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The evolving landscape of medical necessity in healthcare compliance

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There exists an ongoing tension in the American healthcare system between patients receiving the appropriate care they need to treat medical conditions and the high cost of healthcare. For example, when a patient sees an orthopedic surgeon about knee pain and the physician orders a costly MRI to diagnose the underlying condition, is that MRI the right course of treatment, or is a much less expensive course of physical therapy more appropriate? This tension between patients obtaining medical care and the high cost of that care has spilled over to the enforcement arena.

In recent years, there has been an increased focus by government enforcement officials on claims for reimbursement that are alleged to be false or fraudulent because the services rendered were not reasonable or necessary. This has not historically been the case. Many seasoned criminal prosecutors avoided bringing cases based on lack of medical necessity because such cases necessarily rely on the competing opinions of expert physicians, a discord that presumably could create reasonable doubt in the minds of a jury. Despite this historical reluctance, cases alleging fraudulent billing of services to federal healthcare programs based on the lack of medical necessity are becoming commonplace. In light of this trend, providers should consider how to incorporate the medical necessity of services into their compliance program.

Definition of medical necessity

While the Medicare statute does not specifically identify the services to be covered, the concept of the medical necessity is foundational to Medicare coverage. The statute provides: "no payment may be made…for any expenses incurred for items or services which…are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[1] Medicare defines a "reasonable and necessary" service as one that "meets, but does not exceed, the patient's medical need," and is furnished "in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition…in a setting appropriate to the patient's medical needs and condition."[2]

Providers must also consider the medical necessity of services provided to Medicaid members since most providers treat both Medicare and Medicaid patients. While the federal Medicaid statute does not specifically address the medical necessity of services, the state statutes or regulations that implement the state Medicaid programs typically do. For example, the Wisconsin rules for its Medicaid program cover services that are "required to prevent, identify or treat a recipient's illness, injury or disability" and the services must meet nine standards, including that the treatment is consistent with "standards of acceptable quality of care," "cost-effective," and "of proven medical value" and "not experimental."[3]

Who determines medical necessity

The definitions of medical necessity beg the question: Who determines the medical necessity of the services? Historically, the decision of whether a service is medically necessary has been made between the physician and the patient. This model is a remnant of a healthcare system where services were paid exclusively by an individual and physicians often practiced in an independent environment. Despite the revolution in how healthcare services are provided and paid, many physicians continue to view the determination of the medical necessity of a service as a decision that is completely within their domain. As a result, compliance professionals auditing for the medical necessity of the services, as discussed below, may face headwinds when educating physicians on standards for medical necessity. As the American healthcare system has evolved and since the government now pays for an enormous percentage of our healthcare services, it has necessarily stepped into the role of determining which services are medically necessary. However, as a potential counterbalance to the increasing role of the government, professional organizations have also stepped into the discussion in various ways to help define the bounds of medical necessity.

The government standards come primarily from the Centers for Medicare & Medicaid Services (CMS). As a preliminary consideration, CMS generally does not consider experimental treatments to be medically necessary and, therefore, excludes from coverage experimental drugs and biologicals. To be covered by Medicare, drugs or biologicals must be "safe and effective" and "otherwise reasonable and necessary."[4] Drugs and biologicals are considered safe and effective when "approved for marketing by the Food and Drug Administration" and "when used for indications specified on the labeling." For medical devices, Medicare similarly restricts coverage for experimental devices, but it did expand coverage in 2015 by allowing coverage for care furnished to Medicare beneficiaries in certain categories of investigational device exemption studies.[5] A party interested in seeking Medicare coverage for one of these studies (i.e., the study sponsor) must submit a request for review and approval to CMS.

Beyond restrictions on experimental treatments, CMS primarily defines the scope of medically necessary services through national coverage determinations (NCDs) and local coverage determinations (LCDs). An NCD is a national policy statement "granting, limiting, or excluding Medicare coverage for a specific medical item or service"[6] and may be issued either when there is a new procedure or device that may warrant coverage or when the utility of a procedure is in dispute. NCDs are binding on all Medicare administrative contractors (MACs), quality improvement organizations, and health maintenance organizations. When CMS issues an NCD, a "decision memorandum" will first be issued that explains the reasons for the decision, the process followed in making the determination, and a summary of the evidence considered. After the decision memorandum is issued, the actual NCD will be issued. The NCD is the formal instruction to the MACs and other contractors regarding how to process related claims.

CMS also grants authority to the MACs to develop LCDs that make medical necessity determinations specific to their jurisdiction. Each LCD describes the circumstances under which an item or service is considered by the MACs to be reasonable and necessary. In making that determination, the MACs determine whether the service is (1) safe and effective, (2) not experimental or investigational, and (3) appropriate (including the duration and frequency considered appropriate for the item or service).[7] The process to develop an LCD requires the MACs to consider available medical literature, clinical guidelines, consensus documents, and public comment related to the item or service under review. Further, each MAC is required to have a "Contractor Advisory Committee" that includes healthcare providers and that may provide consultation and advice on the development of LCDs.[8] Each LCD may also have a companion article that provides billing and coding guidelines for the covered service or item.

An important trend to counterbalance government determinations of medical necessity is the development of statements by organizations representing specialists to guide clinical decision-making, including so-called consensus statements and clinical guidelines such as appropriate use criteria (AUC). An example of a consensus statement is the "Appropriate Use of Drug Testing in Clinical Addiction Medicine,"[9] published by the American Society of Addiction Medicine in 2017, which provides guidance of the use of urine drug testing in the treatment of substance misuse disorders. Similarly, AUC specify under what circumstances it is appropriate to perform a medical procedure or service and are typically evidence based or, if the evidence is still evolving, derived from expert consensus. In 2009, "Appropriate Use Criteria for Coronary Revascularization" were released to examine and improve patient selection for percutaneous coronary interventions, as well as address concerns about potential overuse.[10] Since that time, several other organizations have developed AUC for procedures. For example, orthopedic surgeons now have AUC for several common procedures, and the American Academy of Dermatology has AUC for Mohs procedures.[11] CMS is in the process of adopting an AUC program for certain advanced imaging services,[12] demonstrating an increasing acceptance of these types of criteria by the government.