

Diagnosis code	Title
428.20 .....	Systolic heart failure, not otherwise specified.
428.21 .....	Acute systolic heart failure.
428.22 .....	Chronic systolic heart failure.
428.23 .....	Acute on chronic systolic heart failure.
428.30 .....	Diastolic heart failure, not otherwise specified.
428.31 .....	Acute diastolic heart failure.
428.32 .....	Chronic diastolic heart failure.
428.33 .....	Acute on chronic diastolic heart failure.
428.40 .....	Systolic/diastolic heart failure, not otherwise specified.
428.41 .....	Acute systolic/diastolic heart failure.
428.42 .....	Chronic systolic/diastolic heart failure.
428.43 .....	Acute on chronic systolic/diastolic heart failure.

These heart failure-related diagnosis codes were new codes as of October 1, 2002. They were an expansion of the previous 4-digit codes for heart failure and provided additional detail about the specific type of heart failure. The codes for heart failure that existed prior to October 1, 2002, are classified as secondary diagnoses of major problems within MDC 15 and are currently assigned to DRGs 387 and DRG 389. We stated in the proposed rule that these other heart failure diagnosis codes should be included as principal diagnosis of major problem codes within MDC 15. However, these heart failure codes are currently listed in the secondary, not principal, diagnoses of major problems within MDC 15.

We agree that diagnosis codes 428.20 through 428.43 listed in the chart above should be included as secondary diagnosis of major problem codes within MDC 15, as are the other heart failure codes. Therefore, we proposed to add them to DRG 387 and 389.

*Comment:* Several commenters supported the proposal to add codes 428.20 through 428.43 (codes for heart failure that became effective October 1, 2002, listed in the chart above) to DRGs 387 and 389. The commenters agreed that the heart failure codes created on October 1, 2002, should be assigned to DRGs 387 and 389 in the same fashion as were those heart failure codes created prior to October 1, 2002.

One commenter indicated that we incorrectly described the addition of diagnosis codes 428.20 through 428.43 listed in the chart to the list of "principal" diagnosis of major problem codes. The commenter stated that we should have indicated that these codes would be added to the list of "secondary" diagnoses of major problem codes because this category is

where the other heart failure codes are currently assigned.

*Response:* We agree that the codes should have been described as an addition to the list of secondary diagnoses of major problem codes within DRGs 387 and 389. We have clarified this point in the description above.

*Comment:* One commenter who supported the addition of the heart failure-related diagnosis codes (428.20 through 428.43) to DRGs 387 and 389, asked for clarification of how diagnoses for combined codes that include congestive heart failure will be handled. The commenter mentioned code 402.91 (Hypertensive heart disease with heart failure, unspecified benign or malignant) as an example.

*Response:* We will conduct an additional review of DRGs 387 and 389 to determine if additional codes should be added to the list of secondary diagnoses of major problems for FY 2005. We encourage commenters to send their recommendations to us to assist in this review.

We are adopting our proposal as final, with the clarification that the major problem codes are secondary, not principal, codes. Accordingly, we are adding codes 428.20 through 428.43 listed above to the list of secondary diagnoses of major problem codes within DRGs 387 and 389.

#### 7. MDC 17 (Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms)

High-dose Interleukin-2 (IL-2) Chemotherapy is a hospital inpatient-based regimen requiring administration by experienced oncology professionals. It is used for the treatment of patients with advanced renal cell cancer and advanced melanoma. Unlike traditional cytotoxic chemotherapies that attack cancer cells themselves, Interleukin-2 is designed to enhance the body's defenses by mimicking the way natural IL-2 activates the immune system and stimulates the growth and activity of cancer-killing cells. The Food and Drug Administration (FDA) approved the IL-2 product on the market for use in 1992.

High-dose IL-2 therapy is performed only in very specialized treatment settings, such as an intensive care unit or a bone marrow transplant unit. This therapy requires oversight by oncology health care professionals experienced in the administration and management of patients undergoing this intensive treatment because of the severity of the side effects. Unlike most cancer 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 are admitted for the second cycle of therapy during 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, we have been informed by industry sources that, allegedly due to the level of payment for the DRGs to which these cases are currently assigned, only 100 to 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