July 12, 2019

Tamara Syrek-Jensen, Director
Coverage & Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Via electronic transmission: Tamara.SyrekJensen@cms.hhs.gov
NCDRequest@cms.hhs.gov

RE: Formal Request for Reconsideration of the National Coverage Determination 20.9.1 (NCD) for Ventricular Assist Devices (VADs) to remove BTT and DT coverage criteria in favor of patient characteristics that support VAD candidacy

Dear Ms. Syrek-Jensen,

Abbott formally requests the reconsideration of NCD 20.9.1 for ventricular assist device (VAD) procedures in modifying the coverage language to focus on patient characteristics for VAD candidacy rather than declaring intent of device at time of implant. CMS's role in prior reconsideration requests for VAD therapy has been instrumental in ensuring medical efficacy and appropriateness of the therapy through establishing operator and facility requirements, credentialing, and the implementation of the INTERMACS® Registry for ongoing data collection.

We request CMS reassess the patient coverage criteria considering the most recent evidence from the MOMENTUM 3 (NCT02224755) clinical trial which demonstrates the strong therapeutic benefit of left ventricular assist devices (LVADs) regardless of device intent (e.g., bridge to transplant -BTT, bridge to candidacy-BTC, and destination therapy-DT). The objective of the formal reconsideration request is to remove the intent to treat criteria and base LVAD coverage requirements on characteristics from the key LVAD pivotal clinical trials and the new scientific evidence from the MOMENTUM 3 trial that demonstrate the clinical benefits of LVADs regardless of intent to treat category. Specifically, our **recommended language** to better support this effort includes revision of LVAD candidacy in the NCD to the following:

> The surgically implanted device must be FDA indicated for patients who require short term (e.g., like bridge to transplantation or myocardial recovery) and long-term (e.g., like destination therapy) mechanical circulatory support.
>
> The VADs are covered for patients who have advanced heart failure symptoms and meet one of the following conditions:
>
> - Failure to respond to guideline directed medical therapy; or
> - Are listed for transplant or
> - Are dependent on treatment with intravenous inotropic therapy or on intra-aortic balloon pump or on an acute mechanical circulatory assist device (e.g., external, temporary, or percutaneous).

As part of this ongoing effort, Abbott would like to thank the Centers for Medicare and Medicaid Services (CMS) Coverage and Analysis Group (CAG) for their input on the MOMENTUM3 trial protocol. Your

valuable feedback helped ensure the endpoints demonstrated the clinical benefits of the Heartmate3™ LVAS (Left Ventricular Assist System) in the Medicare population in defining short and long-term support. This was critical in addressing the clinical community's desire in moving away from traditional indications of Bridge to transplantation (BTT) and Destination Therapy (DT) as presented in the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). We appreciate the ongoing engagement with CAG, the Principal Investigators of the MOMENTUM 3 trial, and clinical experts in reviewing the study results and defining appropriate use. We provide the background and review of the new scientific evidence below that support formal reconsideration of NCD 20.9.1.

Scientific Evidence to Support Reconsideration

Background

In November 2012, CMS convened a MEDCAC meeting that reviewed the management of heart failure with use of VADs.[1] In this forum, many clinicians expressed the challenges of designating patients based on coverage descriptors (BTT and DT) at the time of implant because often, patients' clinical conditions change with disease progression or treatment during the management cycle. To demonstrate that implant strategies change over time and impact outcomes, Teutenberg et al. utilized the INTERMACS Registry and showed LVAD patients differ by the number and types of comorbidities rather than the need for hemodynamic support. In the analysis at two years, 43.5% of BTT patients were no longer listed for transplant (e.g., LVAD is used as DT) and 29.3% of BTC patients were listed for transplant which indicates device strategies change over time and patients may often have longer durations of support than their intended classification.[2] Another challenge with these classifications is that clinicians may delay VAD intervention, until their advanced heart failure symptoms worsen while determining what arbitrary classification patients conform to where patients could have clearly benefited from earlier intervention.

As a result, the MOMENTUM 3 IDE trial was designed to specifically address the advancement in LVAD performance with the HeartMate 3™ LVAS in studying improved survivability benefit in enrolling "all-comers" (BTT, BTC, DT) regardless of therapeutic intent within the same clinical trial.[3,4,5,6] The HeartMate 3™ LVAS provides improvement from earlier LVAD pumps (pulsatile and axial flow technologies) via a centrifugal flow pump to better address patient outcomes as it relates to improving hemocompatibility-related adverse events (decreasing incidences of stroke, gastrointestinal bleeding, and pump thrombosis). The value and premise of a centrifugal flow pump is that wide-blood flow passages and the absence of mechanical bearings with intrinsic pulse design assist with better blood handling to limit the incidences of disabling stroke and the need to replace or remove a malfunctioning device.

---

[1] CMS MEDCAC Meeting-Management of HF with use of VADs. https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=65

[2] Teutenberg et al. Implant strategies change over time and impact outcomes: insights from the INTERMACS. *JACC Heart Fail*. 2013 Oct; 1 (5):369-78.

[3] Heatley et al. Clinical trial design of MOMENTUM3. *JHLT*. 2016.

[4] Mehra et al., A fully magnetically levitated circulatory pump for advanced heart failure. *NEJM.* 2017;375(5):440-50.

[5] Mehra et al., Two-year outcomes with a magnetically levitated cardiac pump in heart failure. *NEJM*. 2018; 378(15):1386-1395.

[6] Mehra et al., A fully magnetically levitated left ventricular assist device- Final report. *NEJM* 2019 March 17. [Epub ahead of print].

MOMENTUM 3 Clinical Trial

The MOMENTUM 3 pivotal trial is a prospective, non-blinded, randomized, multi-center study comparing the HeartMate 3™ LVAD to the HeartMate II™ LVAD. The primary endpoint of the study is survival free of disabling stroke (mRS > 3), or reoperation to replace or remove the device at 6 months after implantation.

The initial 6 months results of the MOMENTUM 3 clinical trial of the short-term cohort (n= 294) demonstrated the following:

- Significant reduction in the need for reoperation due to pump malfunction of the HeartMate 3™ LVAS
- No suspected or confirmed pump thrombosis events with the HeartMate 3™ LVAS, which is often a principal driver of pump exchange
- Similar functional and quality of life improvement in patients treated with either the HeartMate 3™ or the HeartMate II™ LVAS.[3]

HeartMate 3™ LVAS received FDA approval in August 2017 for the short-term hemodynamic support (bridge to transplant and myocardial recovery). As of October 19, 2018, HeartMate 3™ LVAS received FDA approval for long-term hemodynamic support (destination therapy) based on the two-year outcomes of the MOMENTUM 3 long term cohort. Thus, the final FDA indication for HeartMate3™ LVAS is as follows:

The device is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

MOMENTUM 3 Trial Results and Sub-analyses

The 2018 publication of the two-year outcomes of the MOMENTUM 3 long term cohort (n=366) continue the favorable results from the short-term cohort in demonstrating an 83% overall survival, 10% stroke rate, and 1% suspected pump thrombosis with the HeartMate 3™ LVAS. Functional status and quality of life demonstrated sustained and significant improvements in both HeartMate pumps compared to baseline.[4]

The final analysis of the full cohort (1028 enrolled patients) in the MOMENTUM 3 trial was presented at the 2019 American College of Cardiology Scientific Expo with a concurrent publication of the results in the *New England Journal of Medicine*. The final report from the full cohort of patients confirm findings from the smaller trial cohorts that support the short term and long-term indication as well as providing statistical power to demonstrate superiority of the primary endpoint and the secondary endpoint of pump replacement. When compared to the HeartMate II LVAS, the HeartMate 3 LVAS showed non-inferiority and superiority with respect to the primary endpoint of survival free of disabling stroke or reoperation to replace or remove a malfunctioning device (74.7% among HeartMate 3 LVAS patients compared to 60.6% among those assigned to the HeartMate II pump at two years). In addition, the HeartMate 3 LVAS patients continue to experience the fewest hemocompatibility-related adverse events, including:

- Lowest rate of pump thrombosis at 2 years (1.4%) for an LVAD in a randomized clinical trial. Only 1.0% required a reoperation.
- Lowest stroke rate at 2 years (9.9%) for an LVAD in a randomized clinical trial, and
- Significantly lower GI bleeding events (HM3: 24.5% vs. HMII: 30.9%).

Quality of life and functional assessment demonstrated immediate, significant, and sustained improvements compared to baseline at 2 years for both HeartMate pumps.[6]

More importantly, subgroup analysis of the MOMENTUM 3 short-term cohort (Goldstein et al., 2018) focused on five sub-groups (age, sex, race, therapeutic intent [BTT or DT] and disease severity) in determining LVAS outcomes. The subgroup analysis concluded that the observed superiority of the HeartMate 3 LVAS compared with the HeartMate II LVAS is not the result of singular influence of any pre-specified subgroup analyzed and that younger age (≤65years) and device choice demonstrated greater likelihood of survival. These findings provide further observation that characterization of device intent into discrete coverage categories did not provide clinical advantage because patient outcomes improved regardless if patient was BTT or DT.[7]

As part of the continuation of the above analysis, Dr. Goldstein presented at the 2019 International Society of Heart and Lung Transplantation (ISHLT) on the clinical outcomes by intended goal of therapy on the full cohort from the MOMENTUM 3 trial. The intent was to conduct a prespecified analysis of the primary and secondary outcomes and adverse events in the full 1028 patient cohort stratified by pre-implant strategy of BTT/BTC versus DT. The intent to treat strategies were equally represented and distributed between the Heartmate 3 LVAS and the HeartMate 2 LVAS.

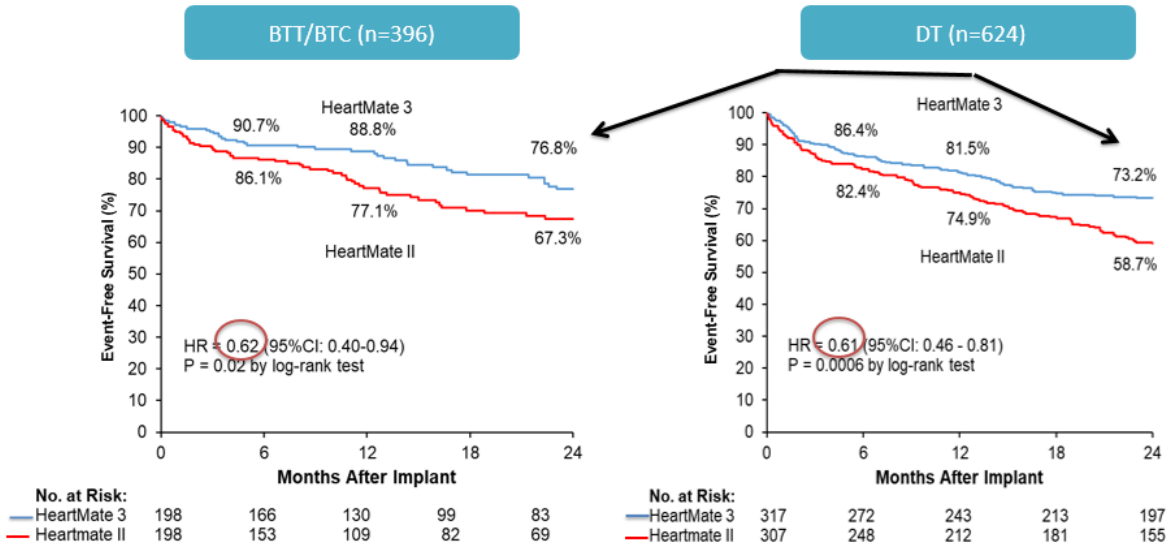
Table 1: Intended Use- Full Cohort per Protocol Population

		HM3 (n=515)	HMII (n=505)	Total (N=1020)*
Continuum of transplant eligibility	**BTT**	112 (22%)	120 (24%)	**232 (23%)**
	BTC	86 (17%)	78 (15%)	**164 (16%)**
	Likely to become eligible for Tx	45 (8%)	43 (9%)	**88 (9%)**
	Moderate likelihood of becoming eligible	32 (6%)	33 (7%)	**65 (6%)**
	Unlikely to become eligible	9 (2%)	2 (0.3%)	**11 (0.8%)**
	DT	317 (62%)	307 (60%)	**624 (61%)**

In comparing the primary endpoint (survival at two years free of disabling stroke (>3 mRS) or reoperation to replace or remove malfunctioning device), the absolute effect of the HeartMate 3 LVAS on the primary endpoint was very similar between BTT/BTC and DT (76.8% survival for BTT/BTC versus 73.2% survival for DT). In addition, the hazard ratios for BTT/BTC (HR =0.62, 95% CI:0.40-0.94) compared to DT (HR= 0.61, 95% CI: 0.46-0.81) are nearly identical which indicates that the magnitude of the positive impact of the HeartMate 3 LVAS on the primary endpoint was almost the same whether patients in the study were transplant eligible (BTT/BTC) or transplant ineligible (DT). (Refer to Table 2.)

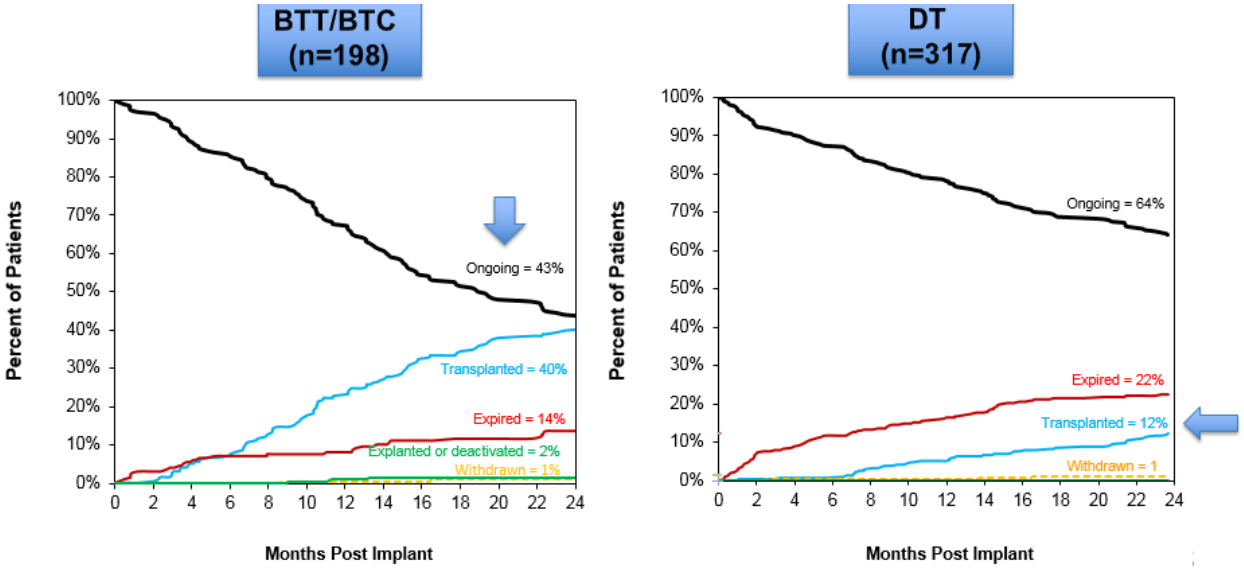
[7] Goldstein et al. Impact of age, sex, therapeutic intent, race and severity of advanced heart failure on short-term principal outcomes in the MOMENTUM 3 trial. *J Heart Lung Transplant*. 2018 Jan; 37(1):7-14.

Table 2: Primary endpoint by Intent to Treat



Another part of the Goldstein et al. (2019) analysis focused on competing outcomes for both HeartMate 2 and HeartMate 3 LVAS patients stratified by pre-implant strategy. The value of this analysis demonstrated that intent to treat may change over time compared to the pre-implant strategy designated because of changes in patients' condition warrant continuation on LVAD therapy even if they were originally classified as BTT/BTC or DT. Table 3 depicts this for HeartMate 3 LVAS patients in showing that 43% of transplantable patients are still on LVAD support beyond two years (typically, two years is the timeframe for clinical designation as DT). While 12% of transplant ineligible (DT) HeartMate 3 patients received transplants. Similar findings were observed for HeartMate 2 LVAS patients whereby 37% of BTT/BTC patients remained on support beyond two years and 15% of DT patients were transplanted.

Table 3: Competing Risk Analysis by Intended Use-HeartMate3 LVAS



The Goldstein presentation (accessed on www.momentum3investigators.com) in comparing clinical outcomes by pre-implant strategy demonstrated an important finding that pre-implant strategy designations are dynamic and may change over time. In reviewing the findings, it is clear that the present use of these arbitrary designations should be abandoned in favor of one pre-implant strategy. This results in improvement in the survival and quality of life of patients with advanced heart failure while reducing the burden of complications with left ventricular assist systems.[8]

Healthcare resources and cost implications

Mehra et al. (2018) reported on the economic implication of the two-year clinical outcomes of the MOMENTUM 3 long-term cohort related to the absence of need for pump exchanges due to pump thrombosis and ~50% reduction in overall stroke rates between the pumps. The improved adverse event profile of the HeartMate 3 compared to the HeartMate II is associated with lower rehospitalizations and costs. This included a 51% reduction in average cost per patient-year and 8.3 fewer hospital days per patient-year, driven by a reduction in device-attributable events including suspected pump thrombosis and stroke-related hospitalizations. The important theme is cost savings were similar in both BTT and DT patients validating the clinical results and ensuing economic benefits are relevant regardless of intent to treat.[9]

Comprehensive stroke analysis

Colombo et al. (2018) demonstrated from the MOMENTUM 3 data that all strokes have detrimental effects in terms of significantly reducing survival regardless of stroke severity (disabling or non-disabling) or subtype (ischemic or hemorrhagic). There was no difference in stroke rate between 0 and 180 days of follow-up between devices. However, stroke incidence in the long-term period (181–730 days after left ventricular assist device) was 3.3 times lower for the HeartMate 3 LVAS group (HM3: 0.04 versus HMII: 0.13 events per patient-year; odds ratio, 0.23; 95% CI, 0.08–0.63; P=0.01). The HeartMate 3 LVAS was the only independent predictor of lower stroke rates at two years. One of the potential device-related adverse effects with traditional LVADs has been stroke attributable to device thrombosis. In this study, it showed that a stroke event significantly lowered two year post implantation survival regardless of subtype or initial severity of neurological impairment compared with patients without a stroke (43±12% for hemorrhagic stroke, 57±9% for ischemic stroke, 51±11% for disabling, and 51±11% for nondisabling compared with 85±2% 2-year survival for patients without stroke). The data from MOMENTUM 3 is compelling as the contemporary centrifugal pumps better manage stroke and help increase survival rates for eligible patients regardless of intent to treat.[10]

Benefit Categories

VAD implants and services fall under Medicare Part A, Part B, and prosthetic benefits under the sections of Social Security Act which include inpatient hospital (Section 1861(b)), physician (Section 1861(q)), and prosthetic services (Section 1861(s8)). VAD implants and services would fall under the above benefit categories set forth based on reasonable and necessary.

---

[8] Goldstein, D.J., Uriel, N., Cleveland, J.C., Mehra, M.R., for the MOMENTUM 3 Investigators. (2019). Clinical Outcomes by Intended Goal of Therapy in the MOMENTUM 3 Clinical Trial: Analysis of the Full Cohort. Presented at ISHLT 2019 Annual Meeting, Orlando, FL. (publication pending)

[9] Mehra et al. Healthcare resource use and cost implications in MOMENTUM3 long-term outcome study. *Circulation.* 2018.

[10] Columbo et al. Comprehensive analysis of stroke in the long-term cohort of the MOMENTUM 3 study: a randomized controlled trial of the HeartMate 3 versus the HeartMate II cardiac pump. *Circulation*. 2018.

Description of Services

A VAD is a surgically implanted mechanical pump that is attached to the heart to help pump blood from the left ventricle to the aorta to deliver oxygen-rich blood throughout the body. With the advancement of technology, there have been technological advancements focused on LVAD pumps in moving from an axial-flow pump (HeartMate 2 LVAS) to a centrifugal-flow pump (e.g., HeartMate 3 LVAS) to mitigate adverse events such as pump thrombosis to significantly improve patient outcomes. The centrifugal-flow pumps allow for better blood handling as there are no mechanical bearings that may cause shearing of the blood resulting in thrombosis and stroke. VAD implants are commonly reported with the following CPT code 33979 (Insertion of ventricular assist device, implantable, intracorporeal, single ventricle).

Indications

The US Food and Drug Administration (FDA) has approved this treatment (HeartMate 2 LVAS) in 2010 first as a device indicated for use as a bridge to transplantation in cardiac transplant candidates at risk for imminent death from non-reversible left ventricular failure, and for use as destination therapy in patients with NYHA Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days and are not candidates for cardiac transplantation.

With the FDA approval of the HeartMate 3 LVAS in 2018 based on the MOMENTUM 3 trial, the FDA language now reflects contemporary language that includes both short-term and long-term support that crosswalks to BTT and DT. The full language is reflected below:

"The device is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure."

Description of Proposed Use of Service for Identified Medical Conditions in Target Medicare Population and Medical Conditions for which it can be used

Table 4 summarizes the key LVAD trials and the key inclusion criteria that have been the basis for supporting VAD candidacy. CMS could leverage these key patient characteristics in considering coverage criteria appropriate for VAD therapy. Abbott and the scientific community strongly believe these patient characteristics are a better indicator of the Medicare patients that should be candidates for LVAD therapy rather than relying on the artificial categories that have been the rationale behind the intent to treat designations (e.g., BTT, DT). This is more apparent considering the recent scientific evidence supporting the positive findings of the MOMENTUM 3 clinical trial which show that BTT and DT patients show equivalent benefit of LVADs regardless of intent to treat.

Table 4: Summary of Major LVAD Pivotal Trials and Patient Characteristics

Key LVAD Trials	REMATCH (NCT00000607)	ROADMAP (NCT01452802)	HeartMate II BTT/DT (BTT: NCT00121472 and DT: NCT00121485)	ENDURANCE (NCT01166347) BTT/DT HeartWare® VAS	MOMENTUM 3 (NCT02224755) BTT, BTD and DT HeartMate II and HeartMate 3 LVAS
Comparator	Optimal Medical Management (OMM)	OMM	BTT Trial: NA DT Trial: HeartMate XVE LVAS	HeartMate II LVAS	HeartMate II LVAS
Inclusion	NYHA CLASS IIIB or IV	NYHA Class IIIB or IV	NYHA Class IIIB or IV	NYHA Class IIIB or IV	NYHA Class IIIB or IV
	Or: Class III or IV for at least 28 days, and	On OMM	Or: Class III or IV for at least 28 days,		Class III with dyspnea upon mild physical activity
Inotropes / Intra-aortic balloon pump (IABP)	And: dependent on IABP or inotropes for 14 days	At least 2 unscheduled ER or infusion clinic visits (may include IV diuretic therapy) for HF in the last 12 months	And: dependent on IABP or inotropes for 14 days	On OMM, including dietary salt restriction and diuretics, for at least 45 out of the last 60 days and are failing to respond; or 3b. In NYHA Class III or NYHA Class IV heart failure for at least 14 days, and dependent on IABP for 7 days and/or inotropes for at least 14 days	Inotrope dependent OR OMM, 45 out of the last 60 days and are failing to respond, Advanced Heart Failure for at least 14 days AND dependent on IABP for at least 7 days

Key LVAD Trials	REMATCH (NCT00000607)	ROADMAP (NCT01452802)	HeartMate II BTT/DT (BTT: NCT00121472 and DT: NCT00121485)	ENDURANCE (NCT01166347) BTT/DT HeartWare® VAS	MOMENTUM 3 (NCT02224755) BTT, BTD and DT HeartMate II and HeartMate 3 LVAS
VO2 Upper	≤ 12, (later ≤ 14)	NA	≤ 14 or <50% predicted	NA	NA
LVEF	< 25%	≤ 25%	< 25%	≤ 25%	≤ 25%

Rationale for how reconsideration of NCD 20.9.1 will improve medical benefit to the Target Population

The current NCD (20.9.1) for VADs forces providers to declare intent to treat (BTT or DT) at the time of implant because of coverage. As expressed consistently by physicians, clinicians, and the medical community, this is often challenging because patients' often move and fluctuate between these stages in terms of needing mechanical circulatory support for short-term and/or long-term needs. As a result, Medicare patients who fall into classifications defined as bridge to candidacy, bridge to recovery, and bridge to decision must wait until their conditions worsen prior to qualifying for VAD therapy. These patients have similar patient characteristics as those with BTT and DT and providers would recommend VAD therapy as an opportunity to improve their disease state, but they are prevented from doing so because of the current coverage language. In delaying timely access to VADs, some Medicare patients may progressively develop co-morbidities and die while waiting or after a more complex LVAD implant accompanied by post-operative organ failure.

The most recent INTERMACS report shows that those patients who fall outside of BTT and DT that received VADs is around 29.7%.[11] These patients are classified as "BTT likely, moderate, and unlikely" for the INTERMACS' categorization. For the purposes of understanding these patients who fall into bridge to decision (BTD), Abbott's analysis of the MOMENTUM 3 long-term cohort compared the primary endpoint success (survival free of disabling stroke or pump replacement or removal for a malfunctioning device) for the 366 patients for HeartMate II LVAS and HeartMate 3 LVAS combined and showed the following:

Intent to treat	N	Primary Endpoint Success
BTT Listed	91	78%
DT	217	67%
Bridge to Decision (BTT Likely, moderate likely and unlikely to be listed)	58	71%

[11] Kormos, RL., et al. The Society of Thoracic Surgeons INTERMACS Database Annual Report: Evolving Indications, Outcomes, and Scientific Partnerships. *Ann Thorac Surg* 2019; 107:341-353.

The MOMENTUM 3 analysis shows that BTD patients do well on contemporary LVAD therapy when they have access to this life-saving treatment earlier in the continuum of their disease state. Elimination of these artificial classifications from the NCD 20.9.1 and replacing them with patient characteristics from the pivotal VAD trials and INTERMACS Registry is more appropriate in identifying Medicare patients who would derive a clear clinical benefit from VADs.

Summary of Formal NCD Reconsideration Request

With the improvements in LVAD technology to address hemocompatibility challenges as it relates to stroke, gastrointestinal bleeding, and pump thrombosis, this technology continues to progress in advancing better patient outcomes. The INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) Registry was established in 2005 to capture the clinical characteristics and outcomes of patients who receive an FDA-approved mechanical circulatory support device to treat advanced heart failure. This robust database captures the patient profiles, device strategy, survival rates, and competing outcomes that provide CMS a better understanding of patients who receive and perform optimally on VADs. Between this Registry and the most recent evidence supporting LVAD therapy, CMS has an opportunity to re-evaluate NCD 20.9.1 to best address patient characteristics that support VAD therapy. Eliminating the intent to treat designations allows for one process for qualification of VAD therapy and results in all implants being tracked the same way. Patients who are eligible for transplants versus those who are not, receive VAD therapy as a medically appropriate option providing physicians and families more time to make that determination based on the patient's condition.

As a result, Abbott strongly endorses revising the patient coverage criteria to remove the classification of therapy intent at time of implant (e.g., bridge to transplant (BTT), bridge to decision (BTD) and destination therapy (DT)) towards criteria that support LVAD candidacy based on the body of evidence.

Our **recommended language** to better support LVAD candidacy in the NCD is as follows (Please also refer to Addendum A for the redline changes to NCD 20.9.1):

The surgically implanted device must be FDA indicated for patients who require short term (e.g., like bridge to transplantation or myocardial recovery) and long-term (e.g., like destination therapy) mechanical circulatory support.

The VADs are covered for patients who have advanced heart failure symptoms and meet one of the following conditions:

- Failure to respond to guideline directed medical therapy; or
- Are listed for transplant or
- Are dependent on treatment with intravenous inotropic therapy or on intra-aortic balloon pump or on an acute mechanical circulatory assist device (e.g., external, temporary, or percutaneous).

(Note: Our proposal maintains the facility and operator requirements in NCD 20.9.1. Since the VAD must be FDA indicated for short term and long term mechanical circulatory report, this would require all facilities that perform implants to be certified by an approved credentialing agency. Most facilities that offer BTT are already certified for DT, so the impact will be minimal. We anticipate when there is a change in the NCD, the certifying organizations have a standard process to update their respective Standards; therefore, there should be no lapse in monitoring or certifying new programs.

As a result of regulatory approval, current and future LVAD systems must receive FDA indication for both short and long-term mechanical circulatory support to qualify for coverage under the revised NCD to best support safety and efficacy.)

With the latest evidence from the two-year outcomes of the MOMENTUM 3 clinical trial, the trial demonstrates that appropriate patients derive the same level of clinical benefit of LVAD therapy regardless of the designated device intent. The MOMENTUM 3 clinical trial is the largest LVAD trial which studied BTT, BTD, and DT patients within the same trial who demonstrated the HeartMate 3™ LVAS successfully achieved its primary endpoint of survival at two years free of disabling stroke (mRS >3) or reoperation to replace or remove a malfunctioning device.

Abbott formally requests reconsideration of NCD 20.9.1 to focus on appropriate patient criteria that supports LVAD therapy by removing the device intent categories as initial implant strategies change over time compared to the indication designated at the time of LVAD implant. More importantly, limiting the intended goal of device therapy would disadvantage patients likely to benefit from LVAD therapy based on the latest evidence from the most recent LVAD trials.

In the last (2013) reconsideration request, the published evidence from the most recent LVAD clinical trials (e.g., MOMENTUM 3 and ENDURANCE) were not included in CMS's review. Abbott respectfully requests CMS review the totality of the evidence and the new literature on LVADs in supporting patient characteristics relevant for identifying coverage candidacy for this therapy.

Please feel free to contact me or Wendy Chan at Robin.Bostic@abbott.com or Wendy.Chan1@abbott.com should you have questions.

Sincerely,

Robin Bostic

Global Division Vice President, Health Economics and Reimbursement

cc: David Dolan, CMS CAG

Lori Ashby, Director, Division of Policy and Evidence Review, CMS CAG

Enclosures:

Addendum A: Proposed Coverage Language Summary

Addendum B: Key Publications/ Scientific Evidence supporting MOMENTUM 3 trial

Addendum A

Proposed Coverage Language Summary [Note language highlighted in red are changes/updates to the NCD 20.9.1]

Benefit Category

Inpatient Hospital Services
Physician Services
Prosthetic Devices

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

~~2. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)~~

~~The VADs used for bridge to transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:~~

- ~~The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.~~

- ~~The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed prior to implantation of the VAD.~~

~~3. Destination Therapy (DT) (effective for services performed on or after October 1, 2003)~~

~~Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.~~

~~Patient Selection (effective November 9, 2010):~~

~~The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:~~

- ~~Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,~~
- ~~Have a left ventricular ejection fraction (LVEF) < 25%; and,~~
- ~~Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.~~

2. FDA approval

The surgically implanted VAD must have received FDA approval for patients who require short term (e.g. like bridge to transplantation or myocardial recovery) and long term (e.g., like destination therapy) mechanical circulatory support. Patient populations

VADs are covered for patients who have advanced heart failure symptoms meet one of the following conditions:

- Failure to respond to guideline directed medical therapy or
- Are listed for transplant or
- Are dependent on treatment with intravenous inotropic therapy or on intra-aortic balloon pump or on an acute mechanical circulatory assist device (e.g., external, temporary, or percutaneous).

Facility criteria

Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure under section 1862(a)(1)(A) of the Social Security Act (the Act):

Operator requirements

Beneficiaries receiving VADs must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

C. Nationally Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

Addendum B: Key Publications/ Scientific Evidence supporting MOMENTUM 3 Trial

(Based on chronological order by publication date. Please go to www.momentum3investigators.com for open access to publications and presentations showcased at the 2019 society scientific meetings.)

Heatley, G, et al. Clinical trial design and rationale of the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3 (MOMENTUM 3) investigational device exemption clinical study protocol. J Heart Lung Transplant. 2016 Apr;35(4):528-36.

Mehra, MR., et al. A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure. N Engl J Med. 2017 Feb 2;376(5):440-450.

Uriel, N., et al. Hemocompatibility-Related Outcomes in the MOMENTUM 3 Trial at 6 Months: A Randomized Controlled Study of a Fully Magnetically Levitated Pump in Advanced Heart Failure. Circulation. 2017 May 23;135(21):2003-2012.

Mehra, MR., et al. Two-Year Outcomes with a Magnetically Levitated Cardiac Pump in Heart Failure. N Engl J Med. 2018 Apr 12;378(15):1386-1395.

Mehra, MR., et al. Healthcare Resource Use and Cost Implications in the MOMENTUM 3 Long-Term Outcome Study. Circulation. 2018 Oct 30;138(18):1923-1934.

Columbo, PC., et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. Circulation. 2018 Jan 8;139(2):155-168.

Potapov, EV, et at. Strategy for surgical correction and mitigation of outflow graft twist with a centrifugal-flow left ventricular assist system. J Heart Lung Transplant. 2018 May;37(5):670-673

Mehra, MR., et al. A tale of the twist in the outflow graft: An analysis from the MOMENTUM 3 trial. J Heart Lung Transplant. 2018 Nov;37(11):1281-1284.

Cowger, JA., et al. Quality of life and functional capacity outcomes in the MOMENTUM 3 trial at 6 months: A call for new metrics for left ventricular assist device patients. J Heart Lung Transplant. 2018 Jan;37(1):15-24.

Goldstein, DJ., et al. Impact of age, sex, therapeutic intent, race and severity of advanced heart failure on short-term principal outcomes in the MOMENTUM 3 trial. J Heart Lung Transplant. 2018 Jan;37(1):7-14.

Mehra, MR., et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. N Engl J Med. 2019 Apr 25;380(17):1618-1627.

Bansal, A., et al. Effects of a fully magnetically levitated centrifugal-flow or axial-flow left ventricular assist device on von Willebrand factor: A prospective multicenter clinical trial. J Heart Lung Transplant. 2019 May 17. doi: 10.1016/j.healun.2019.05.006. [Epub ahead of print]