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Compliance Today - April 2023

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Enforcement actions relating to a lack of medical necessity

by C.J. Wolf, MD, CHC, CPC

In a climate of shrinking margins, diminishing reimbursement, and frequent denials, healthcare organizations may make efforts to increase the volume of services they provide, especially those that are more profitable. Of course, there are proper and improper ways to do so. One of the improper ways is to perform and bill for medically unnecessary services.

Having requisite medical necessity to provide medical services is a fundamental tenet of healthcare compliance. It is not a new concept for compliance professionals. However, we continue to see settlements related to allegations of a lack of medical necessity. Many other experts have previously provided excellent articles and presentations on the legal aspects of medical necessity as it relates to requirements of federal healthcare programs. This article is not an attempt to provide a legal explanation or strategy for dealing with medical necessity allegations; instead, it is an attempt to report on the types of clinical services that are getting some enforcement attention when it comes to medical necessity.

The key for conscientious compliance professionals is not only to follow up internally within their organizations on the same types of services shared in this article but also to consider what each type of enforcement teaches us about medical necessity mistakes because they can happen with any healthcare service or within any clinical specialty.

Vascular procedures for ESRD patients

End stage renal disease (ESRD) patients typically need regular hemodialysis services. When this is the case, patients often have a surgically created fistula (a connection between an artery and vein) in their arm to establish a reliable site for frequent vascular access. Sometimes these fistula access sites can become impaired, and various imaging (e.g., fistulagrams) and therapeutic services (e.g., angioplasties) can be performed to examine the fistula's patency and maintain it as an access site for hemodialysis. However, Medicare coverage guidelines do not allow for the routine billing of these services. Rather, individual medical necessity determinations need to be made each time the service is provided. It can become a medical necessity issue if the criteria are not met. An example might be the routine scheduling and billing of fistulagrams and angioplasties when the criteria are not fully satisfied.

A New York vascular surgeon, for example, paid $800,000, admitted misconduct, and was excluded for four years from participating in federal healthcare programs as a result of allegations he performed medically unnecessary vascular procedures on ESRD patients.[1] According to the U.S. Department of Justice (DOJ), the physician "routinely scheduled patients for fistulagrams and angioplasties three months in advance, and performed fistulagrams and angioplasties on these patients as a matter of routine, regardless of whether there was a

justifiable clinical reason to do so. Furthermore, on multiple occasions he misrepresented the medical conditions of patients in their medical records to make it seem as if they suffered from symptoms that would warrant the procedures when they did not."[2] As previously mentioned, Medicare billing guidelines make it clear that billing for such procedures is not considered medically necessary unless the patient has specific and documented clinical problems, such as not being able to effectively receive dialysis because of fistula complications.

For instance, one Medicare local coverage determination (LCD)[3] lists some of the following clinical indications that could support medical necessity for performing vascular procedures on dialysis fistulas:

"Venous outflow impediment clinical findings include:

- "elevated venous pressure in the arteriovenous dialysis access;
- "elevated venous/arterial ratio (static venous pressure ratio – above 40%);
- "prolonged bleeding following needle removal;
- "inefficient dialysis;
- "recirculation percentage greater than 10%–15%;
- "development of pseudoaneurysm(s);
- "swelling of the extremity, face, or neck;
- "development of large superficial collateral venous channels;
- "loss of "machine-like" bruit, i.e., short sharp bruit; and/or
- "abnormal physical findings, specifically pulsatile graft/fistula or loss of thrill.

"Arterial inflow impediment clinical findings include:

- "low pressure in graft even when outflow is manually occluded;
- "ischemic changes of the extremity (steal syndrome); and/or
- "diminished intra-access flow."

This physician is not alone in such medical necessity scrutiny. A company that ran vascular access centers paid $3.825 million to resolve similar allegations.[4] And, most recently, DOJ has intervened in a case, initially brought by two physicians against Fresenius Vascular Care Inc., that makes similar allegations.[5] In the Fresenius case, the government alleges the defendant created a "clinically timed evaluations" (CTE) scheme. The scheme allegedly began after a nephrologist or dialysis clinic referred a patient to an outpatient surgery facility; the facility routinely scheduled follow-up appointments without a referral from a medical official. The filed complaint alleges that the surgery facility did not request any information about the patient's recent dialysis treatment before a CTE appointment. In some cases, it's alleged the records demonstrated the patient received dialysis without any issues. However, the facilities allegedly performed fistulagrams and angioplasties that did not meet medical necessity criteria while providing directions—that patients not eat or drink for four hours before the appointment time—demonstrating an assumption that the procedures would be necessary. It will be interesting to watch how the case progresses.