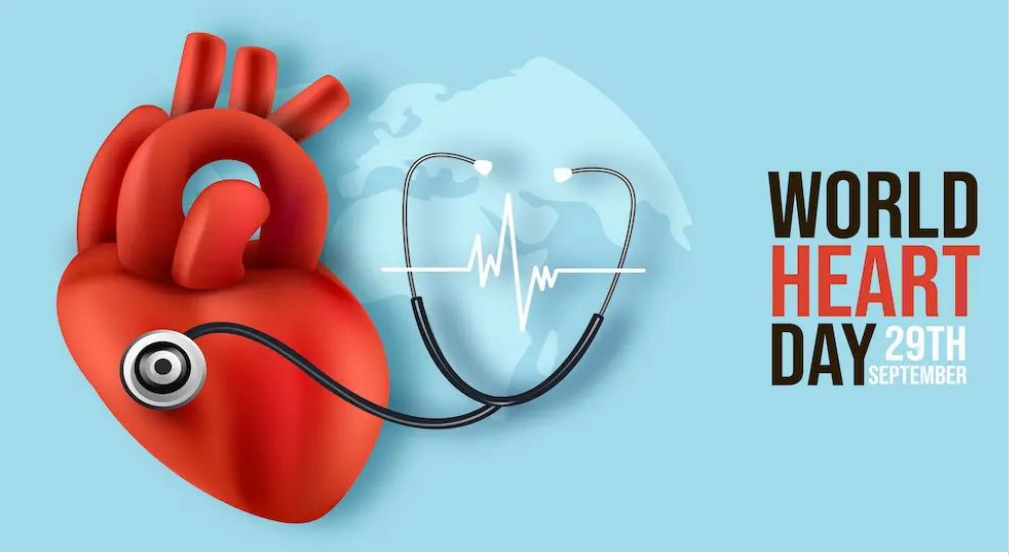

Multispecialty Outpatient Cardiovascular Association

September Edition

Blue Cross Blue Shield ordered to pay $421 million in fraud lawsuit

A jury has awarded $421 million in damages to a group of Louisiana doctors after finding Blue Cross Blue Shield committed fraud and abuse of rights.

The insurance company was found to have withheld payments for approved procedures, including breast reconstruction following cancer treatment, at the Center for Restorative Breast Cancer.

“This landmark victory not only holds Blue Cross and Blue Shield of Louisiana accountable but also exposes a hidden problem in our system,” said Dr. Frank DellaCroce. “This has been very difficult, but we are pleased that the jury saw the truth. It is a victory for all those who have felt bullied by big corporate health insurance and the self-serving things they do to drain resources from care delivery. We work the long hours, we pioneer advancements, we take care of these women, and we fought back for those who work on the front line and the patients who depend on them.”

The doctors with the Center for Restorative Breast Surgery and St. Charles Surgical Hospital claimed Blue Cross tried to coerce them into their network, leading to a trial in both federal and state courts.

After a three-week trial, the jury returned the verdict against Blue Cross and Blue Shield of Louisiana in less than two hours.

“The jury’s finding of misconduct by Blue Cross and Blue Shield of Louisiana shows that the legal system will not allow Blue Cross and Blue Shield of Louisiana to put its self-interest ahead of that of its patients. Physicians and patients have a right to expect Blue Cross and Blue Shield of Louisiana to uphold their promise to provide fair and accurate payment for services,” said attorney Matthew Sherman with Chehardy Sherman Williams.

Blue Cross said it plans to appeal. In a statement to WDSU, the company said: "*While we appreciate and value the legal process, we strongly disagree with the jury’s verdict. We will quickly appeal and expect to be successful.*

"*Our mission is to improve the health and lives of Louisianians. Part of that mission is to work with network providers to offer high-quality care at fair reimbursements, ensuring our members access to affordable, quality care.*

"*Unfortunately, verdicts like this contribute to increasing healthcare costs for Louisianians who depend on us every day.*" Blue Cross Blue Shield ordered to pay $421 million in fraud lawsuit (wdsu.com)

Renal denervation gains class IIb recommendation in ESC guidelines

The treatment—in which energy is targeted through a catheter to the renal nerves to modulate the sympathetic signaling between the kidneys and brain to reduce blood pressure—has been included with a class IIb level of recommendation for treating resistant hypertension in patients with uncontrolled blood pressure, despite the use of three or more blood pressure-lowering drugs.

Additionally, clinicians can consider the interventional treatment in patients with increased cardiovascular risk who have uncontrolled hypertension on fewer than three drugs.
In both instances the guidelines stipulate that the treatment is contingent on patients expressing a preference for renal denervation after a shared risk-benefit discussion and multidisciplinary assessment, and that the procedure is performed at a medium-to-high volume centre. Furthermore, the therapy is not recommended for patients with highly impaired renal function (eGFR <40mL/min/1.73m2) or secondary causes of hypertension.

During a question and answer session following the presentation of the new guidelines at the 2024 ESC congress (30 August–2 September, London, UK), co-chair of the writing committee that drafted the document, John William McEvoy (University of Galway School of Medicine, Galway, Ireland), explained why there is greater emphasis on additional pharmacological interventions—such as the diuretic medication spironolactone or beta blockers—ahead of the device-based treatment in the algorithm for treating resistant hypertension. Renal denervation gains class IIb recommendation

US FDA clears Elucid’s PlaqueIQ imaging analysis software

PlaqueIQ is a non-invasive software that can objectively quantify and classify plaque morphology based on ground-truth histology, and is designed to give physicians new, clinically validated information to help stratify patients and inform patient-specific treatment pathways.

“The fact that low-risk, asymptomatic patients represent such a large portion of the population means that even a small fraction of them account for a substantial number of myocardial infarctions,” said Amir Ahmadi (Icahn School of Medicine at Mount Sinai and Mount Sinai Fuster Heart Hospital at Morningside, New York, USA). “It’s time to shift our focus from merely estimating risk and treating risk of MI to directly visualising and treating the disease itself by looking at the coronary arteries.

“I believe that PlaqueIQ will enable physicians to better ‘see’ the disease—specifically plaque quantity and type—so that we can treat patients with greater precision and in personalised manner, improve their quality of life, and ultimately prevent myocardial infarction (MI) and stroke more effectively.”

PlaqueIQ utilises first-line diagnostic coronary computed tomography angiography (CCTA) and develops reports to help physicians virtually “see” plaque at the vessel level, Elucid says in a press release. The software is able to non-invasively quantify and characterise non-calcified plaque and its components such as lipid-rich necrotic core (LRNC), giving potential insights into high-risk US FDA clears Elucid’s PlaqueIQ imaging analysis software - Cardiovascular News

Medtronic launches VitalFlow ECMO system

The release of VitalFlow follows the Medtronic acquisition of MC3 Cardiopulmonary, which closed in March 2024. The acquisition marked the culmination of an eight-year partnership and distribution agreement with the Medtronic Cardiac Surgery business resulting in the introduction of seven new ECMO products in seven years.

Prior to the acquisition, MC3 Cardiopulmonary developed and manufactured ECMO products which were exclusively distributed by Medtronic.

“The launch of this technology further underscores Medtronic’s unwavering dedication to developing life-restoring medical devices that address both acute and chronic cardiopulmonary clinical needs, and demonstrates our sustained commitment to this vital field,” said Karim Bandali, president of the Cardiac Surgery business within the Cardiovascular portfolio at Medtronic. “This announcement builds on our recent acquisitions, including a Viant Medical contract manufacturing site and the Penditure left atrial appendage exclusion system. Clinicians can continue to expect a global cadence of bold and unique innovations, focused on addressing diverse clinician needs while enhancing our ability to meet the needs of all cardiac surgery patients.”

The VitalFlow system features a touchscreen that centralises real-time performance data, offers configurability, and is built for long-term performance incorporating the proven Medtronic Nautilus ECMO oxygenator design, the press release adds.

“In gathering feedback from hundreds of clinicians with diverse ECMO specialties, we were able to design the VitalFlow system to address the most pressing unmet needs of simplicity, configurability and performance in an ECMO system,” said Bandali. “The simplicity of the VitalFlow system allows multiple users with varying levels of comfort to serve patients confidently and efficiently. It is easily portable from various departments within the hospital setting, with durable and reliable performance.” Medtronic launches VitalFlow ECMO system (cardiovascularnews.com)

Pooled analysis of over 18,000 participants supports benefits of finerenone across cardio-kidney-metabolic conditions

A pooled analysis of three large trials failed to demonstrate significant reductions in cardiovascular death with finerenone, but significantly lower all-cause mortality, cardiovascular events and kidney outcomes were observed, according to late-breaking research presented in a Hot Line session at the European Society of Cardiology (ESC) Congress 2024 (30 August–2 September, London, UK).

Muthiah Vaduganathan (Brigham and Women’s Hospital and Harvard Medical School, Boston, USA) explained why the meta-analysis was conducted: “It is increasingly being recognised that cardiovascular diseases, chronic kidney disease (CKD) and metabolic conditions, such as diabetes, co-exist in the same patients and share common disease pathways. The non-steroidal mineralocorticoid receptor antagonist, finerenone, has been shown to reduce the risk of cardiovascular events and kidney failure in two trials in patients with CKD with type 2 diabetes and has recently been shown to reduce worsening heart failure (HF) events in a trial in patients with HF with mildly reduced or preserved ejection fraction. We combined data from these three large trials, and although we did not observe a significant reduction in cardiovascular death, all-cause mortality was significantly reduced and there were clinically relevant improvements in other outcomes.”

The participant-level pooled FINE-HEART analysis was conducted with data from the FIDELIO-DKD2 and FIGARO-DKD3 trials in patients with CKD and type 2 diabetes and the FINEARTS-HF4 trial in patients with heart failure (HF) and mildly reduced or preserved ejection fraction. The pre-specified primary outcome was time to cardiovascular death. The definition of cardiovascular death differed slightly between the three trials and was harmonised for FINE-HEART as time to cardiovascular death (excluding undetermined deaths). Other pre-specified outcomes included a kidney composite outcome (defined as a sustained decrease in estimated glomerular filtration rate [eGFR] to ≥50% from baseline, sustained decline in eGFR to <15 mL/min/1.73 m2, kidney failure and death due to kidney causes), HF hospitalisation, composite of cardiovascular death or HF hospitalisation, and all-cause death. Pooled analysis of over 18,000 participants supports benefits of finerenone across cardio-kidney-metabolic conditions - Cardiovascular News

Cardiology Experts Warn of Rising Heart Failure Rates and Worsening Disparities in New 2024 Report

WASHINGTON, DC (SEPTEMBER 24, 2024) – The latest findings on heart failure (HF) published by Heart Failure Society of America (HFSA) reveal a concerning rise in the prevalence, mortality, and impact of this debilitating condition in the United States. According to the *HF Stats 2024: Heart Failure Epidemiology and Outcomes Statistics*, approximately 6.7 million Americans over the age of 20 currently live with heart failure, a figure projected to rise to 8.7 million by 2030, 10.3 million by 2040, and a staggering 11.4 million by 2050. The report was published today in the *Journal of Cardiac Failure (JCF)*.

This year’s findings underscore some of the most alarming trends seen in heart failure in recent years. While HF rates have steadily increased over the last decade, the 2024 report shows that the problem is growing even more severe, particularly in younger populations, racial and ethnic minority groups, and those with multiple health conditions.

While trends among patient populations are concerning, the report also identifies challenges with implementation and reporting. Despite established guidelines emphasizing the timely initiation of guideline directed medical therapies (GMDT), the data indicate that implementation is falling short, which may be fueling the increase in both mortality and hospitalization rates for HF, particularly among at-risk populations. Inconsistent coding practices that fail to recognize HF as a primary underlying cause of death may lead to under-detection and under-reporting of HF deaths, suggesting that the actual burden of HF may be higher than current data shows.

“The shifts in age distribution, worsening in mortality rates, widening racial and ethnic disparities –which may be a reflection of systematic and structural barriers to appropriate and timely health care – should be a wake-up call for clinicians, payers, legislators, funding agencies, and the overall healthcare system,” said Biykem Bozkurt, MD, PhD, Baylor College of Medicine and chair of the HFSA Data in HF Committee. “We need to address worsening trends in heart failure, not only through medical interventions and properly implemented GDMT, but by tackling the growing challenges in health care regarding access and coverage for appropriate and timely care, the effect of mis-incentivization of wrong care such as inappropriate discontinuation of therapies, and social determinants of health that are driving widening disparities.”

The HF Stats 2024: Heart Failure Epidemiology and Outcomes Statistics highlights several key findings, revealing an evolving crisis that could impact millions of Americans over the coming decades Cardiology Experts Warn of Rising Heart Failure Rates and Worsening Disparities in New 2024 Report | HFSA

Announcements:

- Thank you to those that joined us during our meeting last week - We had a great conversations with the Michigan Association of Health Plans and have some new ideas moving forward!