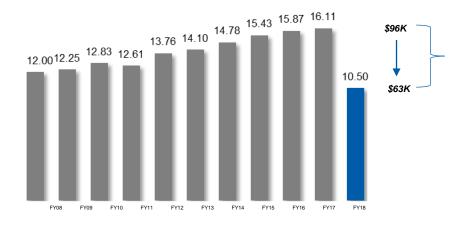
IPPS PROPOSED RULE DISCUSSION MS-DRG 215 (OTHER HEART ASSIST SYSTEM IMPLANT)

- DRG 215 comprises critically ill cardiovascular patients who require the implantation of a heart pump in the operating room or catheterization lab after a heart attack or decompensating heart failure
- Proposed decrease of 35% for DRG 215 is the largest reduction in the Proposed Rule (other DRGs in the same category ranging from -7% to 3.5%)
- Dramatic decrease is not the result of a new policy proposal, and is contrary to the goal of ICD-10 implementation to accurately replicate ICD-9 DRG assignments and avoid unintended payment redistributions
- As a result of ICD-10 coding changes, some cases that were assigned to DRG 215 in FY 2016 are now reassigned which has significantly affected the type of cases in DRG 215 and dramatically reduced the relative weight of the DRG
- Recent AHA coding changes and new FDA indications not accounted for in the proposed rule will result in higher acuity and cost patients being assigned to DRG 215 in FY 2018
- In FY 2018 Final Rule CMS should provide a transition period for DRG 215, and other DRGs that have a decrease greater than 10% due to shift to ICD-10

MEDICARE MS-DRG 215 WEIGHTS 10 YR TREND



Significant decrease impacted by:

- 1. 1st yr. ICD10 coding & related DRG 215 mapping
- 2. DRG volume extremely low, <300 cases /yr
- 3. A few surgical LVAD moves, high cost
- 4. A few new PVAD related claims included
- 5. Prior to new AHA Coding Clinic guidance, new FDA Indications & majority were new hospitals

IPPS MS-DRG PROPOSED RULE - MOST SIGNIFICANT REDUCTION

FY 2018 PROPOSED RULE, TABLE 5.—LIST OF MEDICARE SEVERITY DIAGNOSIS-RELATED GROUPS (MS-DRGS)			
MS-DRG	MS-DRG Title	FY 2018 Proposed Weights compared to FY 2017 Weights (% Change)	
215	OTHER HEART ASSIST SYSTEM IMPLANT	-35%	
780	FALSE LABOR	-28%	
332	RECTAL RESECTION W MCC	-24%	
517	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC/MCC	-24%	
333	RECTAL RESECTION W CC	-21%	
454	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W CC	-21%	
734	PELVIC EVISCERATION, RAD HYSTERECTOMY & RAD VULVECTOMY W CC/MCC	-20%	
770	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY		
455	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W/O CC/MCC	-20% -20%	
768	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C		
334	RECTAL RESECTION W/O CC/MCC	-19% -19%	
423	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES W MCC		
867	OTHER INFECTIOUS & PARASITIC DISEASES DIAGNOSES W MCC		
327	STOMACH, ESOPHAGEAL & DUODENAL PROC W CC		
830	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS W OTHER PROCEDURE W/O CC/MCC	-15%	
326	STOMACH, ESOPHAGEAL & DUODENAL PROC W MCC	-15%	
951	OTHER FACTORS INFLUENCING HEALTH STATUS	-15%	
712	TESTES PROCEDURES W/O CC/MCC	-14%	
769	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	-14%	
290	ACUTE & SUBACUTE ENDOCARDITIS W/O CC/MCC	-13%	
344	MINOR SMALL & LARGE BOWEL PROCEDURES W MCC	-13%	
981	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS W MCC	-12%	
777	ECTOPIC PREGNANCY	-12%	
148	EAR, NOSE, MOUTH & THROAT MALIGNANCY W/O CC/MCC	-12%	
713	TRANSURETHRAL PROSTATECTOMY W CC/MCC	-11%	
346	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC/MCC	-11%	
453	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W MCC	-11%	

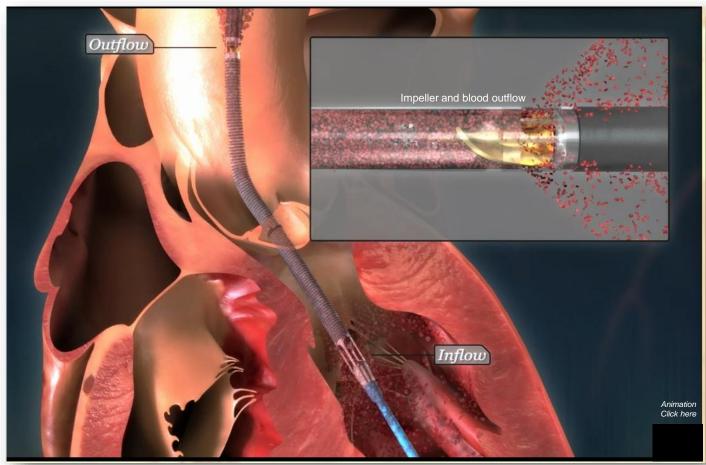
>10% Reduction N=27

IMPELLA® HEART PUMP: HOW IT WORKS



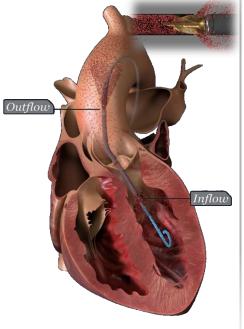






CLINICAL VALUE OF IMPELLA – HEART RECOVERY

Unloads the Heart



End Organ Perfusion



Left & Right Support



Ambulation







2015 - 2016



American CMS 2016 - 2017



2018 (proposed)

NEW FDA PMA APPROVALS

New Impella Technologies and New First of a Kind Clinical indications

NEW AHA CODING GUIDANCE

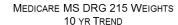
New AHA Coding Clinic Guidance to Address FDA Indications, Multiple Products

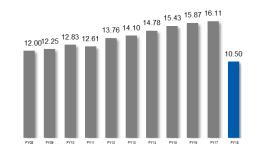
IPPS PAYMENT **PROPOSAL**

Proposed IPPS Rule Base Rate Tables

- FDA PMA Indication for AMI Cardiogenic Shock, Heart Recovery, 4-6 days
- FDA PMA Indication for PCI in high risk patients, 6 hours - 2days
- FDA HDE Indication for right side heart failure, use as bi-ventricular support with left side. PMA expected 2017.
- Impella (PVAD) product line expanded to Impella 2.5, CP, 5.0, LD, RP with unique FDA labeling for each

- Left side heart failure, right side heart failure, bi-ventricular
- Treatment in cath lab, OR, ICU and hospital transfer scenarios
- Impella 2.5, CP, 5.0, LD, RP





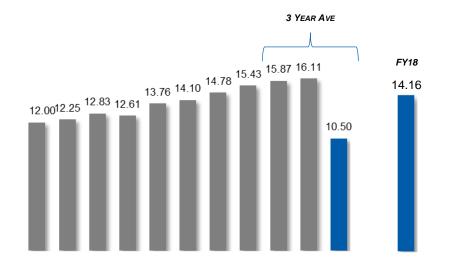
PROPOSED RECOMMENDATIONS: TRANSITION

Option 1:

Revise assignment of ICD-10 codes to replicate MS-DRG assignments based on ICD-9 codes

For MS-DRGs with >10% Reduction

MEDICARE MS DRG 215 WEIGHTS



Option 2:

Cap Reductions at 10% Reduction
For MS-DRGs with >10% Reduction

	FY17 Base	FY18 Base Rate	
MS-DRG	Rate	Recommendation	% Change
215	16.108	14.497	-10%

N = 285 claims

SUMMARY

- IPPS Proposed rule adversely effects a severely ill Medicare population with new FDA indicated therapies for cardiac assist now available
- Changes would be a disincentive for hospitals treating the sickest Medicare heart failure patients (i.e. cardiogenic shock, advanced heart failure with PCI)
- Proposed FY 2018 relative weight for DRG 215 would not accurately reflect the cost of the higher acuity cases moving into DRG 215 in FY 2018
- In the Final Rule should provide a transition period by either:
 - Revising the assignment of ICD-10 codes to MS-DRG 215 for the calculation of FY
 2018 relative weights to replicate the MS-DRG assignments based on ICD-9 codes; or
 - Implementing a multi-year transition period for or cap on cuts in relative weight in excess of 10%

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