

hospitals (only one Medicare patient was included in the sample). All 31 cases were from DRG 498. The average standardized charge for these cases was \$47,172. Based on these data, the average standardized charge exceeds the threshold for DRG 498. However, we note that this limited sample excludes any cases from DRG 497.

We note that, effective for discharges occurring on or after October 1, 2002, ICD-9-CM codes 84.51 (Insertion of interbody spinal fusion device) and 84.52 (Insertion of recombinant bone morphogenetic protein) are effective to identify cases involving this technology. Therefore, in an effort to resolve the difficulties in obtaining sufficient data upon which to determine whether this technology exceeds the applicable threshold, we intend to review available MedPAR data for the first several months of FY 2003 to identify these cases and calculate their average standardized charges to compare with the thresholds. We anticipate some of these cases will involve multilevel spinal fusions, and it will be necessary to identify those cases in order to remove them from the calculation of the average charges.

If the technology meets the cost threshold based on the MedPAR data, we will evaluate whether it qualifies as a substantial clinical improvement. According to the applicant:

“InFUSE™ Bone Graft is more appropriate to use and has been proven more effective in its use than autogenous iliac crest bone graft, when either is placed in the LT-Cage™ Lumbar Tapered Fusion Device for anterior lumbar interbody fusion. Use of InFUSE™ Bone Graft instead of autogenous iliac crest bone graft:

- Obviates iliac crest bone graft donor site morbidity.
- Reduces operative time, blood loss and hospitalization.
- Results in greater fusion success.
- We found that the Oswestry Low Back Pain Disability score and SF-36 Physical Component and Pain Index score were consistently 10 percent better in the InFUSE™ Bone Graft group than the autogenous iliac bone graft group.

- Enables earlier return to work.”

Among the issues we will consider are: Does avoiding the complications associated with the iliac crest bone harvesting procedure constitute a substantial clinical improvement; and, with the increased rate of osteoarthritis and osteoporosis in the Medicare population, is there evidence that the technology represents a substantial clinical improvement in spinal fusions among this population? We are

particularly interested in data on the results of aged Medicare patients who have been treated with BMP, and any basic biology bench data on the results of using BMP in osteoporotic bones.

b. GLIADEL® Wafer. Glioblastoma Multiforme (GBM) is the most common and most aggressive of the primary brain tumors. Standard care for patients diagnosed with GBM is surgical resection and radiation. According to the manufacturer (Guilford Pharmaceuticals), the GLIADEL® Wafer is indicated for use as an adjunct to surgery to prolong survival in patients with recurrent GBM. Implanted directly into the cavity that is created when a brain tumor is surgically removed, GLIADEL® delivers chemotherapy directly to the site where tumors are most likely to recur.

The FDA approved GLIADEL® Wafer on September 23, 1996, for use as an adjunct to surgery to prolong survival in patients with recurrent GBM for whom surgical resection is indicated. In announcing its approval, the FDA indicated that GLIADEL® was approved:

“ \* \* \* based on the results of a multi-center placebo controlled study in 222 patients who had recurrent malignant glioma after initial treatment with surgery and radiation therapy. Following surgery to remove the tumor, half of the patients were treated with GLIADEL® implants and half with placebo. In patients with glioblastoma multiforme, the 6-month survival rate increased from 36 percent with placebo to 56 percent with GLIADEL®. Median survival increased from 20 weeks with placebo to 28 weeks with GLIADEL®. In patients with pathologic diagnoses other than glioblastoma multiforme, GLIADEL® had no effect on survival.”

Guilford Pharmaceuticals has requested that GLIADEL® still be considered new because, until a new ICD-9-CM code (00.10 Implementation of Chemotherapeutic Agent) was established on October 1, 2002, it was not possible to identify specifically these cases in the MedPAR data. However, as noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the costs of GLIADEL® are currently reflected in the DRG weights (despite the absence of a specific code), GLIADEL® does not meet our criterion that a medical service or technology be “new”. That is, FY 2002 MedPAR data used to calculate the proposed DRG weights for FY 2004 include cases where GLIADEL® was administered (and the corresponding charges of these cases, include charges associated with

GLIADEL®). On February 26, 2003, the FDA approved GLIADEL® for use in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. However, our understanding is that many newly diagnosed patients were already receiving this therapy. To the extent this is true, the charges associated with this use of GLIADEL® are also reflected in the DRG relative weights.

According to Guilford's application, the current average wholesale price of GLIADEL® is \$10,985. Guilford submitted charge data for 23 Medicare patients at 7 hospitals from FY 2000. The charges were then standardized and adjusted for inflation using the hospital market basket inflation factor (from 2000 to 2003) in order to determine an inflated average standardized charge of \$33,002. Guilford points out that this charge narrowly misses the DRG 2 threshold published in Table 10 of the August 1, 2002 IPPS final rule of \$34,673. However, we note that, according to the manufacturer, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Based on this assumption, the qualifying threshold for GLIADEL® would be \$54,312 (60 percent of the DRG 1 threshold of \$67,404, and 40 percent of the DRG 2 threshold of \$34,673).

As mentioned above in section II.B.3.a. of this proposed rule, we examined the definitions of DRGs 1 and 2 to determine whether they could be improved, and we are proposing to create a new DRG for patients with an intracranial vascular procedure and an intracranial hemorrhage and two new DRGs for patients with only a vascular shunt procedure (splitting on the presence or absence of a CC). We also compared the data submitted in the application on the charges for GLIADEL® cases with the charges of other procedures in DRGs 1 and 2. We found that, although the \$33,002 average standardized charge reported is just below the qualifying threshold in DRG 2, it is actually well below the mean average standardized charge for DRG 1 (\$42,092). As noted previously, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Therefore, we do not believe that any change to the DRG assignment of cases receiving GLIADEL® is warranted at this time. However, we will continue to monitor our data to determine whether a change is warranted in the future.

#### 4. Review of the High-Cost Threshold

The current cost threshold for a new technology to qualify for add-on