

reduced amount. Although the marginal payment rate for individual technologies would be reduced, this reduction would be offset by large overall payments to hospitals for new technologies under this provision.

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

Therefore, for FY 2004, we are proposing to 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, we are proposing 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 are estimating 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 are proposing that this 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 will reevaluate our assumptions regarding this estimate based on preliminary claims data from the FY 2003 MedPAR file before the publication of the FY 2004 IPPS final rule.

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 on these applications appears below.

a. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions. An application was submitted by Medtronic Sofamor Danek for the InFUSE™ Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device for approval as a new technology eligible for add-on payments. A similar application was submitted last year but was denied because, based on the available data, the technology did not exceed the one 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™ Bone Graft/LT-CAGE® Lumbar Tapered Fusion, see the August 1, 2002 IPPS final rule (67 FR 50016).

On July 2, 2002, the FDA approved InFUSE™ Bone Graft/LT-CAGE® 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 of \$37,815, we denied this application for add-on payments for FY 2003. For similar reasons, we did not consider data on the charges for multilevel fusions in our analysis of whether this technology meets the cost threshold for FY 2004.

In its application for add-on payments for FY 2004, Medtronic used data from CMS' FY 2001 Standard Analytical File for physicians and hospitals. The analysis linked a 5-percent sample of hospital spinal fusions cases with the corresponding physician claims. Because there were no ICD-9-M codes to identify multilevel fusions in 2001, multilevel fusions were identified using CPT codes on the physician claims. Average charges were taken from actual cases used in clinical trials.

After grouping these cases into one, two, and three or more levels fused in DRGs 497 and 498 (Spinal Fusion Except Cervical With and Without CC, respectively), the applicant then calculated average charges assuming the use of the InFUSE™ Bone Graft/LT-CAGE® for these cases. For DRG 497, the estimated single-level fusion average charge was \$41,321; for DRG 498, the estimated single-level fusion average charge was \$37,200. Because these DRGs are not currently split for different numbers of fusion levels involved, Medtronic has calculated its own standard deviation of average charges to determine the threshold for these DRGs using the 5-percent sample data. For DRG 497, the threshold (calculated by Medtronic) was \$45,646, which is greater than the estimated average charge of \$41,321 for single-level fusions noted above. For DRG 498, the threshold (calculated by Medtronic) was \$36,935, which is less than the average charges for single-level fusions in this DRG as noted above.

However, we note the thresholds to qualify for the new technology add-on payments for FY 2003 published in Table 10 of the August 1, 2002 IPPS final rule for DRGs 497 and 498 were \$58,040 and \$41,923, respectively. These thresholds were computed based on all cases assigned to these DRGs, and do not differentiate between the number of spinal levels fused. Because we are not proposing to redefine these DRGs to differentiate cases on the basis of the number of levels of the spine fused in the manner suggested by the applicant's analysis, the thresholds published in last year's final rule are applicable for a new technology to qualify for add-on payments in these DRGs for FY 2004. Therefore, because the averages calculated by the applicant for single-level fusions do not exceed the published thresholds, we are proposing not to approve this technology on the basis of this analysis.

The applicant also submitted data from actual cases involving the InFUSE™ Bone Graft/LT-CAGE® with single level fusions only. The data submitted included 31 claims from 4