

CKD patients are a very heterogeneous population, and it is likely that they will need varying doses of erythropoietic drugs as their CKD progresses to ESRD. At the present time there are no head-to-head randomized controlled clinical trials that look at erythropoietic drug needs across the spectrum of CKD.

Amgen presented studies that examined the effect of darbepoetin on hemoglobin in this population. Two studies showed a dose conversion ratio (DCR) range between 215–330. These were observational studies similarly affected by the methodological weaknesses of this study design previously discussed for chemotherapy-induced anemia. A third study submitted by Amgen showed a DCR of 168:1 and is the only study that prospectively looked at darbepoetin and epoetin.

We estimate that no more than 10 percent of the Medicare patients who receive darbepoetin in the hospital outpatient setting receive it solely because of CKD. As a result, at this time, we believe that it could be confusing and burdensome for hospitals as well as the Medicare claims processing systems to use different HCPCS codes assigned to different APCs in order to distinguish and pay different amounts for darbepoetin used by patients with CIA from darbepoetin used by patients with CKD. Therefore, given the heterogeneity of the population, the general paucity of scientific evidence on CKD, the estimated low incidence of CKD-only indications in the OPPS population, and the potential burden on providers of requiring different codes for different indications, we are not establishing a different payment rate for darbepoetin for CKD at this time. However, CMS invites the submission of peer reviewed clinical data to further illuminate the issue. Therefore, we are going to use a 330:1 conversion ratio for CKD also and, therefore, a single APC payment rate for darbepoetin alfa, in 2004.

VII. Wage Index Changes for CY 2004

Section 1833(t)(2)(D) of the Act requires that we determine a wage adjustment factor to adjust for geographic wage differences, in a budget neutral manner, that portion of the OPPS payment rate and copayment amount that is attributable to labor and labor-related costs.

We used the proposed Federal fiscal year (FY) 2004 hospital inpatient PPS wage index to make wage adjustments in determining the proposed payment rates set forth in the proposed rule. We also proposed to use the final FY 2004 hospital inpatient wage index to calculate the final CY 2004 payment

rates and coinsurance amounts for OPPS. Therefore, we have used the corrected final FY 2004 hospital inpatient wage index to make wage adjustments in determining the final payments rates set forth in this final rule. The corrected final FY 2004 hospital inpatient wage index published as Tables 4A, 4B, and 4C in the October 6, 2003 **Federal Register** (68 FR 57732 through 57758) is reprinted in this final rule as Addendum H—Wage Index for Urban Areas; Addendum I—Wage Index for Rural Areas; and Addendum J—Wage Index for Hospitals That Are Reclassified. We used the corrected final FY 2004 hospital inpatient wage index to calculate the payment rates and coinsurance amounts published in this final rule to implement the OPPS for CY 2004. We note however, that from time to time, there are mid-year corrections to these wage indices and that our contractors will adopt and implement the mid-year changes for OPPS in the same manner that they make mid-year changes for inpatient hospital prospective payment.

We received several comments on how we apply the wage index in setting rates.

Comment: Commenters stated that we should exempt the device portion of the median cost from wage adjustment. They indicated that the wage index reflects the variation in wages and that applying it to 60 percent of an APC payment where part of that payment is for devices, to which the wage index is not applicable, results in inappropriately low payments in rural areas and discourages the expansion of state of the art technologies to rural hospitals. A commenter indicated that we should work with the commenter to calculate and publish a list of the device percentages for each APC and that the wage index adjustment should not be applied to that portion of the APC.

Response: To apply the wage index only to the non-device portion of the APC payment will mean a significant revision to the methodology used to calculate the relative weights and the conversion factor as well as changes to the system that applies the wage index on individual claims. When we calculate median costs, we divide 60 percent of the cost by the wage index for the hospital to neutralize the cost for the effects of the wage index. In addition, when we determine the conversion factor, we calculate a wage adjustment scalar to adjust for any increase or decrease that may occur to total payments from changes in the wage index. Moreover, it cannot be assumed that not applying the wage index to the device portion of the APC payment will

result in increased payment for APCs that require devices. In localities that have high wage indices, this change could result in reductions in payments for device APCs. For example, if the wage index is 1.5 and the national APC payment is \$10,000, the wage index applied to 60 percent of the APC increases the payment to the high wage index hospital to \$13,000. If the wage index is 0.9, the wage index applied to 60 percent of the APC decreases the payment to the hospital to \$9,400. However, if the wage index is applied only to 20 percent of the APC payment because 80 percent of the cost of the APC is for the device, the hospital in the high wage index area will now get \$11,000 (a \$2,000 loss) and the hospital in the low wage index area will now get \$9,800 (a \$400 gain).

Also, because the wage index is used to neutralize costs derived from charges and is a factor in the conversion factor, the \$10,000 payment in the example may change. To gauge the full impact of such a change, we would have to undertake significant statistical analysis. We will continue to apply the wage index to 60 percent of the APC for 2004. However, we recognize the need to reassess whether this percentage is correct in view of the packaging of high cost devices into APCs and will make every effort to do a reassessment for 2005 OPPS proposed rule. If we determine that a change to the percentage might be appropriate, we will propose it in the 2005 OPPS NPRM.

VIII. Copayment for CY 2004

In the November 30, 2001 final rule (66 FR 59887), we adopted a methodology that applied five rules for calculating APC copayment amounts when payments for APC groups change because the APCs' relative weights are recalibrated or when individual services are reclassified from one APC group to another. In calculating the unadjusted copayment amounts for 2004, we encountered circumstances that the methodology in the November 30, 2001 final rule either did not address or whose applicability was ambiguous. Therefore, we proposed to revise and clarify the methodology we would follow to calculate unadjusted copayment amounts, including situations in which recalibration of the relative payment weight of an existing APC results in a change in the APC payment; situations in which reclassification of HCPCS codes from an existing APC to another APC results in a change in the APC payment; and situations in which newly created APCs are comprised of HCPCS codes from existing APCs.