

cases is very similar. The commenter contended that, absent another appropriate craniotomy DRG, the same argument could be applied to assigning cases with GLIADEL® wafer to DRG 484.

In a comment on the proposed rule, the manufacturer of this implant provided estimated FY 2003 average costs and charges for these cases. Its report indicated that the costs of the cases of \$24,280 would be the same for cases assigned to DRG 1 and DRG 2, and the charges of the cases of \$50,394 would be the same for both DRGs. The manufacturer requested that we analyze the available data in the FY 2003 MedPAR file to identify GLIADEL® cases. The manufacturer believed these data support the need for a DRG change.

One commenter agreed with our determination that this technology is currently reflected within the DRG weights and does not meet the definition of a new technology.

Response: In our analysis of the data from the March 2003 update of the FY 2003 MedPAR file, we found a total of 61 cases in which the ICD-9-CM procedure code 00.10 (Implantation of a chemotherapeutic agent) was reported for cases assigned to DRGs 1 and 2. There were 38 cases assigned to DRG 1 and 23 cases assigned to DRG 2. Consistent with the GROUPER logic for these DRGs that splits cases based on the presence or absence of CCs, we found that the average standardized charges in DRGs 1 and 2 were approximately \$64,864 and \$42,624, respectively. We believe that while the charges for GLIADEL® wafer cases may be higher than the average standardized charges for DRG 2, they are within the normal variation of the overall charges within each DRG.

We note that the DRGs are a system of averages, and there is expected to be variation in the average charges for different procedures and services across all DRGs. Hospitals are expected to be able to finance some higher cost procedures with lower cost procedures within the same DRG as well as across DRGs. Although the average charges of the cases we identified in our analysis are somewhat higher than the average charges of all cases in these DRGs, they are within the range of other procedures included in these DRGs. By way of comparison, we are creating a new DRG for cases with an intracranial vascular procedure and a principal diagnosis of an intracranial hemorrhage on the basis of our analysis that showed the average charges for these cases were \$113,884. This is approximately \$59,000 more than the average charges in DRG 1 (more than the total charges for the GLIADEL®

cases reported by the commenter) and approximately \$84,000 more than the average charges in DRG 2.

We also are concerned that there may be insufficient volume of cases to warrant the establishment of a new DRG for this technology. Thus, before considering the creation of a new DRG for these cases, we would like to review a full year of data, as well as consider alternative options if they appear warranted. It would also be necessary to provide opportunity for public comment on any potential changes to the DRG assignment of these cases before proceeding with a final change.

Currently, DRG 484 includes complex, multiple significant trauma cases; that is, patients with a principal diagnosis of trauma and at least two significant trauma diagnosis codes (either as principal or secondary diagnosis) from different body site categories. While this DRG includes craniotomy, it is assigned to MDC 24 (Multiple Significant Trauma). While the treatment for glioblastoma multiforme is significant, we do not believe these cases are clinically similar to other cases currently assigned to DRG 484.

We also are concerned that there may be insufficient volume to warrant the establishment of a new DRG for this technology, and we would like to review a full year of data, as well as consider alternative options if they appear warranted. It also would be necessary to provide opportunity for public comment on any potential changes before proceeding with a final change.

Comment: Two commenters pointed out a typographical error in our proposal. The commenters indicated that we proposed new DRGs 529 and 530 for placement in MDC 5; the correct MDC should have been MDC 1.

Response: We agree with the commenters and have corrected this placement, as indicated in the discussion above.

After consideration of the comments received, we are adopting as final the three new proposed DRGs 528, 529, and 530. These DRGs will be effective for discharges occurring on or after October 1, 2003.

b. DRG 23 (Nontraumatic Stupor and Coma)

In DRG 23 (Nontraumatic Stupor and Coma), there are currently six principal diagnoses identified by the following ICD-9-CM diagnosis codes: 348.4, Compression of the brain; 348.5, Cerebral edema; 780.01, Coma; 780.02, Transient alteration of awareness; 780.03, Persistent vegetative state; and

780.09, Other alteration of consciousness. Code 780.02 is often used to describe the diagnosis of psychiatric patients rather than the diagnosis of patients with severe neurological disorders. The treatment plan for a patient with "transient alteration of awareness" is clinically very different from the treatment plan for a coma patient. Furthermore, many patients with this diagnosis are treated in psychiatric facilities rather than in acute care hospitals.

Although there are neurological patients who present with the complaint of "transient alteration of awareness," the cause of this alteration of consciousness is commonly identified, and the principal diagnosis for the hospital admission is the etiology of the alteration of consciousness rather than the symptom itself. For the few remaining neurological patients for whom the cause is not identified and for whom code 780.02 is assigned as the principal diagnosis, we believe that the care of these patients is different than the care of patients with coma or cerebral edema.

Because we believe the patients with a principal diagnosis of "transient alteration of consciousness" are more clinically related to the patients in DRG 429 (Organic Disturbances and Mental Retardation) in MDC 19 (Mental Diseases and Disorders), we proposed that patients who are assigned a principal diagnosis of code 780.02 would be assigned to DRG 429 instead of DRG 23. DRG 429 also contains similar diagnoses, such as code 293.81, Organic delusional syndrome and code 293.82, Organic hallucinosis syndrome. (We note that the charges for the patient cases in DRGs 23 and 429 are very similar (\$11,559 and \$11,713, respectively), so the proposed movement of code 780.02 from DRG 23 to DRG 429 would have minimal payment impact.) Moving this diagnosis code as proposed would also consolidate diagnoses treated frequently in psychiatric hospitals in those DRGs that are likely to be a part of the upcoming proposed Medicare psychiatric facility PPS.

Comment: An organization representing hospitals supported our proposed change, while other commenters opposed the change. The commenters who opposed the change stated that code 780.02 is included in the ICD-9-CM chapter for signs and symptoms of ill-defined conditions. The commenters believed that since this code is included in a chapter with ill-defined conditions, it would be inappropriate to move the code to DRG 429. The commenters stated that this