



ESA payment changes: Chasing a moving target

Staying one step ahead of clarifications, revisions of
EPO payment, and reporting rules

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Much has been written over the past year on the clinical concerns of using erythropoiesis-stimulating agents to treat end-stage renal disease patients. While it appears that the first round of new, U.S. Food & Drug Administration approved relabeling for ESAs reconfirms the therapeutic approach to treating anemia (see “Amgen updates ESA labeling,” National News, 12/07, NN&I), the myriad reimbursement changes for the drug remain a moving target for administrators and for vendors who must develop the software to keep them up-to-date. Providers need to quickly generate bills so as not to jeopardize cash flow but want to assure that their claims will be in compliance with rules that continue to be vague and changing. This article looks at the maze of payment approaches that the Centers for Medicare & Medicaid Services has developed over the last two years and what we have to look forward to in 2008.

In the beginning; In 2006, the Centers for Medicare & Medicaid Services instituted a new policy for the reimbursement of ESAs for ESRD patients: If by the end of the month, hematocrit value was greater than 39% (hemoglobin greater than 13 g/dL), the succeeding doses (in the next month) were to be reduced by at least 25% and acknowledged by the caregiver with a “GS” modifier on the claim. In absence of this indication, payment would be reduced for the amount given by 25%. This rule became more complicated when the industry requested the definition

of “dose.” Initially, it was understood that for CMS the dose would be the total amount of EPO administered during the previous month ♦ the monthly dose.

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However, because patients have different numbers of treatments month-to-month, comparing monthly total doses could be wildly inaccurate as a measure of EPO used per treatment. As a result, CMS initially changed its approach to have reimbursement based on a per treatment average dose, and the GS modifier acknowledged that the provider had reduced the per treatment dose by 25% in accordance with the CMS regulation. This mandate was relaxed last year and a “significant” reduction in EPO use (not necessarily 25%) in response to elevated hematocrits would qualify for using the GS modifier. A fundamental element of using the GS modifier was that it was basically a version of an “honor system”—i.e., the clinic was verifying that it had faithfully complied with the EPO reduction rules.

The moving target

In this ongoing environment of evolving regulations, CMS obviates some of the previous rules by changing the billing format from the existing one to “line item billing,” effective this month. With the line item approach, clinic managers report EPO dosing each treatment and compliance with dose reduction rules can be determined on a per treatment basis by CMS ♦ even though the GS modifier is still required. Similar to previous experience, there has been limited guidance regarding whether the GS modifier should be entered for each treatment subsequent to a dose modification or just for the initially modified EPO administration. Each provider is currently deciding which approach they wish to take. With this modified methodology, it is unclear if compliance is defined by each dose being reduced “significantly” or if an average dose reduction over the month will suffice. These continually changing requirements and a paucity of guidance by CMS and their fiscal intermediaries have, over the past two years, resulted in considerably anxiety in the provider community. The reason for this anxiety is that absent any feedback from fiscal intermediaries, such as contested claims, the provider is attesting that they are in compliance with the rules without knowing exactly how the rules are being interpreted. An added concern is that rule interpretation could be determined by CMS long after the clinic added the GS modifier to the claim,

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and because there have been a sequence of rules, providers feel vulnerable. These reimbursement regulations, as in the past, dictate details of clinical practice that can contradict medical judgment and/or necessity. It is also not clear how CMS and its fiscal intermediaries can or will monitor this compliance. The data sent in 2007 to the Medicare fiscal intermediaries consisted of total EPO administered during a given number of treatments. It would be possible for the fiscal intermediaries to calculate the average dose, but it would not be possible to determine if each treatment was in compliance in the absence of an audit. This will change with line item billing.

ED vs. EE

An overlapping regulation is the month-to-month tracking of the serial hematocrit/hemoglobin levels. Starting in January 2008, added modifiers will be required for high hematocrit/hemoglobin patients. For a patient with monthly hematocrits over 39% (hemoglobins over 13 g/dL) for three consecutive months, an “ED” modifier will be required; for a patient with elevated values for at least one month in three, an “EE” modifier will be required. Patients with hematocrits less than 39% during the three months will not need a modifier. These averages must be re-computed each month and the appropriate modifier applied to the Medicare claim. Thus the introduction of these modifiers obviates the previous rule that required action only if the previous month’s hematocrit was elevated and has substituted elevated levels in any month over a three month period as the criteria for EPO reduction. Current guidelines are that three consecutive months with elevated hematocrits (i.e., requiring a ED modifier) will result in a 50% reduction of payment for EPO used.

Conclusion

One strongly suspects that CMS put forth the EPO regulations to rein in aggressive use of this drug by establishing rules for “allowable” doses based on the patient’s measured hematocrit/hemoglobin. The regulations, however, are too vague for precise implementation of the rules by providers. In addition, they continue to change so that reliable protocols cannot be set up, and apparently fiscal intermediaries are ill-prepared or reluctant to offer providers guidance regarding their interpretation. Providers are naturally concerned that interpretations have and can change after they have faithfully attempted to work within the regulations. It is nearly impossible to deal with all of the above described complexities—“if this; then do that”—without automation. On the other hand, this puts vendors of

automated systems in a difficult position because one needs to have unequivocal business rules in order to automate such a complicated process. It is also frustrating to implement an automated approach with the rules continually changing. This challenge can be appreciated when one considers the evolving approaches, interpretations, and formats described above. The increased attention and regulation of anemia management for ESRD patients suggest that Medicare rules are aimed at reducing the use of EPO, and the mechanism seems to be to create sufficient unease and anxiety in the provider community to generate a quasivoluntary process of lower EPO usage. The result has been concern and considerable pressure to automate a process of reporting and claim generation in response to ill-defined and changing governing regulations. In this atmosphere, there is considerable frustration, paranoia, and extra effort on the part of providers and their suppliers to conform to regulations that have yet to be completely defined.

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