

split the budget neutrality adjustment for DRG reclassification and recalibration into two components in order to isolate the reduction associated with add-on payments for new technologies.

Commenters did not agree that add-on payments for new technology should be budget neutral, and explained that the purpose of having additional payments for high-cost items was to compensate a hospital for its unrecovered cost. Because of budget neutrality, these high-cost items are not being properly paid. The commenter also noted that these high-cost items are also the cause of a higher than expected outlier payment.

One commenter recommended that CMS develop a separate pool of money to fund new technology and remove it from the budget neutrality calculation. The commenter explained that, while the technology is new, there should be money set aside and accessed only by those hospitals utilizing that technology.

Response: When we approve a new technology for add-on payments, we conduct an analysis based on the latest data available to estimate the total add-on payments that will be made for the new technology during the upcoming fiscal year and include the results in the annual proposed and final rules. Analyses of technologies approved for add-on payments for FY 2004 are presented below. These analyses include our analysis of available FY 2003 MedPAR data on the utilization of Xigris® and the basis for our estimated payments for new technologies approved for FY 2004. We also discuss this analysis in our description of budget neutrality in section II.A.4.a. of the Addendum to this final rule. We note that, based on our analysis, we have reduced considerably our estimate of add-on payments for Xigris® from the FY 2003 level, which led to a smaller budget neutrality offset to the standardized amounts.

As we stated above, the Congressional Report language accompanying section 533 of Pub. L. 106–554 clearly indicated Congress' intent that this provision be implemented in a budget neutral manner. Therefore, Congress is the appropriate body to consider concerns about the budget neutrality of this provision.

We do not believe it necessary to establish a separate budget neutrality calculation or pool for these payments. The amount of the payments is clearly identified in the final rule. Like all of the budget neutrality calculations, it is a prospective estimate.

Comment: Commenters recommended that CMS eliminate the use of case-

weighted averages in the calculation of the cost threshold for technologies that occur in more than one DRG. The commenter believed that the goal of add-on payments is to provide adequate payment for new technologies in the DRGs in which the technology is used. The commenter added that the use of a case-weighted average biases the cost threshold against technologies that occur in more than one DRG and places hospitals at a disadvantage in DRGs where the threshold would otherwise be met except for application of the case-weighted average.

Commenters argued that our criteria for what is considered a new technology is not consistent with section 1886(d)(5)(K)(ii)(II) of the Act. The commenter stated that this provision was intended to provide for the collection of data with respect to the costs of a new medical service or technology for a period of not less than 2 years and not more than 3 years, "beginning on the date on which an inpatient hospital code is issued with respect to the service or technology." Therefore, the commenter recommended that, instead of no longer considering technologies new because the related charges are already captured in the MedPAR data, CMS should only view a technology as ineligible on the grounds that it is no longer new if the agency can specifically identify a significant sample of cases involving use of the technology in the MedPAR data. One commenter noted that sufficient charge data to assess whether the new technology meets the cost threshold criterion are often only available through the MedPAR data after the new ICD–9–CM code becomes effective. Some commenters also recommended that CMS raise the add-on payment amount from 50 percent of the cost of the new technology to an 80-percent or 100-percent marginal cost factor.

Another commenter asked CMS to provide established clinical requirements or criteria that would control substantial clinical improvement determinations.

One commenter recommended that CMS deem products that fall within one of the following categories designated by the FDA to have met the substantial clinical improvement criterion: Drugs or biologicals that obtain fast track or accelerated approval; and drugs or biologicals approved after priority review or approved for orphan indication. The commenter recommended that CMS defer to the clinical expertise of the FDA with respect to these products and find that any product falling in the above

categories satisfy the substantial clinical improvement criterion without further CMS analysis.

In addition, many commenters addressed the proposed change to the cost threshold criterion. (We are addressing these comments in our discussion of specific proposals later in this section of the preamble.)

Response: We appreciate the interest of the many stakeholders in ensuring that Medicare beneficiaries have full access to improvements in medical technology. We have previously discussed our position on each of the issues raised by the commenters on the proposed rule in detail in the September 7, 2001 final rule (66 FR 46905) and the August 1, 2002 final rule (67 FR 50009). Our rationales for these policies have not changed since we discussed them in those final rules, and we did not propose changes to these policies in the May 19, 2003 proposed rule. Therefore, readers are referred to the September 7, 2001 final rule and the August 1, 2002 final rule for our responses to these comments. However, we will continue to assess each of these policies and would appreciate the commenters' continued input on these issues.

Comment: One commenter suggested that CMS conduct a historical review of technologies that would have likely met the "new" and substantial improvement criteria and determine the relationship between the costs of those items and the new technology cost threshold. The commenter noted that such an analysis might provide useful insights as to whether a more flexible cost criterion is needed.

Response: We will take this suggestion under consideration.

2. FY 2004 Status of Technology Approved for FY 2003 Add-On Payments: Drotrecogin Alfa (Activated)—Xigris®

In the August 1, 2002 IPPS final rule, we stated that cases involving the administration of Xigris® (a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC)) as identified by the presence of code 00.11 (Infusion of drotrecogin alfa (activated)) are eligible for additional payments of up to \$3,400 (50 percent of the average cost of the drug) (67 FR 50013). (The August 1, 2002 final rule contains a detailed discussion of this technology.) Although Xigris® was approved by the FDA in November 2001, it did not qualify for add-on payments until discharges on or after October 1, 2002. Consequently, FY 2002 discharges (between October 1, 2001 and September 30, 2002) may not reflect full