Medicare Covers Screening Ultrasounds for Abdominal Aortic Aneurysm

Renewed hope for regenerative stem cell cardiac therapies

Early Successes in Transcatheter Aortic Valve Replacement Trial

Cardiac Imaging Program Makes a Global Impact in Cardiac CT Training
An estimated 2 million Americans are living with undiagnosed abdominal aortic aneurysms (AAA). But free, one-time screening tests available to people entering Medicare can help reduce risks posed by the 13th leading cause of death in the United States.

If an undetected aneurysm ruptures, mortality is 85 to 90 percent. Yet most patients suffering from AAA are asymptomatic, making the availability of screening ultrasound tests vital.

SAAAVE Act offers help
Thanks to the Screening Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act, at-risk patients entering Medicare can receive a free, one-time ultrasound screening for AAA. The act allows for the screening as part of the “Welcome to Medicare Physical Exam,” officially known as an Initial Preventative Physical Examination. To be covered by Medicare, the AAA screening ultrasound must be ordered at the time of the Welcome to Medicare Physical Exam, and must be performed within the first year of Medicare enrollment.

Few clear symptoms for AAA
Diagnosing AAA can be difficult because most patients are asymptomatic. Some patients might complain of vague, constant or throbbing abdominal or back pain. If the AAA is rapidly expanding, the patient might experience intense pain. AAA should be considered for any elderly patient with abdominal, flank or back pain.

Some gastrointestinal symptoms also can occur. For example, early satiety, nausea and weight loss might indicate abdominal compression caused by AAA. Additionally, AAA should be considered for lower extremity emboli if a cardiac cause has already been ruled out.

Patients should be questioned about their lifestyle and family medical histories. A tender, pulsatile mass also may be palpable upon examination.
Renewed hope for regenerative stem cell cardiac therapies

Four clinical trials bring the latest adult stem cell therapies to Cincinnati

For more than 20 years, medical researchers have envisioned a day when the human heart could be stimulated to repair the damage of heart attacks and the longer-term deterioration caused by heart failure. Several early attempts to develop adult stem cell therapy, some involving studies dating back to the early 1990s, failed to produce breakthrough treatments. Now, a new wave of clinical trials brings new hope to the field of regenerative cardiac therapy.

The Carl and Edyth Lindner Research Center participates in four important clinical trials that explore potential regenerative treatments for post-heart attack care, medically refractory angina and advanced heart failure.

“Regenerative therapy offers tremendous potential. Several approaches are beginning to show benefit in specific patients and will help expand the portfolio of treatments available to patients with advanced cardiac disease,” says Dean Kereakes, MD, medical director of The Christ Hospital Heart and Vascular Center and the Lindner Research Center.

Normally, adults are limited in their ability to produce new myocardial cells and to replace damaged heart tissue. Patients with heart failure may benefit from medicines and procedures that support the function of the remaining viable myocardium. More advanced cases may require either a heart transplant or the implantation of a left-ventricular assist device (LVAD). Should they continue to prove successful in larger-scale clinical trials, regenerative therapies offer the possibility of repairing or restoring cardiac function. These treatments could significantly impact both quantity and quality of life. Moreover, cell therapies can be administered via minimally invasive, catheter-based techniques, thus making the treatment more available to a much wider range of patients than other more complex surgical procedures.

“I think we are entering an exciting new phase,” says Eugene Chung, MD, director of outcomes for The Christ Hospital Heart and Vascular Center. “The newer concepts offer sophisticated ways to entice the body into healing itself. Thus regenerative therapy has the potential to fill a void between conventional medical treatments and transplantation.”

These clinical trials are available through the Lindner Research Center:

**Amorcye PreSERVE trial for heart attack survivors**

This therapy, developed by New Jersey-based Amorcye, LLC, a NeoStem, Inc. company, offers to help people who have recently (within 5-11 days) suffered a significant heart attack by administering their own stem cells to preserve heart muscle and prevent subsequent major adverse cardiac events.

The process involves collecting millions of CD34+ stem cells selected from a small sample of bone marrow and then infusing these cells into the damaged area of heart tissue via the coronary artery during a heart catheterization procedure. Investigators believe this therapy may increase microvascular blood flow in the myocardium (heart muscle) via neangiogenesis (development and formation of new blood vessels), thereby reversing post-heart attack induced ischemia (restriction of blood supply) and rescuing tissue from hibernation and preventing eventual cell death (apoptosis).

**Baxter trial for medically refractory angina**

The RENEW study collects endothelial progenitor cells (CD34+ cells) from the patient’s own blood to be used as a therapy for those who continue to suffer angina symptoms despite taking the maximum tolerated doses of their anti-angina medications.

**Aastrom trial for heart failure**

This clinical trial evaluates the effectiveness of ismylo oid-T, a patient-specific, expanded multi-cellular therapy developed by Aastrom Biosciences of Ann Arbor, Mich., to treat ischemic dilated cardiomyopathy (ischemic DCM), a common cause of heart failure.

This therapy involves collecting a small amount of bone marrow from the patient, then using a patented process to multiply targeted types of cells, including CD34+ mesenchymal cells, CD14+ monocytes and alternatively activated macrophages. The process can multiply these cells up to 300 times the levels normally found in bone marrow.

Aastrom believes the multiple cell types in ismylocel-T, which are normally found in bone marrow, but in different quantities, possess several functions required for tissue remodeling, reduction of inflammation, and promotion of angiogenesis.

This cellular therapy is delivered directly to heart tissue via the NOGA™ MyoStar™ injection catheter. The clinical trial will include patients with heart failure caused by ischemic DCM who have a left ventricular ejection fraction of 30% or less and meet other criteria.

**Juventas trial for heart failure**

This clinical trial examines the potential value of a novel approach to stem cell therapy developed by Cleveland-based Juventas Therapeutics.

Instead of harvesting and re-injecting stem cells into damaged heart tissues, this treatment involves boosting the body’s natural ability to attract stem cells to the site of organ damage. The JVS-100 treatment injects DNA that encodes for Stromal-cell Derived Factor 1 (SDF-1), which promotes cardiac repair by stimulating blood vessel growth, prevents programmed cardiac cell death, and attracts circulating stem cells. The treatment involves using the BioCardia helical infusion catheter to inject the SDF-1 gene in as many as 15 locations in the hearts of patients with advanced heart failure.

The clinical trial will involve patients with advanced heart failure who meet several criteria.

**Mid-stage research**

Except for the Baxter study (a Phase II study), these clinical trials are considered Phase II research studies, which means the treatments have demonstrated safety during Phase I trials involving small numbers of patients.

Phase II studies generally expand the numbers of patients involved in testing while investigators determine ideal dose levels and further test for safety and efficacy. Before new treatments can win U.S. FDA approval, they must also complete larger-scale Phase III clinical trials to confirm safety and effectiveness. For these four regenerative therapies, the Lindner Research Center expects to enroll six to 10 patients per clinical trial. Study results will likely be available by later 2012.

“The important message for patients with advanced heart disease is to not give up hope,” Dr. Chung says. “So much change has occurred in recent years. It’s very important for patients to continue to educate themselves, and they are counting on their physicians to play a very important role in helping them understand all of their options.”

For more information about our current clinical trials, call 513.585.1777. Each clinical trial has specific criteria for participation.
Early Successes in Transcatheter Aortic Valve Replacement Trial

Two area seniors report positive experiences after participating in a clinical trial to evaluate a transapical approach to transcatheter aortic valve replacement (TAVR).

The Carl and Edyth Lindner Research Center is participating in the nationwide PARTNER II clinical trial to evaluate a balloon-expandable heart valve and two delivery approaches. TAVR offers a potential alternative for patients who need heart valve replacement but face increased risk from open-heart surgery because of frailty, previous radiation to the chest or other pre-existing conditions.

TAVR involves delivering an expandable valve to the heart through the femoral artery, known as a transfemoral approach, or via a transapical approach, meaning through the apex of the left ventricle. Patients with small-size vessels or severe peripheral vascular disease are often better candidates for the transapical approach. However, this approach is not yet approved by the U.S. FDA.

Gary Hamm, 61, of Goshen, Ohio, and Donald Grob, 82, of Florence, Kentucky, who could not have the valve inserted via the transfemoral approach, recently underwent the new transapical procedure.

“I feel as good as my old high school wrestling days,” says Hamm, a veteran who had the transapical procedure in May. “I’m looking forward to many more treasured moments with my family and grandchildren, fishing by the lake and playing with the kids at the beach.”

Hamm had been living in North Carolina but moved to the Cincinnati area to receive treatment under the care of Dean Kereiakes, MD, Medical Director of The Christ Hospital Heart and Vascular Center.

“Many patients are too frail to sustain open heart surgery, and even if they survive, they may experience stroke, multi-system failure or prolonged rehabilitation,” says Dr. Kereiakes, lead investigator for the PARTNER II trial at The Christ Hospital. “I am looking forward to many more treasured moments with my family and grandchildren, fishing by the lake and playing with the kids at the beach.”

Donald Grob was diagnosed with a defective heart valve but was not an operative candidate because of calcium build-up in his aorta. Accessing his femoral artery was also difficult, so Grob’s procedure was performed using the transapical approach with great success. Grob’s procedure was performed using the transapical approach with great success. Patients with small-size vessels or severe peripheral vascular disease are often better candidates for the transapical approach. However, this approach is not yet approved by the U.S. FDA.

The Carl and Edyth Lindner Research Center is participating in the nationwide PARTNER II clinical trial to evaluate a balloon-expandable heart valve and two delivery systems: NovaFlex (transapical access) and Ascendra2 (transapical access) in patients with symptomatic, calcific, severe aortic stenosis. Study patients will undergo clinical follow-up at discharge, 30 days, six months, and one year, then annually for a minimum of five years.

For more information about this procedure and clinical trial enrollment requirements, contact The Lindner Research Center at 513.585.1777.

Cardiac Imaging Program Makes a Global Impact in Cardiac CT Training

Specialists at The Christ Hospital’s Advanced Cardiac Imaging Program are sharing their expertise in early detection and treatment of coronary artery disease (CAD) with the world.

Our educational outreach continued recently with a four-day training course for physicians in the Saudi Arabia region.

Dr. Pelberg and Mazur are among the few physicians in Greater Cincinnati with level III training in cardiac CT. They have authored two books: Cardiac CT Angiography Manual and Vascular CT Angiography Manual. They also are working on a third book: CT Atlas of Adult Congenital Heart Disease.

“I feel this learning was necessary to lead the fight against CAD in Saudi Arabia and I am eager to apply this extremely useful technology to benefit our patients,” says Dr. Alasnag.

The training course in Saudi Arabia is one of many ways The Christ Hospital shares its expertise in cardiac imaging. Physicians from Australia, Canada, Egypt, India, United Kingdom and throughout the United States also have traveled to The Christ Hospital to learn the latest cardiac imaging techniques and technologies.

Dr. Pelberg says the visit was an eye-opening experience.

“It was interesting to learn coronary artery disease is disturbingly severe and begins much earlier in life than what we typically see in the U.S.” Dr. Pelberg says. “This course will most likely become one of many in Saudi Arabia, and we have plans to expand our training to other areas in the Middle East with the help of our Saudi partners.”

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Humana Covers LVAD Implantation at The Carl H. and Edyth Lindner Heart Failure Treatment Center at The Christ Hospital

Heart failure patients insured by Humana can now receive coverage for stand-alone left ventricular assist device (LVAD) implantation at The Christ Hospital in Cincinnati.

Typically, hospital programs receiving coverage provide both heart transplant and LVAD implantation. The Christ Hospital is the first non-transplant hospital in the region to gain coverage for stand-alone LVAD procedures.

“Our goal is to provide LVAD implants to patients close to home, to allow for more involvement of families in their continuing care. Studies have shown that outcomes improve when patients’ family and friends participate in their healthcare,” says Santosh Menon, MD, medical director, The Carl H. & Edyth Lindner Heart Failure Treatment Center at The Christ Hospital.

The Mechanical Heart Assist Device Program at The Christ Hospital has been active for more than a year. The program is certified by Medicare and has received a Gold Seal of Approval from the Joint Commission. Humana based its coverage decision on these certifications and the hospital’s relationships with heart transplant programs at St. Vincent’s Hospital in Indianapolis, Indiana, and the Ohio State University Medical Center in Columbus, Ohio.

“We will refer patients to transplant at St. Vincent’s and Ohio State as needed. Our program uses the same protocols as St Vincent’s, which ensures streamlined and consistently high quality care for these patients,” says Chris Thomson, executive director, The Christ Hospital Heart and Vascular Service Line. “This model is a pilot program that we hope will later be used to extend care to more Americans needing treatment for heart failure.”

With a chronic shortage of organs available for transplant and continued improvement in device technology, LVAD implantation is becoming more accepted as a destination therapy for heart failure patients, not just as a bridge to transplant. For patients who qualify, LVADs offer a high quality, lower-cost option that does not require remaining indefinitely on immunosuppressive drugs.

For more information about the Mechanical Heart Assist Device Program, please call 513.585.2531.