On August 7, the Centers for Medicare and Medicaid Services issued a National Coverage Decision (NCD) for transcatheter mitral valve repair (TMVR) under Coverage with Evidence Development (CED). According to the decision summary, CMS clarifies three criteria for Medicare coverage of TMVR:

- TMVR is covered for the treatment of significant symptomatic degenerative mitral regurgitation when furnished according to an FDA approved indication and when all of the following conditions are met.
- TMVR is covered for uses that are not expressly listed as an FDA approved indication when performed within a FDA-approved randomized controlled trial that fulfills specific criteria.
- All CMS-approved clinical trials and registries must adhere to the specific standards of scientific integrity and relevance to the Medicare population.

The new coverage decision also defines which specialists are permitted to perform TMVR procedures, which CMS revised to include interventional cardiologists and cardiothoracic surgeons.

The coverage decision was commended by stakeholders in the vascular care community including the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons.
Low Income and Lower Education Levels Associated with Peripheral Vascular Disease in U.S. Adults

Recent findings published by the American Heart Association reveal that U.S. adults with lower socioeconomic status are at higher risk for developing Peripheral Vascular Disease (PVD) – highlighting the need for education and advocacy among at-risk populations.

According to the study published in Circulation: Cardiovascular Quality and Outcomes, individuals with low income and lower education had significantly higher PAD prevalence. In fact, data showed that the odds of PAD were more than twice as high for patients in the lowest of six poverty-income ratio categories compared with those in the highest poverty-income ratio category.

Researchers at Brigham and Women’s Hospital in Boston analyzed nearly 7,000 patients in order to identify correlation between education, income and PAD. Specifically, investigators utilized poverty-income ratio – a ratio of self-reported income relative to the poverty line – and reported attained education levels in order to devise measures of socioeconomic status.

JAMA Surgery: Aortic Stents Safer for Aneurysm Repairs

Post-operative complications and mortality rates were significantly lower for patients with abdominal aortic aneurysms repaired via endovascular stent grafts, according to new research published in the Journal of the American Medical Association (JAMA).

Although anecdotal evidence and randomized clinical trials have long supported that endovascular repair is safer than more invasive, open surgeries, the published findings mark the first time data have definitely shown safety benefits of endovascular repair. Of the 70,946 abdominal aortic aneurysm repair surgeries analyzed, patients who underwent the minimally invasive endovascular procedure had a 42 percent reduction in preventable post-operative complications, and a 72 percent reduction in overall mortality when compared to patients who received open repair surgeries.

The Patient Safety Indicators (PSIs) analyzed by researchers included wound infection, blood infection, accidental puncture or laceration, transfusion reaction, as well as mortality.

Open repair surgery of abdominal aortic aneurysms involves a large incision into a patient’s abdomen and sewing in an implantable graft. In contrast, endovascular aortic aneurysm repairs are accomplished by inserting a metallic stent into the body through a blood vessel in the patient’s groin and guiding the stent with the help of X-ray imaging. Once in place, the stent is expanded in order to repair the aneurysm.
Dark Chocolate Improves Walking Autonomy in Patients With Peripheral Artery Disease

Patients with Peripheral Artery Disease (PAD) might find relief from dark chocolate, according to research published in the Journal of the American Heart Association. PAD – a common circulatory problem where narrowed arteries reduce blood flow to the limbs – often results in pain when blood flow cannot keep up with the body’s demands, particularly with movement and exercise.

Researchers from Sapienza University of Rome in Italy have discovered that patients with PAD who ate dark chocolate were able to walk 11 percent farther than patients with PAD who ate milk chocolate.

The benefits of consuming dark chocolate observed in the study are possibly attributable to compounds in cocoa, which may reduce oxidative stress and improve blood flow in the peripheral arteries. Dark chocolate used in the study – with a cocoa content of more than 85 percent – is rich in polyphenols, whereas the milk chocolate had a smaller concentration of the substance.

Researchers believe that the polyphenol content of the dark chocolate affects an enzyme that plays a pivotal role in human artery dilation and oxidative stress production. Of the 20 patients studied in the small, single-blind study, those who consumed dark chocolate not only showed an 11 percent increase in maximal walking distance, but also a 15 percent increase in maximal walking time.

Extended Release Niacin-Laropiprant Proves More Harmful than Helpful in High-Risk Patients

Patients receiving statin therapy for high cholesterol who additionally received a combination of extended-release niacin and laropiprant, saw reductions in their HDL, but saw no difference in the rate of major vascular events. The test group, in fact, experienced a higher rate of adverse events and complications when compared to patients taking a placebo.

The troubling findings, published in the New England Journal of Medicine, add to a body of evidence showing no beneficial effect of niacin, but reveals concerning new information about risks.

Of the 25,000 patients studied, the rate of major vascular events between the test and placebo groups remained nearly the same (13.2 percent and 13.7 percent, respectively). Serious adverse events, however, were more evident in the test group (55.6 percent versus 52.7). Those events included serious complications related to diabetes, infection, bleeding, gastrointestinal issues, and skin-related problems.

A separate editorial commentary in the NEJM urged caution in the usage of niacin for cholesterol, considering previous research findings and the most recent evidence of potential harm.
Scientists Discover Genetic Switch that Can Prevent Peripheral Vascular Disease in Mice

Scientists at the University of Texas Health Science Center at Houston have tested a non-surgical treatment in mice that could improve Peripheral Vascular Disease (PVD) by increasing blood circulation in the extremities.

Researchers were able to identify a genetic “switch” that suppresses blood vessel development, and then turn off that switch in mice – allowing for prevention of PVD and acceleration of the natural process of blood vessel regeneration.

The genetic switch used by scientists in the study is called peroxisome proliferator-activated receptor gamma co-activator 1 beta (PGC1beta). Researchers say their next step will be to test the treatment in models of other conditions that dramatically decrease circulation – like diabetes and atherosclerosis.

The CardioVascular Coalition (CVC), established in 2014, is a nonprofit organization representing freestanding cardiovascular centers. CVC members are comprised of national organizations representing providers (National Cardiovascular Partners and the Outpatient Endovascular and Interventional Society) and manufacturers (Cardiovascular Systems, Inc. and Covidien).

The mission of the CVC is to advance patient access to community-based cardiovascular and endovascular care. Recognizing that cardiovascular disease is a leading – and preventable – cause of death in the United States, the physicians, care providers, advocates, and manufacturers who comprise the Coalition are dedicated to community-based solutions designed to improve awareness and prevention of cardiovascular disease and peripheral artery disease, reduce geographic disparities in access to care, and secure patient access to high-quality, cost-effective, community-based interventional treatment across America.