

shock as a principal diagnosis. We proposed to establish new DRG 535 (Cardiac Defibrillator Implant With Cardiac Catheterization and With Acute Myocardial Infarction, Heart Failure, or Shock) and new DRG 536 (Cardiac Defibrillator Implant With Cardiac Catheterization and Without Acute Myocardial Infarction, Heart Failure, or Shock). Proposed new DRG 536 would exclude the following principal diagnosis codes from MDC 5 associated with acute myocardial infarction, heart failure, or shock.

- 398.91, Rheumatic heart failure
- 402.01, Malignant hypertensive heart disease with heart failure
- 402.11, Benign hypertensive heart disease with heart failure
- 402.91, Hypertensive heart disease not otherwise specified with heart failure
- 404.01, Malignant hypertensive heart and renal disease with heart failure
- 404.03, Malignant hypertensive heart and renal disease with heart failure and renal failure
- 404.11, Benign hypertensive heart and renal disease with heart failure
- 404.13, Benign hypertensive heart and renal disease with heart failure and renal failure
- 404.91, Hypertensive heart and renal disease not otherwise specified with heart failure
- 404.93, Hypertensive heart and renal disease not otherwise specified with heart failure and renal failure
- 410.01, AMI anterolateral, initial
- 410.11, AMI anterior wall, initial
- 410.21, AMI inferolateral, initial
- 410.31, AMI inferopost, initial
- 410.41, AMI inferior wall, initial
- 410.51, AMI lateral not elsewhere classified, initial
- 410.61, True posterior infarction, initial
- 410.71, Subendocardial infarction, initial
- 410.81, AMI not elsewhere classified, initial
- 410.91, AMI not otherwise specified, initial
- 428.0, Congestive heart failure, not otherwise specified
- 428.1, Left heart failure
- 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, Combined systolic and diastolic heart failure not otherwise specified
- 428.41, Acquired combined systolic and diastolic heart failure
- 428.42, Chronic combined systolic and diastolic heart failure
- 428.43, Acute on chronic combined systolic and diastolic heart failure
- 428.9, Heart failure, not otherwise specified
- 785.50, Shock, not otherwise specified
- 785.51, Cardiogenic shock

(2) Cardiac Resynchronization Therapy (CRT)

Prior to the publication of the proposed rule, we received a comment from a provider who pointed out that we did not include the following combination of codes under the list of procedure combinations that would lead to an assignment of DRG 514 or DRG 515:

- 37.95, Implantation of automatic cardioverter/defibrillator lead(s) only
- 00.54, Implantation or replacement of cardiac resynchronization defibrillator, pulse generator device only [CRT-D]

The commenter pointed out that cases are assigned to DRGs 514 and 515 when a total cardiodefibrillator or CRT-D system is implanted. In addition, cases are assigned to DRGs 514 and 515 when implantation of a variety of combinations of defibrillator leads and device combinations is reported. The commenter indicated that a total defibrillator and CRT-D system may be replaced with a completely new system or all new devices and leads, and added that it is also possible to replace a generator, a lead, or a combination of generators and up to three leads.

When the CRT-D generator (code 00.54) and one of the cardioverter/defibrillator leads are replaced, the case currently is assigned to DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure, or Shock or AICD Lead or Generator Procedure). The commenter recommended that we include the combination of codes 37.95 and 00.54 as a combination that would result in assignment to DRG 514 or DRG 515, as do other combinations of generators and leads. Our medical advisors agree with this recommendation. As discussed previously, we proposed to delete DRG 514 and replace it with proposed new DRGs 535 and 536. Therefore, we proposed to add codes 37.95 and 00.54 to the list of procedure combinations

that would result in assignment to DRG 515 or new proposed DRGs 535 and 536.

Comment: Several commenters supported our proposed revision to DRG 514 so that it would be split based on the presence or absence of a principal diagnosis of acute myocardial infarction, heart failure, or shock.

One commenter pointed out a typographical error in the proposed rule in the code number cited for the procedure, Implantation of automatic cardioverter/defibrillator lead(s) only. The code number should have been 37.95 instead of 39.75.

Response: We appreciate the support for our proposed revision of DRG 514. We have corrected the code number for Implantation of automatic cardioverter/defibrillator lead(s) only to 37.95 in the description of this issue above.

Comment: Several commenters supported the addition of codes 37.95 and 00.54 to the list of procedure combinations that would lead to an assignment of DRG 515 and new DRGs 535 and 536. However, one commenter suggested that, in addition to this combination, codes 37.97 (Replacement of automatic cardioverter/defibrillator lead(s) only and 00.54 also should be added to the procedure combination list under DRG 515 and new DRGs 535 and 536. The commenter pointed out that both procedures would involve the insertion of a pulse generator and a lead so that resources required are equivalent to those for a total system implant.

Response: We agree with the commenter that the combination of codes 37.97 and 00.54 also would involve the implantation of a pulse generator and a lead. Therefore, in this final rule, we are adding the combination of procedure codes 37.97 and 00.54 to the list of procedure combinations that will lead to assignment to DRG 515 and new DRGs 535 and 536.

Comment: One commenter recommended that CMS also consider modifying DRGs 115 and 116 to recognize more combination groups of devices and leads. Specifically, the commenter recommended adding the following combination of codes to the list of procedure combinations under DRGs 115 and 116:

- 00.53, Implantation or replacement of CRT-P pulse generator only
- 37.74, Implantation or replacement of epicardial pacemaker lead.

Response: DRGs 115 and 116 have one of the most complex assignment structures of all the DRGs. The DRG logic for DRGs 115 and 116 involves three separate combinations of code groups that can possibly lead to these DRG assignments. Before making a