COSMOS
Navigate the Compliance Universe

Report on Medicare Compliance Volume 28, Number 35. October 07, 2019
MACs Move Codes From LCDs to Local Coverage Articles; TPEs May Be Based on the Latter

By Nina Youngstrom

Hospitals should get used to stripped-down versions of local coverage determinations (LCDs) from Medicare administrative contractors (MACs), because they won't include CPT and ICD-10 codes anymore. At CMS's direction, MACs must move the codes to local coverage articles, and ultimately, they won't be in the same place as clinical coverage criteria. MACs also are required to give the industry a head's up about LCD changes and consider its input. The transition, announced in January 2019 without a deadline, has moved slowly and caused some confusion, as some MACs continue to update LCDs with diagnosis codes.

A CMS spokesperson tells *RMC* that "CMS has instructed the Medicare administrative contractors to have their codes moved to articles by January 2020."

With LCDs and local coverage articles in flux, it has been challenging for hospitals to ensure services are medically necessary, says Vera Phillips, compliance specialist at Olympic Medical Center in Port Angeles, Washington. The shift also seems to coincide with the targets of the MAC's Targeted Probe and Educate (TPE) reviews, she says. "I see a pattern. It worries me."

Moving from the LCDs to local coverage articles means they can be reissued and updated without formal notice and comment, says Steve Gillis, director of compliance coding, billing and audit at Partners HealthCare in Boston. MACs can add or delete codes beyond the usual coding updates without input from hospitals.

The LCD bifurcation stems from a provision in the 21st Century Cures Act of 2016 that required transparency in LCD development, says Valerie Rock, a principal at PYA. CMS later elaborated in Medicare Transmittal 854,[1] which requires the migration of codes to local coverage articles. "MACs shall remove all codes from LCDs and place them in billing & coding articles that are linked to the LCD," according to the transmittal (Change Request 10901), which was published in January 2019. "For all new and revised LCDs, MACs shall no longer include national policy language found in statute, regulations, rulings, interpretive manual instructions, etc. in the coverage and indications section of their LCDs."

Rock thinks it seems like an improvement because hospitals won't have to sort through clinical policy language to find the codes that are covered for a service that has been ordered for the patient. "Coding and billing policies are not clinical issues, and they wanted to move that to a separate document," she explains.

In recent days and weeks, MACs have been making the conversion, including Noridian Healthcare Solutions, National Government Services (NGS) and Palmetto GBA, although it's a work in progress. For example, in a September notice about revisions to its local coverage articles, NGS said "consistent with Change Request 10901, all coding information, national coverage provisions and associated information…have been removed from the LCD and placed in the related billing and coding article, A57024."

That conforms to the provisions in the 21st Century Cures Act,[2] which require MACs to post on their website their plans to develop an LCD 45 days in advance, a link to the LCD and a summary of the evidence used to develop

it. That would be a hassle for every code change because code sets are updated at least annually, although Gillis says hospitals could informally advocate for additional codes for a particular service in a local coverage article.

Are Articles a Circumvention?

But in some circumstances, local coverage articles perhaps could be used to circumvent the new transparent LCD process, Gillis says—or at least that's what the Alliance of Wound Care Stakeholders argued in a February letter to Noridian.

The alliance asked Noridian to withdraw local coverage articles A56155 and A56156 on the use of amniotic membrane derived skin substitute. "The distinction between informal interpretations such as Coverage Articles (that can be issued unilaterally by a MAC and do not require public notice and comment) and formal changes in Medicare coverage or reimbursement is embedded in the Medicare statute. Since 1987, Congress has set a specific standard that requires public notice and comment whenever there is any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services'.42 U.S.C. § 1395hh(a)(2) . This standard that requires notice-and-comment rulemaking in a wider range of circumstances was endorsed by the United States Court of Appeals for the District of Columbia Circuit. *Allina Health Services v. Price* 863 F.3d 937 (D.C. Cir. 2017) ...," the letter stated.[3] "The Alliance respectfully submits that the Coverage Articles made substantive changes to reduce Medicare coverage but did not follow CMS's rules for changing coverage and are not a substitute for an LCD. They improperly attempt to achieve the same goal as an LCD because they state comprehensively that the use of amniotic membrane derived skin substitutes for treatment of any condition other than a DSU or VSU is 'not reasonable and necessary and non-covered.' There are no exceptions. These Coverage Articles also are not a clarification of an existing policy or CMS regulation already in effect, as is the case with other Coverage Articles. Rather, the Coverage Articles created a new substantive standard for Medicare coverage." The alliance did not respond to a request for comment on Noridian's response. The Supreme Court in a June 3 decision agreed with the appeals court in the Allina case, saying CMS is required to use the rulemaking process, with its notice and comment period, to make "substantive" changes to policies that affect payment, although the same isn't true for "procedural" changes.[4]

Local Coverage Article Only Has Scenarios

Another problem has cropped up with a Noridian local coverage article on Parenteral Iron Administration Coverage in Non-Dialysis Usage (A55734) that's not associated with an LCD or national coverage determination (NCD), although there's an NCD for parenteral iron administration in dialysis patients, Phillips says. There are no codes in the local coverage article, leaving hospitals to figure out whether the physician's order fits one of five scenarios for "Coverage for parenteral iron in iron deficiency anemia (IDA):

1. When oral supplementation has been tried and the patient has demonstrated significant gastrointestinal distress whereas compliance with an oral regimen is no longer feasible. This includes patients with chronic kidney disease who are not yet requiring dialysis;

2. In beneficiaries who have a pathological or anatomical presentation where oral iron is unlikely to be absorbed or may further cause exacerbation of the underlying gastrointestinal disorder. This primarily includes use in patients with proven inflammatory bowel disease, short bowel/short gut syndrome and following gastric bypass surgery. This includes patients with a known abnormally high hepcidin level and those with iron refractory iron deficiency anemia;

3. Beneficiaries with chemotherapy induced anemia when an erythropoietin stimulating agent is being used in accordance with Medicare guidelines and where oral supplementation is unlikely to be sufficient or the

anemia is so severe as to require more urgent iron supplementation. If treating anemia exacerbated cardiac disease one should give precedence to transfusions in the acute setting;

4. In a beneficiary who has ongoing iron losses (such as severe menorrhagia, Rendu-Osler-Weber disease) where oral iron replenishment is inadequate or contraindicated only until definitive intervention, when available, is successfully undertaken;

5. Use in the pregnant beneficiary when iron stores are depleted such that the mother and/or the fetus are at risk of adverse outcomes and oral iron replenishment is either not tolerated or the anemia is of such severity as to require more immediate replenishment. Additionally, use in the peripartum period may be indicated when intra/post-partum hemorrhage is severe and by administering parenteral iron a transfusion may be avoided. This indication does not replace the strong consideration for transfusions when the hemorrhage is potentially life threatening."

That's a lot more voluble and subjective than a handful of diagnosis codes, which the hospital could compare to the physician order, Phillips says. "I am not sure after reading chart notes if a patient qualifies or not. We then have to send the scenarios to the physician and ask if they meet criteria," she says. "This does not go over so well."

The CMS spokesperson says even when there's no related LCD or NCD, "MACs are still permitted to use articles as a vehicle for educating stakeholders. Only codes within an LCD are being relocated into billing and coding articles. MACs have always had other educational articles that may not be related to an LCD or be a billing and coding article, and these may be retained as is."

Phillips says she sought Noridian's advice about the scenarios and was told if there's no obvious answer, hospitals should ask patients to sign an advance beneficiary notice (ABN). But how can they explain on the form why Medicare wouldn't consider the service medically necessary when it's ambiguous? There's not enough room on an ABN for a scenario anyway, Phillips says.

With Local Coverage Articles Came TPE Reviews

Meanwhile, she has watched as Noridian updated LCDs with codes in the first couple days of October, although they are supposed to be moved to local coverage articles. Rock says it looks like Noridian revised the LCDs first and then moved the codes to local coverage articles. Diagnosis codes for 2020 take effect Oct. 1, so it makes sense to see an update now, Rock surmises. "The ICD-10-CM update may have been the impetus for Noridian to complete the revisions of its LCDs. For instance, Palmetto GBA updated its article on allergy skin testing on Oct. 1 and the related LCD was not revised on the same date, because the LCD already complied with the new format."

Even before local coverage articles had codes in them, Phillips says her hospital noticed it was faced with TPE reviews based on them. There have been TPE reviews of cataract surgery, sleep studies, hydration, and the drugs Prolia and Rituxin. The TPEs, which used to be rooted in LCDs, are now based on the articles, she says. "They are watching."

Appeals are another concern, Gillis says. What will qualified independent contractors and administrative law judges (ALJs) think about LCDs versus local coverage articles? He wonders how much weight they will carry during appeals.

Attorney David Glaser points out that LCDs and local coverage articles aren't binding on ALJs and attorney adjudicators in the Office of Medicare Hearings and Appeals.[5] In fact, hospitals could ignore them altogether and still bill Medicare, although they may have to appeal to keep their money, he says. "You can make a choice,"

says Glaser, who has clients that don't follow LCDs if they think a noncovered service is in the patient's best interest. "It's not fraud." But LCDs are given "substantial deference if they're applicable to a particular case," says Glaser, with Fredrikson & Byron in Minneapolis.

In fact, on Sept. 9, the U.S. Court of Appeals for the 11th Circuit in its decision in the AseraCare case said "LCDs are not clinical benchmarks or mandatory requirements.... The LCDs themselves explicitly state that they are non-binding."[6]

Phillips is worried about the prospect of parsing the medical necessity of genetic testing. There are upwards of 20 local coverage articles on genetic tests, and they're complicated. "You have to look up the procedure code and see if the code is excluded or not," she says. "I spent 45 minutes one day on the phone with the cancer center trying to figure out if a patient had to sign an ABN. We have a large cancer center here for a small community."

Contact Phillips at vphillips@olympicmedical.org, Rock at vrock@pyapc.com, Glaser at dglaser@fredlaw.com and Gillis at sjgillis@partners.org.

1 Pub. 100-08, Medicare Program Integrity Manual, Local Coverage Determinations (LCDs), Trans. 854 (Jan. 11, 2019), https://go.cms.gov/2oNTwdF.
2 21st Century Cures Act, Pub. L. No. 114-255 (2016)
3 Marcia Nusgart, "Re: Local Coverage Articles A56155 and A56156 Medicare Coverage for Amniotic Membrane Derived Skin Substitutes," Alliance of Wound Care Stakeholders, February 17, 2019, http://bit.ly/2Vc0XYi.
4 Nina Youngstrom, "In Ruling That Will Shake Up How CMS Issues Guidance, Supreme Court Rejects DSH Formula," *Report on Medicare Compliance* 28, no. 21 (June 10, 2019),http://bit.ly/2AEa7TU.
542 C.F.R. § 405.1062(a) .
6 Nina Youngstrom, "In AseraCare FCA Case, Court Says a Contrary Medical Opinion Is Not Enough," *Report on Medicare Compliance* 28, no. 32 (September 16, 2019), http://bit.ly/330Pdul.