KEY CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) FINAL RULE FOR FY 2016

This memo highlights the key payment policy changes described in the rule, which can be found here:

EXECUTIVE SUMMARY

On July 31, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that updates fiscal year (FY) 2016 Medicare payment policies and rates for inpatient stays at general acute care and long-term care hospitals (LTCHs), and implements statutory provisions from the Affordable Care Act (ACA), Pathway for Sustainable Growth Reform (SGR) Act of 2013, the Protecting Access to Medicare Act of 2014, and other legislation.

How to Comment

Please note that CMS will accept comments from the public all payment policies discussed in the final rule. The comment deadline is 5 p.m. EST on September 29, 2015. CMS encourages comments to be submitted electronically at:
http://www.regulations.gov/

I. TECHNICAL CHANGES

- Final Changes in the Inpatient Hospital Update for FY 2016
  - Payment for hospitals will be directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users.

II. FINAL RULE POLICIES THAT ARE NOT TECHNOLOGY SPECIFIC

- ICD-10 Conversion
  - Implementation is still on-track for October 2015.
  - Section “X” is a new subcategory within the ICD-10-PCS that will capture new medical services and technologies that are not usually captured by coders or are not specifically identified in the current ICD-10-PCS structure. The Section “X” codes implemented in FY 2016 will be used to identify NTAPs approved for payment starting October 1, 2015.

- Two-Midnight Rule
  - CMS addressed changes to the two-midnight rule in the calendar year (CY) 2016 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System
proposed rule, which was released on July 1, 2015. In this ruling, CMS proposed that in certain instances, an inpatient admission of fewer than two midnights may be acceptable to justify as a short-stay inpatient admission. CMS will respond to public comments on the two-midnight rule in the CY 2016 OPPS/ASC final rule with comment period (which is expected to be issued in November 2015).

- Disproportionate Share Hospital (DSH) Payment
  - CMS projects that Medicare DSH payments and additional payments for uncompensated care made for FY 2016 would reduce payments overall by approximately 1% compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2015.

- Proposals to Improve Quality of Care during Hospital Inpatient Stays
  - CMS has finalized measures and financial incentives in programs such as the Hospital Acquired Condition (HAC) Reduction program, Hospital Value-Based Purchasing (VBP) program, and Hospital Inpatient Quality Reporting (IQR) Program.

III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

- New Technology Add-On Payment (NTAP) Applications
  - Three out of a total of six (50%) of NTAP applications were approved for FY 2016:
    - BLINCYTO™ (Blinatumomab, Amgen, Inc.)
    - LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty Catheter (CR BARD Inc.)
    - IN PACT™ Admiral Paclitaxel Coated Percutaneous Transluminal Angioplasty Balloon (Medtronic)

- Medicare Severity Diagnosis Related Groups (MS-DRGs) Classifications: Payment Updates
  - CMS approved the following requests made to establish new MS-DRGs or reassign procedures to existing (higher paying) MS-DRGs:
    - To remove percutaneous intracardiac procedures from MS-DRGs 246-251 into their own MS-DRGs:
      - MS-DRG 273: Percutaneous Intracardiac Procedures with MCC
      - MS-DRG 274: Percutaneous Intracardiac Procedures without MCC
    - To delete MS-DRGs 237 and 238 and creating five new MS-DRGs that would: (1) contain the more complex, more invasive aortic and heart assist procedures currently assigned to MS-DRGs 237 and 238 (MS-DRGs 268-269) and (2) contain cardiovascular procedures that were designated as the less complex, less invasive procedures (MS-DRGs 270-272):
      - MS-DRG 268: Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
      - MS-DRG 269: Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
      - MS-DRG 270: Other Major Cardiovascular Procedures with MCC
      - MS-DRG 271: Other Major Cardiovascular Procedures with CC
      - MS-DRG 272: Other Major Cardiovascular Procedures without CC/MCC
    - To update procedure code assignments and DRG titles to accurately replicate and better reflect the ICD-10 MS-DRGs Version 33 assignments.
KEY CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) FINAL RULE FOR FY 2016

SUMMARY OF PAYMENT AND POLICY CHANGES

I. TECHNICAL CHANGES

❖ Changes in the Inpatient Hospital Update for FY 2016

In FY 2015, CMS implemented major changes that affected hospital-specific DRG payment rates. This year, payment for hospitals will continue to be directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users.

In FY 2016, there are four possible scenarios for payment:

1. For hospitals that do not submit quality data and are not meaningful EHR users, the applicable percentage adjustment is -0.1% to the operating standardized amount.
2. For hospitals that submit quality data but are not meaningful EHR users, the applicable percentage adjustment is 0.5% to the operating standardized amount.
3. For hospitals that do not submit quality data but are meaningful EHR users, the applicable percentage adjustment is 1.1% to the operating standardized amount.
4. For hospitals that submit quality data and are meaningful EHR users, the applicable percentage adjustment is 1.7% to the operating standardized amount.

Combined with the FY 2016 documentation and coding recoupment adjustment of -0.8% on the national standardized amount under the American Taxpayer Relief Act of 2012, hospitals that submit quality data and are meaningful EHR users will experience a 0.9% increase in payments in FY 2016 relative to FY 2015.

II. PROPOSED RULE POLICIES THAT ARE NOT TECHNOLOGY SPECIFIC

❖ ICD-10 Conversion

ICD-10-CM/PCS implementation is planned for October 1, 2015. For FY 2016, CMS has finalized the ICD-10 MS-DRGs Version 33 as the replacement logic for the ICD-9-CM MS-DRGs Version 32. CMS intends for the transition from an ICD-10 based MS-DRG system to mirror the MS-DRG assignments under ICD-9.

❖ Section “X” Codes for New Technologies and Inpatient Services

Section “X” is a new subcategory within the ICD-10-PCS that will capture new medical services and technologies that are not usually captured by coders or are not specifically identified in the current ICD-10-PCS structure. Examples of these types of services and technologies include drugs, biologicals and newer medical devices being tested in clinical trials. This new set of codes was requested to identify and report technologies and inpatient services for purposes of approving and subsequently paying for eligible new technology add-on payment (NTAP) submissions as well as analyzing and tracking the use of these technologies and inpatient services.
Section “X” Codes Timelines:

- The new Section “X” codes will be implemented October 1, 2015 and will be used to identify NTAPs approved for payment starting October 1, 2015
  - A list of the Section “X” codes that will be implemented in FY 2016 is published by CMS on the following webpage:
- Any updated to ICD-10-CM/PCS, including updates to Section “X” codes, will be presented at future ICD-10 Coordination and Maintenance Committee meetings for public comments.

Two-Midnight Rule

CMS addressed changes to the two-midnight rule in the CY 2016 OPPS/ASC proposed rule, which was released July 1, 2015. In this rule, CMS proposed changes for stays expected to last fewer than two midnights. For patient stays in which a physician expects to need fewer than two midnights of hospital care, and the procedure is not on the inpatient-only list or otherwise listed as a national exception, an inpatient admission would be payable under Medicare Part A on a case-by-case basis per the judgment of the admitting physician. The following documentation would be needed to support the medical necessity of such an inpatient admission:

- The severity of the signs and symptoms exhibited by the patient
- The medical predictability of something adverse happening to the patient
- The need for diagnostic studies that are more appropriately outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more)

Responsibility for enforcement and education of the two-midnight rule will fall to quality improvement organizations (QIO) instead of recovery auditors. CMS will respond to public comment received on the two-midnight rule in the CY 2016 OPPS/ASC final rule with comment period (which is expected to be issued in November 2015). For comments to be considered, they must be submitted to CMS no later than 5 p.m. EST on August 31, 2015.

Disproportionate Share Hospital (DSH) Payment

Disproportionate Share Hospitals (DSHs) serve a high number of low-income patients and as such, qualify for additional Medicare payments.

- Payment Methodology Changes Due to Affordable Care Act

CMS continues to implement the changes to DSH hospital payment as mandated by the Affordable Care Act (ACA). Hospitals that receive Medicare DSH payments receive 25% of the amount they previously would have received prior to ACA. The remainder, equal to 75% of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments.
For FY 2016, hospitals will still receive the initial 25% payment. However, CMS has finalized their proposal to provide approximately 47.76% (63.69% of the remaining 75%) of the estimated Medicare DSH payments prior to the ACA as additional payment to hospitals for their relative share of the total amount of uncompensated care. This policy will cut overall DSH payments by $1.3 billion in FY 2016.

CMS projects that Medicare DSH payments and additional payments for uncompensated care made for FY 2016 will reduce payments overall by approximately 1% as compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2015.

❖ Proposals to Improve Quality of Care during Hospital Inpatient Stays

The final rule will update the measures and financial incentives in the Hospital Acquired Condition Reduction, Hospital Value-Based Purchasing and Hospital Readmissions Reduction programs, as well as the Hospital Inpatient Quality Reporting (IQR) Program and Electronic Health Records Incentive Program. It also addresses the Long-Term Care Hospital (LTCH) Quality Reporting Program and the Bundled Payments for Care Improvement (BPCI) Initiative. The information below summarizes the major quality-related provisions of the final rule.

❖ Hospital-Acquired Condition (HAC) Reduction Program

Section 3008 of the Affordable Care Act requires CMS to establish a financial incentive program for IPPS hospitals to improve patient safety by applying a 1% payment reduction to hospitals that rank in the lowest performing quartile of all subsection (d) hospitals1 relative to a national average of HACs acquired during an applicable hospital stay. HACs are conditions that patients did not have upon admission to a hospital, but that developed during the hospital stay.

Under the scoring methodology to calculate a Total HAC Score for each hospital, hospitals are given a score for each measure within two domains:

Domain 1: Comprises the Patient Safety Indicator (PSI) 90 measure; an administrative claim based measure developed by the Agency for Healthcare Research and Quality (AHRQ). PSI-90 is a composite of 8 measures: 1) PSI-03 Pressure Ulcer; 2) PSI-06 Iatrogenic Pneumothorax; 3) PSI-07 Central Venous Catheter-related bloodstream infections; 4) PSI-08 Postoperative Hip fracture; 5) PSI-12 Postoperative Pulmonary Embolism or Deep Venous Thrombosis; 6) PSI-13 Postoperative Sepsis; 7) PSI-14 Postoperative Wound Dehiscence; and 8) PSI-15 Accidental Puncture or Laceration. CMS is not proposing to add or remove any measures for FY 2016.

Domain 2: Measures include Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI) and Colon and Abdominal Hysterectomy Surgical Site Infection (SSI). CMS is not proposing to add or remove any measures for FY 2016. In the FY 2015 IPPS/LTCH PPS final rule, CMS finalized the inclusion of two new measures for use in the FY 2017 program: Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia, and Clostridium difficile (CDI).

1 Subsection (d) hospitals are hospitals that are paid under the hospital IPPS and are located in one of the 50 states or the District of Columbia.
A score is calculated for each domain and the two domains are weighted to determine a Total HAC Score. For FY 2016, the weight of Domain 1 is 25% and the weight of Domain 2 is 75%. For FY 2017, CMS has finalized their proposal to adjust the weight of Domain 1 to 15% and the weight of Domain 2 to 85%. Hospitals with a Total HAC Score in the lowest performing quartile are subject to a 1% payment penalty.

For FY 2018, CMS has finalized their proposal to expand the patient population covered by the CLABSI and CAUTI measures to include data from patients in select nonintensive care unit sites within a hospital (i.e., pediatric and adult medical ward, surgical ward, and medical/surgical ward locations).

Additionally, CMS has finalized an extraordinary circumstance exception policy for the HAC Reduction Program beginning in FY 2016 and for subsequent years.

- **Hospital Readmissions Reduction Program**

The Hospital Readmissions Reduction program began on October 1, 2012 and adjusts payments based on each hospital’s ratio of actual versus expected readmissions.

CMS has finalized their proposal to refine the National Quality Forum (NQF) endorsed CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure, beginning with the FY 2017 payment determination. This measure currently only captures hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. This proposal would expand the measure cohort to include hospitalizations for patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and for patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as POA, but does not include patients with a principal discharge diagnosis of respiratory failure or patients with a principal discharge of diagnosis of sepsis if they are coded as having severe sepsis.

In parallel with the HAC Reduction Program, CMS will adopt an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016.

- **Hospital Inpatient Quality Reporting (IQR) Program and the EHR Incentive Program**

The Hospital IQR Program grew out of the Hospital Quality Initiative developed by CMS in consultation with hospital groups. Since the implementation of this financial penalty, hospital participation has increased to well over 99% of Medicare-participating hospitals that are paid under the IPPS.

Measures reported under the Hospital IQR Program are published on the Hospital Compare Web site (http://www.medicare.gov/hospitalcompare/search.html), and may later be adopted for use in the Hospital VBP Program.

For the FY 2018 payment determination and subsequent years, CMS has finalized their proposal to remove the chart-abstracted version of seven measures (STK-01: Venous Thromboembolism (VTE) Prophylaxis; STK-06: Discharged on Statin Medication; STK-08: Stroke Education; VTE-1: Venous Thromboembolism Prophylaxis; VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis; VTE-
3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy; AMI-7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival) but retain STK-06, STK-08, VTE-1, VTE-2, VTE-3, AMI-7a as electronic quality measures.

In addition, CMS has finalized their decision to remove two measures (IMM-1: Pneumococcal Immunization and SCIP-Inf-4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose) for the FY 2018 payment determination and subsequent years.

In parallel, CMS has finalized the adoption of four new measures to the Hospital IQR Program for the FY 2018 payment determination and subsequent years, which include new claims-based measures and one new structural measure (Hospital Survey on Patient Safety Culture; Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA; Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction; and Excess Days in Acute Care after Hospitalization for Heart Failure). CMS has finalized the adoption of three new claims-based measures in the Hospital IQR Program for FY 2019 payment determination and subsequent years (Kidney/UTI Clinical Episode-Based Payment Measure; Cellulitis Clinical Episode-Based Payment Measure; Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure).

For the FY 2018 payment determination and subsequent years, hospitals are required to submit 16 measures electronically for the Hospital IQR Program to support alignment with requirements under the Medicare EHR Incentive Program. To decrease burden on hospitals, CMS has finalized their proposal that hospitals be required to submit population and sample size data only for measures that a hospital submits as chart-abstracted measures.

- **Value Based Purchasing Program (VBP)**

The final rule outlines an expansion of the Value Based Purchasing Program (VPB) program, which funds incentive payments to high performing hospitals through a coefficient reduction in base operating DRG payments for all hospital discharges.

- In FY 2014, the coefficient for the reduction was set at 1.25%
- In FY 2015, the coefficient for the reduction was set at 1.5%;
- **In FY 2016, the coefficient will be 1.75%**
- In FY 2017 and beyond, the coefficient will be 2%

In other words, all the base payment reductions will be reallocated within the IPPS system in order to fund an equivalent amount of value-based incentive payments, and the size of the reallocations will increase for the next several years before maxing out in FY 2017.

CMS has finalized their proposal to remove two measures from the FY 2018 performance measurement set (IMM-2 Influenza Immunization and AMI-7a Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival).

CMS has finalized the addition of two measures to the VBP program. They plan to include the 3-Item Care Transition Measure (CTM-3) beginning in FY 2018 and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization Measure in FY 2021.
• **Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)**

Section 3004(a) of the Affordable Care Act established the LTCHQR Program. Beginning in FY 2014, the applicable annual increase factor for any LTCH that did not submit the required quality data to CMS was reduced by two percentage points.

For the FY 2018 payment determination and subsequent years, CMS finalized the addition of four quality measures (Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function; Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure).

CMS has finalized their proposal to publicly report LTCH quality data beginning in Fall 2016, on a website such as Hospital Compare, after a 30 day preview period. They are proposing to initially publicly report quality data on four quality measures (NHSN CAUTI Outcome Measure; NHSN CLABSI Outcome Measure; Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay); and All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs)

Additionally, CMS is extending their quarterly data submission deadlines from 45 days to 135 days beyond the end of each calendar year quarter beginning with the fourth quarter of 2015 to align with other quality reporting program data submission timelines.

• **Bundled Payments for Care Improvement (BPCI) Initiative**

Medicare traditionally makes separate payments to providers (e.g., physicians and hospitals) for services provided to beneficiaries during a single illness or course of treatment. CMS developed the BPCI initiative to evaluate whether bundled payments result in higher quality and more coordinated care at a lower cost to Medicare. Organizations that participate in the BPCI initiative receive a discounted bundled payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare fee-for-service (FFS).

In the FY 2016 IPPS proposed rule, CMS is requested comments from the public on how the expansion of the BPCI program could encourage high-quality, high-value care at an appropriate payment rate for providers to encourage coordination of care and open access to care for Medicare beneficiaries. In the FY 2016 IPPS final rule, CMS acknowledged it had received over 75 public comments considering the potential future expansion of the BPCI (including evaluation of BPCI models, further testing of the BPCI initiative, target pricing methodologies, etc.) which CMS will take into consideration if the BPCI is expanded in future rulemaking.
III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

❖ New Technology Add-On Payment (NTAP) Applications

For FY 2016, CMS received nine New Technology Add-On Payment (NTAP) applications. Of the nine NTAP applications reviewed in the proposed rule, two applicants were withdrawn during the comment period (Angel Medical Guardian® Ischemia Monitoring Device and Ceftazidime Avibactam), one applicant did not receive FDA approval by July 1, 2015, and was thus not eligible for consideration under the NTAP criteria (Idarucizumab).

The six remaining applications reviewed by CMS are as follows:

1) Blinatumomab (BLINCYTO™) (Amgen, Inc.)
2) DIAMONDBACK® 360 Coronary Orbital Atherectomy System (Cardiovascular Systems, Inc.)
3) CRESEMA® (Isavuconazonium) (Astellas Pharma US, Inc.)
4) LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (CR Bard Inc. and Medtronic)
5) VERASENSE™ Knee Balancer System (VKS) (OrthoSensor)
6) WATCHMAN® Left Atrial Appendage Closure Technology (Boston Scientific Corporation)

In the final rule, CMS considered public comments and expressed favor or concern on whether the remaining applicants met the eligibility criteria for NTAP. The criteria for evaluating whether a new technology is substantially similar to an existing technology is based on the following: (1) whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome (newness criterion); (2) whether a product is assigned to the same or different MS-DRG (coding criterion); and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population (clinical improvement criterion).

If a technology meets all three criteria above, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

Table I: FY 2016 NTAP Applications and CMS’ Response

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<thead>
<tr>
<th>Technology (Manufacturer)</th>
<th>Description</th>
<th>CMS’ Response</th>
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<tr>
<td>Angel Medical Guardian® Ischemia Monitoring Device (Angel Medical Systems, Inc.)</td>
<td>The Guardian® implantable ischemia detection system provides early detection and patient alerts for ischemic and other cardiac events experienced by ambulatory patients. The implantable monitoring device (IMD) monitors the patient’s current cardiac data and compares these data to the patient’s historical baseline. Upon detection of a cardiac anomaly, the IMD signals an alert, which prompt the patient to initiate emergency and/or preventative actions.</td>
<td>Withdrawn.</td>
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</tbody>
</table>
### Technology (Manufacturer) | Description | CMS’ Response
--- | --- | ---
Blinatumomab (BLINCYTO™) (Amgen, Inc.) | Blinatumomab (BLINCYTO™) is a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. The BLINCYTO™ technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. BLINCYTO™ is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. | Approved. CMS has determined the BLINCYTO technology meets all of the approval criteria for NTAP for FY 2016. Cases involving BLINCYTO technology that are eligible for NTAP will be identified by ICD-10-PCS procedure codes XW03351 or XW04351. NTAP payment amount for a case involving the use of BLINCYTO is $27,017.85 for FY 2016.

Ceftazidime Avibactam (AVYCAZ) (Cerexa, Inc.) | AVYCAZ is used for the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis and complicated Intra-abdominal Infections (cIAIs), for which there are limited or no available treatment options. AVYCAZ is administered as a treatment to patients 18 years of age, or older, who have been diagnosed with a cUTI and/or a cIAI. | Withdrawn.

DIAMONDBACK® 360 Coronary Orbital Atherectomy System (Cardiovascular Systems, Inc.) | The DIAMONDBACK® Coronary OAS is a percutaneous orbital atherectomy system used to facilitate stent delivery in patients who have been diagnosed with coronary artery disease and severely calcified coronary artery lesions. The system uses an electrically driven, diamond-coated crown to reduce calcified lesions in coronary blood vessels. | Not approved. CMS has determined the the DIAMONDBACK Coronary OAS does not meet the newness criteria for NTAP. Additionally, CMS does not believe that the device represents a substantial clinical improvement over existing currently available treatment options. Therefore, it did not meet the criterion to qualify for NTAP under the IPPS in FY 2016.

CRESEMBA® (Isavuconazonium) (Astellas Pharma US, Inc.) | CRESEMBA® is an intravenous and oral broad-spectrum antifungal used for the treatment of adults who have severe invasive and life-threatening fungal infections, including invasive aspergillosis and mucormycosis (zygomycosis). | Not approved. CMS has determined that CRESEMBA does not meet the newness criteria for NTAP. Additionally, CMS does not believe that the technology represents a substantial clinical improvement over existing technologies. Therefore, it did not meet the criterion to qualify for NTAP under the IPPS in FY 2016.

Idarucizumab (Boehringer Ingelheim Pharmaceuticals, Inc.) | Idarucizumab, a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran). Dabigatran is Not eligible. Applicant did not receive FDA approval by July 1, 2015, and was thus not eligible for NTAP.
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<thead>
<tr>
<th>Technology (Manufacturer)</th>
<th>Description</th>
<th>CMS’ Response</th>
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</thead>
<tbody>
<tr>
<td><strong>LUTONIX® Drug Coated Balloon (DCB)</strong></td>
<td>Both are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). The applicants stated that the drug-coated balloon catheter is a device-drug combination product comprised of a device component (an over-the-wire balloon catheter) and a drug component (a paclitaxel-urea coating in the case of IN.PACT™ and a paclitaxel- sorbitol for LUTONIX™ Admiral™) on the balloon, intended for the treatment of patients with PAD, specifically superficial femoral artery (SFA) and popliteal artery disease.</td>
<td>Approved. CMS has determined the LUTONIX and IN.PACT technologies meet all of the approval criteria for NTAP for FY 2016. NTAP payment amount for a case involving the use of either the LUTONIX or IN.PACT is $1,035.72 for FY 2016. A complete list of ICD-10-PCS procedure codes for LUTONIX and IN.PACT can be found in the FY 2016 IPPS Final Rule.</td>
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<td><strong>VERASENSE™ Knee Balancer System (VKS)</strong> (OrthoSensor)</td>
<td>The VKS is a sterile, single patient use device to intraoperatively provide a means to dynamically balance the patient’s knee during total knee arthroplasty (TKA) surgery.</td>
<td>Not approved. CMS has determined that the VERASENSE Knee Balancer System does not represent a substantial clinical improvement over existing technologies. Therefore, it did not meet the criterion to qualify for NTAP under the IPPS in FY 2016.</td>
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<td><strong>WATCHMAN® Left Atrial Appendage Closure Technology (Boston Scientific Corporation)</strong></td>
<td>The WATCHMAN® Left Atrial Appendage Closure Device is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy in those patients diagnosed with nonvalvular atrial fibrillation (AF) and who are eligible for Warfarin therapy.</td>
<td>Not approved. CMS has determined that the WATCHMAN Left Atrial Appendage Closure Technology does not represent a substantial clinical improvement over existing technologies. Therefore, it did not meet the criterion to qualify for NTAP under the IPPS in FY 2016.</td>
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</table>
**MS-DRG Classifications: Final Changes**

### Table II: MS-DRG Updates

<table>
<thead>
<tr>
<th>Request</th>
<th>CMS Response and Rationale</th>
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<tbody>
<tr>
<td><strong>MDC 1 (Diseases and Disorders of the Nervous System)</strong></td>
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<td>CMS received a request to change the MS-DRG assignment for the following ICD-9-CM procedure codes representing endovascular embolization procedures and additional intracranial procedures:</td>
<td>CMS is maintaining the current MS-DRG assignments for endovascular intracranial embolization and other endovascular procedures.</td>
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<td>• 00.62</td>
<td>CMS noted that while there are some procedures within MS-DRGs 023-027 which have higher average costs, it is expected that within a given MS-DRG there would be procedures with higher average costs and procedures with lower average costs.</td>
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<td>• 39.72</td>
<td>CMS, and their clinical advisors, believes that the procedures within these DRGs are clinically similar given their surgical techniques and intended patient population.</td>
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<td>• 39.74</td>
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<td>• 39.76</td>
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<td>• 39.79</td>
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<td><strong>MDC 5 (Diseases and Disorders of the Circulatory System)</strong></td>
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<td>A request was submitted to remove cardiac ablation and other percutaneous intracardiac procedures from DRGs 246-251, which include the following ICD-9-CM procedure codes:</td>
<td>CMS finalized their proposal to remove percutaneous intracardiac procedures from DRGs 246-251 into their own MS-DRGs:</td>
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<td>• 35.52</td>
<td>• MS-DRG 273: Percutaneous Intracardiac Procedures with MCC</td>
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<tr>
<td>• 35.96</td>
<td>• MS-DRG 274: Percutaneous Intracardiac Procedures without MCC</td>
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<td>• 35.97</td>
<td>After reviewing claims data from the December 2014 update of the FY 2014 MedPAR file, CMS determined that the results of the data analysis supported subdividing MS-DRGs based on the application of the criteria established in the FY 2008 IPPS final rule (72 FR 47169). Additionally, CMS’ clinical advisors believed the differentiation would improve the clinical homogeneity of the MS-DRGs by separating percutaneous intracardiac procedures from percutaneous intracoronary procedures, and also better reflect resource cost of specialized equipment used to perform more complex structures of electrical conduction systems during cardiac ablation procedures.</td>
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<td>• 37.90</td>
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<td>In the FY 2015 IPPS proposed rule-making cycle, a request was submitted to add severity levels to DRGs 245-251.</td>
<td>CMS is maintaining the existing severity level splits for DRGs 245-251. CMS determined that the comment was outside of the scope of the FY2015 IPPS proposed rule, but would consider this comment during future rulemaking, which they did in the FY 2016 IPPS proposed rule.</td>
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<td>CMS received a request to either establish a new family of MS-DRGs for drug-eluting stents used in the peripheral (noncoronary) vasculature or to assign all Zilver® PTX® cases, identified with ICD-9-CM 00.60, to MS-DRG 252 even if there is no MCC.</td>
<td>CMS is maintaining the current MS-DRG assignments for these cases in MS-DRGs 252, 253, and 254.</td>
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<td>CMS did not believe that the small number of Zilver cases (n=601) justified the creation of a new MS-DRG. Additionally, FY 2014 MedPAR claims data did</td>
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### Key Proposed Changes to IPPS for FY 2016

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<thead>
<tr>
<th>Request</th>
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<tbody>
<tr>
<td>CMS received a request to reassign procedure code 39.78 to the highest severity level in MS-DRGs 237 and 238, including in instances when there is not an MCC present, or to create a new MS-DRG that would contain all endovascular aneurysm repair procedures.</td>
<td>not support assigning all Zilver procedures to the highest severity DRG.</td>
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</table>
| CMS deleted MS-DRGs 237 and 238 and created two new MS-DRGs that would contain the more complex, more invasive aortic and heart assist procedures currently assigned to MS-DRGs 237 and 238: | • MS-DRG 268: Aortic and Heart Assist Procedures Except Pulsion Balloon with MCC \  
• MS-DRG 269: Aortic and Heart Assist Procedures Except Pulsion Balloon without MCC \  
CMS is also creating three new MS-DRGs for cardiovascular procedures that were designated as the less complex, less invasive procedures: |                                                             |
| • MS-DRG 270: Other Major Cardiovascular Procedures with MCC \  
• MS-DRG 271: Other Major Cardiovascular Procedures with CC \  
• MS-DRG 272: Other Major Cardiovascular Procedures without CC/MCC | After reviewing claims data from the December 2014 update of the FY 2014 MedPAR file, CMS determined that the results of the data analysis supported subdividing MS-DRGs based on the application of the criteria established in the FY 2008 IPPS final rule (72 FR 47169). Additionally, the new DRGs will allow for more clinical and resource appropriate groupings of more or less complex and invasive cardiovascular procedures. |

#### MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

| CMS received two comments that the logic for ICD-10 MS-DRGs Version 32 does not work the same as it does for the ICD-9-CM based MS-DRGs Version 32 for joint revisions. | CMS agreed to add the appropriate joint revision code combinations to MS-DRGs 466, 467, as well as MS-DRGs 628, 629, and 630 for Version 33 MS-DRG, as both sets of MR-DRGs contain the same joint revision codes. |
| CMS received a request to revise the titles of MS-DRGs 456, 457, and 458 so that they more closely correspond to the terminology used to describe the ICD-10-PCS procedure codes. | CMS revised following titles to MS-DRGs 456, 457, and 458 for the FY 2016 ICD-10 MS-DRGs Version 33 as follows: \  
• MS-DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with MCC) \  
• MS-DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with CC) \  
• MS-DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion without CC/MCC) |   
CMS agreed with the requestor that revising the titles of these MS-DRGs would more appropriately identify the procedures classified under these groupings. |
## Key Proposed Changes to IPPS for FY 2016

### MDC 14 (Pregnancy, Childbirth and the Puerperium)

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<td>CMS received a request to modify the logic for ICD-10 MS-DRG 775 so that the procedure code for the induction of labor with a cervical ripening gel (3E0P7GC) would not group to the incorrect MS-DRG when a normal delivery has occurred.</td>
<td>CMS determined to make ICD-10-PCS procedure code 3E0P7GC a non-O.R. code so that cases reporting this procedure code will group to the appropriate MS-DRG assignment when a normal delivery has occurred. CMS has also made the following procedure codes non-O.R. codes: 3E0P76Z, 3E0P77Z, 3E0P75F, 3E0P83Z, 3E0P86Z, 3E0P87Z, 3E0P86G and 3E0P88F. MS-DRG 775 is for vaginal delivery procedures with complicating diagnosis. Due to the fact that the above listed procedures may be performed without complicating circumstances, CMS agreed that these modifications to the MS-DRG assignment should be made.</td>
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### MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)

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<td>CMS received a request that CMS change the MS-DRG assignment for CroFab antivenom cases from MS-DRG 917 and 918.</td>
<td>CMS is maintaining the existing MS-DRG assignment for CroFab antivenom drugs for snake bites. After reviewing claims data from the December 2014 update of the FY 2014 MedPAR file, CMS determined that the small number of cases (n=19) does not provide justification for creating a new MS-DRG. Additionally, CMS clinical advisors believe that these procedures are clinically similar to other poisoning cases currently assigned to MS-DRGs 917-918.</td>
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### MDC 22 (Burns)

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<td>CMS received a request to add an additional severity level to MS-DRG 927 as there was concern about payment for severe burn cases that used dermal regenerative grafts, captured by procedure code 86.67.</td>
<td>CMS is maintaining the current MS-DRG 927 structure without additional severity levels. After reviewing claims data from the December 2014 update of the FY 2014 MedPAR file, CMS determined that the results of the data analysis did not support the addition of severity levels for MS-DRG 927 based on the application of the criteria established in the FY 2008 IPPS final rule (72 FR 47169). Specifically, the requested severity level did not meet the criterion that there are at least 500 cases in the CC or MCC subgroup. Additionally, clinical advisors agreed that dermal regenerative graft cases are clinically similar to other cases within MS-DRG 927.</td>
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