insurance plans often provide coverage for these devices only through clinical trials.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Carmella Bocchino
Executive Vice President, Clinical Affairs and Strategic Planning