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OIG Targets Hospital Claims for Anti-Nausea Drug; Lack of Edits Raises Risk of Errors

Emend, an anti-nausea medication for patients undergoing chemotherapy, is a brand-new focus of HHS Office of Inspector General auditors. This development doesn't bode well for hospitals, which face a rocky path to compliance because Emend coverage is complicated by an interface of Medicare Parts B and D, and CMS lacks edits to help avert overpayments in this area.

The Emend audit is OIG's latest crackdown on Medicare billing for drugs. OIG recently launched an audit of Medicare claims for discarded units of Herceptin *(RMC 10/24/11, p. 1),* and blood-clotting factor on inpatient claims has received OIG scrutiny in the past year. While Herceptin audits were foreshadowed in the OIG Work Plan and blood-clotting factor is mentioned in past audits, Emend is nowhere to be found on the OIG website.

"We are seeing a number of audits focused on the accuracy of drug units, methods of administration and HCPCS reporting," says Stephen Gillis, director of billing compliance at Massachusetts General Hospital in Boston. They reflect OIG's data-driven approach to identifying potential risk areas, he notes.

According to an October letter from the OIG Office of Audit Services, the purpose of the Emend review is to determine whether hospitals complied with Medicare coverage criteria for Emend and "appropriately billed certain claims associated with the procedure code J8501," which is the oral version of Emend (aprepitant). As a "first step," OIG invites hospitals to audit problematic claims and fix them or explain why OIG has gotten the wrong idea.

Medicare billing rules for Emend are tricky. Coverage under Medicare Part B is governed by National Coverage Decision (NCD) 110.18, which sets forth two conditions of coverage. First, Emend is paid for only when patients are undergoing chemotherapy with nine drugs that are highly "emetogenic" (vomit-inducing). The nine drugs and their HCPCS codes are:

- Carmustine (J9050)
- Cisplatin (J9060, J9062)
- Cyclophosphamide (J9070, J9080, J9091-J9097)
- Dacarbazine (J9130, J9140)
- Doxorubicin (J9000, J9001)
- Epirubicin (J9178)
- Lomustine (C9017, S0178)
- Mechlorethamine (J9230)
- Streptozocin (J9320)

Second, Emend comes in IV and pill form, and Medicare Part B pays for both, but there's a catch. The latter is a three-drug cocktail made up of Emend, Dexamethasone, and a 5-HT3 antagonist (e.g., Zofran), and all three must be billed together on the same Part B claim form, according to *MLN Matters* SE 0910. Medicare Part B payment for the three drugs is $225, Gillis says.

Although the NCD limits Part B Emend coverage to beneficiaries undergoing one of the nine chemotherapies, physicians can prescribe Emend for other kinds of chemo. However, in these cases Medicare coverage will shift from Part B to Part D, which usually means beneficiaries get the pills at their neighborhood pharmacy with their Medicare prescription cards, Gillis says.

There is also a third, hybrid reimbursement coverage option: Medicare Part B pays for IV Emend on day one and Part D pays for days two and three of oral Emend.

Chargemaster Is at the Root of One Problem

Massachusetts General Hospital is one of many targets of the Emend audits. OIG questioned a lot of Emend claims paid to Mass General between January and December 2010, but Gillis says OIG is wrong about 40% of the presumed errors. A chargemaster set-up error resulted in the incorrect submission of the drug dexamethasone under revenue code 250, which doesn't require a HCPCS code. But the drug was, in fact, given to patients. "OIG's data assessment quickly identified that the services were not rendered in a manner consistent with the NCD," says Gillis, who thinks he can explain what happened and turn those denials around. The hospital made a mistake, but CMS bears some responsibility for Emend billing errors, Gillis says. "If

Medicare had edits in place to prevent paying for this, we could have identified the problem early on and fixed it."

Other hospitals may soon learn that some of their Emend claims are not up to snuff. For one thing, hospitals may have billed outside the NCD, Gillis says. During long courses of treatment, "people develop sensitivity to chemotherapy drugs that are not on the list but that are just as toxic and sickening," he says, so their physicians order treatment with Emend. Hospitals bill for it, unaware the drug is ineligible for reimbursement through Part B. Because there is no Medicare edit, the claims are paid by the Medicare contractor despite the fact that none of the nine NCD chemo drugs is in use. Some hospitals may realize when beneficiaries don't qualify for Part B coverage and send them to the pharmacy with a prescription for the three-drug cocktail. But that hasn't been a panacea, for beneficiaries or hospitals, Gillis says. Even when hospitals have billed in compliance with the NCD, their claims may be denied if they failed to report one of the three drugs on the Part B claim.

Although CMS will pay for Emend under Part D even when it's outside the NCD or only two of the three drugs are taken, that doesn't do the hospital any good, and beneficiaries also are out of luck because they have to pay a hefty copay, Gillis says. Hospitals can argue about the medical necessity of Emend for a wider range of patients, but OIG's "trump card is they are going to say 'we are not arguing about medical necessity. We are arguing about which way it should be billed'" — Medicare Part B versus Part D.

In another twist, Mass General gave a limited number of patients an equivalent of Zofran, one of the three drugs in the cocktail, but the equivalent (Aloxi) only comes in IV form, so OIG said it was out of compliance with the NCD. Again, the government is not denying a patient's treatment; it is shifting payment from Part B to Part D. The net effect, however, is that hospitals lose reimbursement and patients pick up more of the tab for their treatment, Gillis notes.

OIG's audits are driven by data mining. According to the OIG letter to hospitals, OIG extracted paid claims from CMS's National Claims History file for J8501 that were billed with the procedure code for the oral form of Emend but not the procedure codes for the other two drugs in the threesome (the 5-HT3 antagonist and the Dexamethasone). OIG is also pulling paid claims for J8501 that lacked a charge for administration of one of the nine chemo agents.

Where does this leave hospitals in terms of Medicare compliance moving forward? Here are some compliance tips from Gillis:

◆ ***Evaluate your chargemaster set-up for Dexamethasone and Zofran***. It's important to ensure that the chargemaster enables reporting these drugs using a 636 revenue code with a HCPCS. They should not be bundled through revenue code 250, with no HCPCS, or OIG will deny Part B claims for the Emend cocktail, he notes.

◆ ***Request special edits in your pre-submission claim scrubbing system to flag Part B claims that contain Emend-related errors***. The edit would detect when (1) oral Emend is charged but the claim is missing a charge for either oral Dexamethasone or oral Zofran, or both, or (2) Emend is on the claim, but there are no charges for one of the nine chemo diagnoses on the NCD. Gillis thinks that after the OIG audit, CMS may add a standard edit that would be replicated by most vendor claim scrubbing software.

◆ ***Evaluate whether your hospital has the ability to process Emend through Medicare Part D.*** It's unclear why CMS didn't implement a Medicare edit for Emend when it's an easy way to prevent overpayments. Edits also spare auditors and law enforcers from the pay-and-chase version of program integrity (e.g., postpayment audits, false claims lawsuits), says former CMS attorney Judy Waltz, with Foley & Lardner, LLP in San Francisco. But the absence of an edit probably won't get hospitals off the hook. In fact, providers should monitor their own edits to ensure they're working properly because, in the government's eyes, a failed edit is just as bad as no edit, and providers are liable for all aspects of their claims.

The government believes that "claims should be clean when they come in," says Waltz, who has represented two providers who settled false claims cases when their edits failed and erroneous claims were repeatedly submitted to Medicare as a result. "In both cases, good data were going in, but they relied on an edit that wasn't working," she says.

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