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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.

Eye procedures and tests

A Georgia physician recently paid $1.85 million to resolve allegations of medically unnecessary surgeries as well as some diagnostic tests.[6]

Specifically, the allegations included the performance of medically unnecessary cataract extraction surgeries and Yttrium-Aluminum Garnet laser capsulotomies. According to court documents, the government claimed that "Cataract extraction surgery is not medically necessary unless the cataract has affected the patient's vision to the point that the patient's visual function no longer allows them to perform their normal activities of daily living. The decision to perform cataract surgery requires both that the physician observe and document objective effects on the patient's vision justifying cataract extraction, such as refracted visual acuity worse than 20/40, as well the patient's own assessment of his/her vision in order to determine whether surgery is necessary."[7] With this in mind, the allegations included medically unnecessary cataract surgeries on Medicare beneficiaries who had only minimal or no complaints of vision loss and whose measure of visual acuity did not reflect vision problems that would justify surgery.

In addition to surgical procedures, it was alleged the physician submitted claims for diagnostic testing that, among other things, were of worthless value and/or never interrupted. For example, it was alleged the physician billed for visual field tests that were not medically necessary as outlined in Medicare's National Coverage Determination policy which was in effect at the time. Additionally, visual field tests were often not fully completed as required, and the physician allegedly did not use the tests' results in treating her patients. Thus, the tests were billed even though the government claims they were of no diagnostic value and/or were never interpreted by the physician. Another type of diagnostic test that was alleged to frequently have been billed without requisite medical necessity was optical coherence tomography (OCT). To compliantly bill certain OCT tests to Medicare, a qualifying diagnosis is required, such as glaucoma, age-related macular degeneration, or diabetic retinopathy. And the test requires a valid report be interpreted by the physician that should be demonstrated in the medical record. It was alleged that the physician billed for these tests even though the patient's clinical signs and symptoms did not justify the test. The defendant also supposedly routinely billed Medicare for OCT tests even though the test report provided no results of diagnostic quality.

Dental services

Medical necessity enforcement is not limited to Medicare alone. There are also examples of Medicaid enforcement as it relates to the billing of medically unnecessary services.

In New York State, the attorney general recently announced a settlement from a pediatric dentistry group for allegedly performing unnecessary dental procedures.[8] The group agreed to pay $750,000 to resolve allegations of performing and billing medically unnecessary pediatric root canals, also known as pulpotomies or "baby root canals." A former employee (who was originally hired as an office manager) initially filed the case under the federal, New York, and New Jersey False Claims Act.

The claims against the dental group included examples of dentists performing therapeutic pulpotomies on pediatric patients' primary teeth "even though there was no dental decay in the inner third of the dentin."[9]

An additional allegation from the original complaint filed by the qui tam relator described a dentist who applied composite filling to the surfaces of patients' teeth. However, he billed these treatments as fillings, even though he did not drill any teeth (or drilled only one or two teeth and put composite on other teeth, all billed as fillings). Supposedly, this fraudulent practice was known as "thumb print dentistry."

What do these examples teach us about medical necessity compliance?

Compliance professionals whose organizations offer any of the services outlined in the examples above should be aware of the specifics of these cases, as it may be prudent to proactively audit or monitor similar types of services.

However, even if an organization does not perform any of the services outlined above, useful takeaways can be concluded from these examples:

1. Very few medical services should be routinely scheduled without first determining that specific medical necessity criteria have been met for individual patients at individual times.
2. Providers need to read the required indications listed in local coverage determinations (LCDs), national coverage determinations (NCDs), or any other payer-specific policy such as Medicaid. The coverage requirements for medical necessity might differ from some clinical standards for ordering or performing the procedure. In other words, an LCD or NCD will not tell a physician what they can or cannot do, but it will specify when a service is or is not considered covered by Medicare.
3. Can it be demonstrated, from a medical standpoint, that billed diagnostic tests are, in fact complete and used in a medically necessary fashion to further assess, care for, and/or treat the patient based on the results of the diagnostic test?

Conclusion

If you have worked in healthcare compliance for even a short period of time, you have likely heard of the importance of medical necessity as it relates to billing for services, especially for services billed to federal healthcare programs.

There are many ways medical necessity requirements can be violated and are not limited to specific services or clinical specialties. However, special attention should be placed on Medicare services for which an LCD or NCD exists, for services that seem to be routinely scheduled with little or no ordering physician input, and for diagnostic tests that are either incomplete or do not seem to be actively used in patient care and/or treatment decisions.

Takeaways

- Payer definitions of medical necessity for coverage and reimbursement purposes often differ from what a clinician might feel is in the best medical interest of a given patient.
- Many local Medicare administrative contractors have published policies such as local coverage determinations that often describe medical necessity requirements for coverage purposes.
- Medicare publishes some national coverage determinations policies applicable nationwide and often describe medical necessity requirements.
- Medical necessity decisions are typically patient-specific and time specific. This means any services that are automatic or routinely done without an individual medical necessity decision for each patient could be suspect.
- If there are allegations that services are not medically necessary, compliance programs typically need to involve professionals with a clinical understanding and background to successfully assess the issue and

bring it to closure.

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9 Settlement Agreement, *United States et al. ex rel. Simpson v. HQRC et al.*, No. 2017-cv-02823 (D. N.J. 2022) https://www.justice.gov/usao-nj/press-release/file/1541086/download.