

therapies, high-dose IL-2 therapy is associated with predictable toxicities that require extensive monitoring. Often patients require one-on-one nursing or physician care for extended portions of their stay.

High-dose IL-2 therapy is significantly different from conventional chemotherapy in terms of the resources required to administer it. Conventional chemotherapy may be given to patients either on an outpatient basis or through a series of short (that is, 1 to 3 day) inpatient stays.

High-dose IL-2 therapy is given during two separate hospital admissions. For the first cycle, the IL-2 is administered every 8 hours over 5 days. Patients are then discharged to rest at home for several days and then are admitted for the second cycle of therapy, in which the same regimen and dosing is repeated. The two cycles complete the first course of high-dose IL-2 therapy. This regimen may be repeated at 8 to 12 weeks if the patient is responding. The maximum number of courses for any one patient is predicted to be five courses.

Not all patients with end-stage renal cell carcinoma or end-stage melanoma are appropriate candidates for high-dose IL-2 chemotherapy. It is estimated that there are between 15,000 and 20,000 patients in the United States who have one of these two types of cancer.

However, only 20 percent of those patients will be appropriate candidates for the rigors of the treatment regimen. It is further estimated that, annually, approximately 1,300 of these patients will be Medicare beneficiaries. However, allegedly due to the level of payment for the DRGs to which these cases are currently assigned, we have been informed by industry sources that only between 100 and 200 Medicare patients receive the treatment each year. According to these industry sources, several treatment centers have had to discontinue their high-dose IL-2 therapy programs for end-stage renal cell carcinoma or end-stage melanoma because of the low Medicare payment.

According to industry sources, the wholesale cost of IL-2 is approximately \$700 per vial. Dosages range between 15 and 20 vials per treatment, or between \$10,500 and \$14,000 per patient, per cycle, for the cost of the IL-2 drug alone. There is no ICD-9-CM procedure code that currently identifies patients receiving this therapy. Therefore, it is not possible to identify directly these cases in the MedPAR data. Currently, this therapy is coded using the more general ICD-9-CM code 99.28 (Injection or infusion of biologic response modifier). When we addressed this issue

previously in the August 1, 2000 IPPS final rule (65 FR 47067) by examining cases for which procedure code 99.28 was present, our analysis was inconclusive due to the wide range of cases identified (1,179 cases across in 136 DRGs). However, recent data collected by the industry on 30 Medicare beneficiaries who received high-dose IL-2 therapy during FY 2002 show average charges for these cases of approximately \$54,000.

Depending on the principal diagnosis reported, patients receiving high-dose IL-2 therapy may be assigned to one of the following five DRGs: DRG 272 (Major Skin Disorder With CC) and DRG 273 (Major Skin Disorder Without CC) in MDC 9; DRG 318 (Kidney and Urinary Tract Neoplasms With CC) and DRG 319 (Kidney and Urinary Tract Neoplasms Without CC) in MDC 11; and DRG 410 (Chemotherapy Without Leukemia as Secondary Diagnosis) in MDC 17. The following table illustrates the average charges for patients in these DRGs.

DRG	Average charges
272 .....	\$14,997
273 .....	9,128
318 .....	16,892
319 .....	9,583
410 .....	16,103

Because of the need to identify the subset of patients receiving this type of treatment, the ICD-9-CM Coordination and Maintenance Committee determined, based on its consideration at the December 6, 2002 public meeting, that a new code for high-dose IL-2 therapy was warranted. Therefore, a new code has been created in the 00 Chapter of ICD-9-CM (Procedures and Interventions, Not Elsewhere Classified), in category 00.1 (Pharmaceuticals) at 00.15 (High-dose infusion Interleukin-2 (IL-2)), effective October 1, 2003.

We believe patients receiving high-dose IL-2 therapy are clinically similar to other cases currently assigned to DRG 492 (Chemotherapy With Acute Leukemia as Secondary Diagnosis) in MDC 17. The average charge for patients currently assigned to DRG 492 is \$55,581. Currently, DRG 492 requires one of the following two principal diagnoses:

- V58.1, Encounter for chemotherapy
- V67.2, Followup examination following chemotherapy
- And one of the following secondary diagnoses:
  - 204.00, Acute lymphoid leukemia without mention of remission

- 204.01, Acute lymphoid leukemia with remission
- 205.00, Acute myeloid leukemia without mention of remission
  - 205.01, Acute myeloid leukemia with remission
- 206.00, Acute monocytic leukemia without mention of remission
  - 206.01, Acute monocytic leukemia with remission
- 207.00, Acute erythremia and erythroleukemia without mention of remission
  - 207.01, Acute erythremia and erythroleukemia with remission
- 208.00, Acute leukemia of unspecified cell type without mention of remission
  - 208.01, Acute leukemia of unspecified cell type without mention of remission

We are proposing to modify DRG 492 by adding new procedure code 00.15 to the logic. Assignment to this DRG would require the same two V-code principal diagnosis codes as listed above (V58.1 and V67.2), but would require either one of the leukemia codes listed as a secondary diagnosis, or would require the procedure code 00.15. In addition, we are proposing to change the title of DRG 492 to "Chemotherapy With Acute Leukemia or With Use of High Dose Chemotherapy Agent".

We will monitor cases with procedure code 00.15 as these data become available, and consider potential further refinements to DRG 492 as necessary.

#### 8. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services)

a. Implantable Devices. We received a comment regarding three ICD-9-CM diagnosis codes that are currently assigned to MDC 23: V53.01 (Fitting and adjustment of cerebral ventricular (communicating) shunt); V53.02 (Neuropacemaker (brain) (peripheral nerve) (spinal cord)); and V53.09 (Fitting and adjustment of other devices related to nervous system and special senses). The commenter suggested that we move these three codes from MDC 23 to MDC 1 (Diseases and Disorders of the Nervous System) because these codes are used as the principal diagnosis for admissions involving removal, replacement, and reprogramming of devices such as cerebral ventricular shunts, neurostimulators, intrathecal infusion pumps and thalamic stimulators.

Currently, if these diagnosis codes are reported alone without an O.R. procedure, the case would be assigned to DRG 467 (Other Factors Influencing Health Status). However, if an O.R. procedure is reported with the principal