

utilization of the technology due to the absence of the add-on payment.

Therefore, for FY 2004, we will continue to make add-on payments for cases involving the administration of Xigris® as identified by the presence of code 00.11. Based on preliminary analysis of the incidence of Xigris® in the first quarter FY 2003 MedPAR file, in the May 19, 2003 proposed rule, we proposed to revise downward our estimate of total add-on payments for Xigris®. For FY 2003, we estimated that total add-on payments would be approximately \$74.8 million (22,000 Medicare patients who would be eligible for a \$3,400 add-on payment). For FY 2004, we estimated in the proposed rule the total add-on payments would be approximately \$50 million (based on 14,000 Medicare patients who would be eligible for a \$3,400 add-on payment). We indicated that this proposed additional payment would be included in the DRG reclassification and recalibration budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts. However, we indicated that, before the publication of the FY 2004 IPPS final rule, we would reevaluate our assumptions regarding this estimate based on preliminary claims data from the FY 2003 MedPAR file.

We have analyzed the claims from the March 2003 update to the FY 2003 MedPAR file. We identified claims that had received Xigris® based on the inclusion of procedure code 00.11. We identified only 1,500 claims from this file. Although the March 2003 update of the FY 2003 MedPAR probably only realistically includes about 5 months' worth of claims, it appears that a lower than expected number of cases are receiving this new technology at the present time.

Therefore, in this final rule for FY 2004, we are lowering the total payments in proportion to the cases that have actually received this drug. We are doubling the number of cases in our March 2003 MedPAR update to an estimated 3,000 cases that will receive Xigris® in FY 2003. We recognize there may actually be more cases than this by the end of the year, as only about 5 months of data are accounted for in our analysis. Also, this estimate does not account for future increased use of the drug. However, these potential underestimates are offset by the fact that we are assuming all cases will qualify for the full \$3,400 add-on payment. We believe these effects will largely offset one another. Therefore, the final projected costs for add-on payments are estimated to be \$10 million. We will use

this estimate in our budget neutrality calculations.

Comment: One commenter supported our decision to continue paying add on payments for Xigris®, but disagreed with the proposed estimated decline in add-on payments in FY 2004 from \$74.8 million to \$50 million. The commenter explained that this conclusion was made using only first quarter FY 2003 MedPAR data and, since this technology is still in its infancy, the commenter believed FY 2003 MedPAR data will reflect an upward trend in its use and overall availability.

Some commenters were concerned that first year utilization of any new technology is an inappropriate measure for CMS to rely on in determining the full extent of use of a new technology. They asserted that the gradual adoption of new technology and the time required for hospitals to adapt their coding and charge structures to new technologies make it difficult to base projections of the ultimate utilization and costs of new technology immediately following its introduction. In addition, one commenter explained that CMS' system delays in processing claims have led to a negative impact on both uptake of the technology and the data collection associated with its use.

Also, the commenter explained that Congress required data relating to the cost of the technology be collected for not less than 2 years and not more than 3 years after an appropriate inpatient hospital service code is established. The commenter added that, because CMS publishes its proposed and final rules before the completion of a fiscal year, CMS would make its decision for FY 2005 with less than 2 full year's worth of data. As a result, the commenters recommended that CMS make additional payments for the full 3 years so when it moves a new technology into a DRG, it does so based on accurate and reliable information about its cost and clinical use.

Response: Before each fiscal year, we use the latest available data to determine if we should continue to pay add-on payments for approved new technologies. As stated above, we are continuing to pay for Xigris® for FY 2004 because FY 2002 discharges may not reflect full utilization of the technology. Based on the March update of the FY 2003 MedPAR file, we lowered our cost estimates from the proposed rule because a lower than projected number of cases is receiving this technology at the present time. Before FY 2005, we will again use the latest available data to determine whether we would propose to continue

to make add-on payments for Xigris® for FY 2005.

3. FY 2004 Applicants for New Technology Add-On Payments

We received two applications for new technologies to be designated eligible for inpatient add-on payments for new technology for FY 2004. A discussion of these applications and our determinations appear below.

a. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions

An application was submitted for the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device (InFUSE™) for approval as a new technology eligible for add-on payments. A similar application was submitted last year. However, we denied it because, based on the available data, the technology did not exceed the 1 standard deviation threshold above the average charges for the DRGs to which the technology is assigned.

The product is applied through use of an absorbable collagen sponge and an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This procedure is done in place of the more traditional use of autogenous iliac crest bone graft. For a more detailed discussion about InFUSE™, see the August 1, 2002 IPPS final rule (67 FR 50016).

On July 2, 2002, the FDA approved InFUSE™ for spinal fusion procedures in skeletally mature patients at one level. Therefore, based on the FDA's approval, multilevel use of this technology would be off-label. In the August 1, 2002 IPPS final rule (67 FR 50017), we stated this technology would meet the cost threshold only if the added costs of multilevel fusions were taken into account. Because the FDA had not approved this technology for multilevel fusions, and the applicant had not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions (the clinical trial upon which the application was based was a single-level fusion trial), we could not issue a substantial clinical improvement determination for multilevel fusions and, consequently, did not consider the costs associated with multilevel fusions in our analysis of whether this technology met the cost threshold. Therefore, because the average charges for this new technology, when used for single-level spinal fusions, did not exceed the threshold to qualify for new technology add-on payment, we denied this application for