E-BRIEF SERIES

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Whistleblowers and Watchdogs: Vascular Procedures Under the Microscope

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Over the last many years, enforcement agencies have scrutinized the billing of medical procedures involving the vasculature. Below is a review of some of these significant cases.

U.S. DEPARTMENT OF JUSTICE (DOJ)

In Manhattan, a vascular surgery clinic and surgeon agreed to pay $1.15 million to resolve allegations that vascular procedures they performed were not medically necessary. Specifically, the services in question related to fistula procedures of patients with end-stage renal disease (ESRD). ESRD patients regularly require long-term dialysis. In order to achieve this, patients need vascular access which is typically accomplished by the surgical creation of a fistula. Occasionally, the fistulas need to be radiographically visualized and/or opened through angioplasties, for example.

In this case, it was alleged the doctor performed these procedures on a routine basis without meeting medical necessity and billing requirements. Medicare in this case requires clinical findings to support the need for vascular procedures before performing them. The particular policy at the time required evidence of a 50% or greater restriction of the blood vessels before angioplasty was deemed medically necessary. Reportedly, the doctor and clinic were scheduling patients up to three months in advance on a routine basis which called into question the necessity of the procedures.

In another case in New York, the jury is still out (so to speak) about similar circumstances and allegations. Though a settlement or trial has yet to occur, the DOJ has filed a civil complaint against Fresenius Vascular Care alleging they were also routinely performing vascular procedures for fistulas that did not require the procedures. This case was initially brought to the attention of the DOJ through a whistleblower lawsuit filed by two nephrologists who claim many of the procedures were not medically necessary or didn't meet Medicare coverage criteria.

In a third case, Vascular Access Centers, L.P. agreed to pay up to $18.3 million for the same allegations. The company operated 22 office-based surgical sites in 12 states. The government alleged they were also performing routine fistula procedures as a matter of routine, regardless of whether there was a justifiable clinical reason to do so.

It is not just fistula procedures under the microscope. In a case in Pennsylvania, the DOJ filed a complaint against an interventional radiologist for performing medically unnecessary vascular procedures in other arteries in the body. Specifically, the allegations claim the doctor performed and billed for unnecessary angioplasty, atherectomy, and the placement of stents, as well as the indiscriminate use of intravenous ultrasound. A fellow interventional radiologist blew the whistle by filing a False Claims Act complaint and highlighted the allegations to the DOJ.

Lastly, a North Carolina cardiologist agreed to pay $5 million to resolve billing allegations of medically unnecessary atherectomy procedures to remove minor plaque blockage in leg arteries of patients. The government also alleged the physician overstated the stenosis (aka narrowing or blockage) percentage to justify the performance of the procedures. This case was also initially brought to the government's attention through a whistleblower.

HHS OIG

The OIG has likely taken notice of many of these cases as they have added two items to their Work Plan regarding peripheral vascular procedures. In fact, in announcing both Work Plan items, the OIG mentions "CMS and whistleblower fraud investigations have identified these surgeries as vulnerable to improper payments."

Utilization and CMS Integrity Efforts

According to the OIG, Medicare paid more than $600 million for atherectomies and angioplasties with and without a stent in peripheral arteries in 2022. These minimally invasive surgeries are designed to improve blood flow when arteries narrow or become blocked, but they are recommended only after patients have tried medical and exercise therapy and have lifestyle-limiting symptoms.

The OIG seems intent on finding out how this problem is. They wish to determine trends in Medicare fee-for-service for surgeries in peripheral arteries over several years and identify paid claims that exhibit questionable characteristics. They will also describe the program integrity activities that CMS and its contractors have taken to combat fraud, waste, and abuse specific to procedures in peripheral arteries.

Lower Extremity Vascular Procedures in the Office Setting

The performance of peripheral vascular procedures in the office setting has increased among Medicare beneficiaries over the past decade. In the two calendar years for 2022 and 2023, Medicare paid approximately $1.16 billion for lower extremity peripheral vascular procedures in office settings.

These procedures can help improve blood flow but are generally only recommended after more conservative treatment has failed. Included in these treatments are medical therapy, exercise therapy, and lifestyle changes.

The OIG plans to analyze Medicare fee-for-service for peripheral vascular procedures for questionable characteristics and review the program integrity activities of CMS and its contractors to combat fraud, waste, and abuse specific to these procedures. Additionally, they will assess whether these procedures complied with CMS requirements and met applicable treatment guidelines.

WATCHDOG JOURNALISM

Though they are not a government enforcement agency, watchdog journalists can have a significant effect on drawing attention to medically unnecessary peripheral vascular procedures.

For example, ProPublica has posted multiple stories on overuse of invasive treatments for peripheral artery disease. **One article** draws attention to both the risks to the patient as well as billing schemes. **Another speaks** of patients potentially receiving vascular procedures too soon or unnecessarily. And **another** draws attention to a single physician who has been repeatedly investigated for allegedly performing medically unnecessary peripheral vascular procedures.

Needless to say, there are many eyes scrutinizing these procedures. A conscientious compliance professional should at least monitor the performance and billing of these procedures to ensure appropriate due diligence on the institution's part has taken place.

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>
> -OIG

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CJ Wolf is a healthcare professional with more than 20 years of experience in hospital and physician revenue cycle, practice management, compliance, coding, billing, and client services. He has provided healthcare consulting and solution services to hospitals and physician organizations throughout the country.

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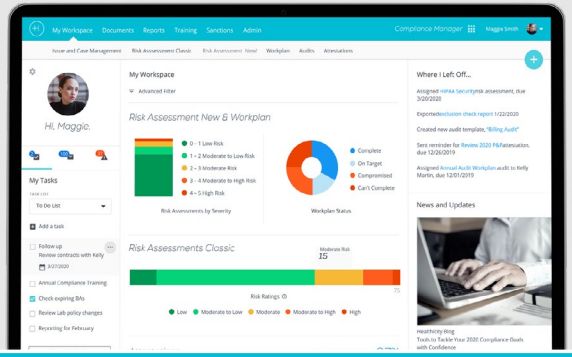

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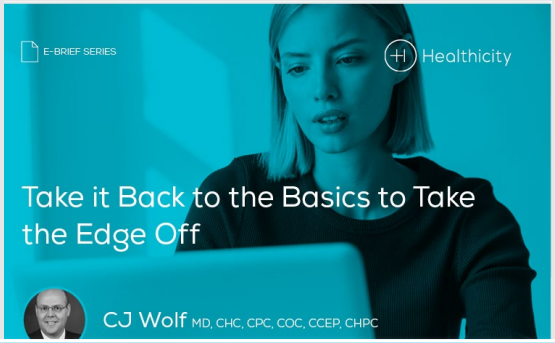

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