CAR-T Medicare Reimbursement

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Today's Focus

- Demystifying Medicare's inpatient payment for Chimeric Antigen Receptor T-cell (CAR-T) Therapy, including a review of the New Technology Add-on Payment (NTAP) and outlier formulas
- Case study demonstrating the financial impact to hospitals of providing CAR-T therapy

3 Take-Aways For Today

- <u>Take away #1:</u> hospital billed charges fundamentally impact the Medicare payments hospitals receive but have nothing to do with what patients pay out of pocket
- <u>Take away #2</u>: even the simplest CAR-T case results in a loss regardless of how well a hospital bills its charges relative to the NTAP approved by Medicare
- <u>Take away #3:</u> even with hospital specific adjustments and additional payment opportunities, Medicare's inpatient payment for CAR-T is NOT financially viable for hospitals

30,000 Foot View of Medicare's Inpatient Payment Calculation

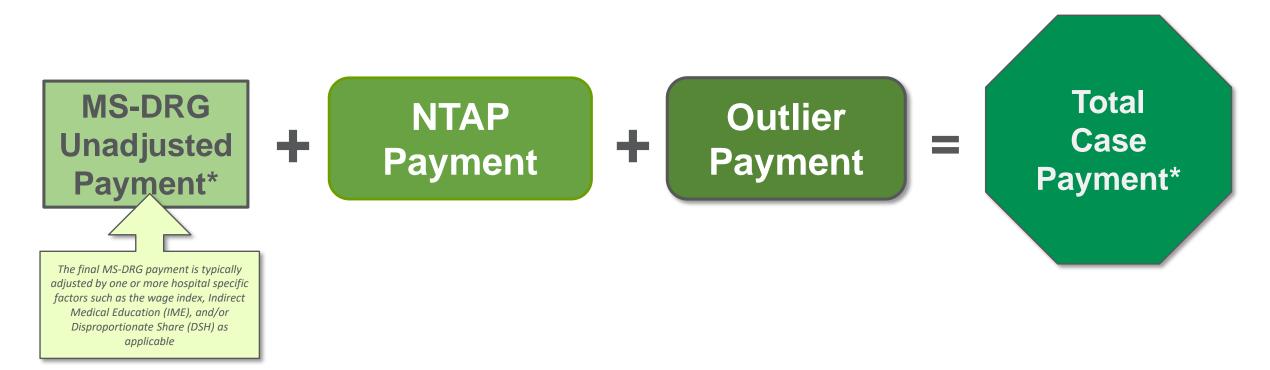


- Clinical cases and associated care charges
- Hospital charging practices
- Operating hospital cost-to-charge ratio (CCR) from the most recently filed cost report
- Hospital specific adjustment factors

Medicare Payment System Specifics Final Hospital Case Payment

- MS-DRG assignment
- New Technology Add-On Payment (NTAP) if CMS has awarded it to an applicant drug or device
- Outlier
- And others...

Understanding IPPS Payment Rates



* Hospital specific adjusted MS-DRG and case payment is reflective of the hospital specific wage index, indirect medical education, and disproportionate share, and other adjustments. For details, see CMS's Acute Care Hospital Inpatient Prospective Payment System Medicare Learning Network booklet; ICN 006815 March 2018

FY 2019 Final Medicare Inpatient CAR-T Payment

 Inpatient CAR-T cases are grouped to MS-DRG 016 based on <u>the presence of one of two CAR-T ICD-10-PCS codes</u> (XW033C3 and XW043C3)

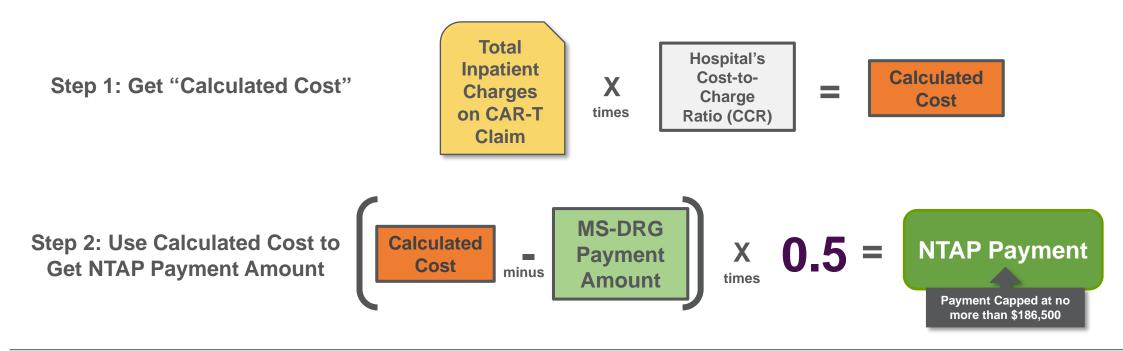
MS-DRG 016 Title	National Unadjusted PPS Payment*
Autologous Bone Marrow Transplant with CC/MCC or T- cell Immunotherapy	\$39,951

- The national unadjusted PPS payment represents the payment amount before hospital specific adjustments are applied which will impact overall payment
- In addition to the MS-DRG case payment, hospitals may receive additional payment through either:
 - The NTAP formula
 - The Outlier formula
- Both the NTAP and the outlier are <u>dependent</u> on the total billed charges for the case and the hospital's overall
 operating cost to charge ratio (CCR) which comes from each hospital's Medicare cost report

^{*} PPS-exempt hospitals have a different payment mechanism

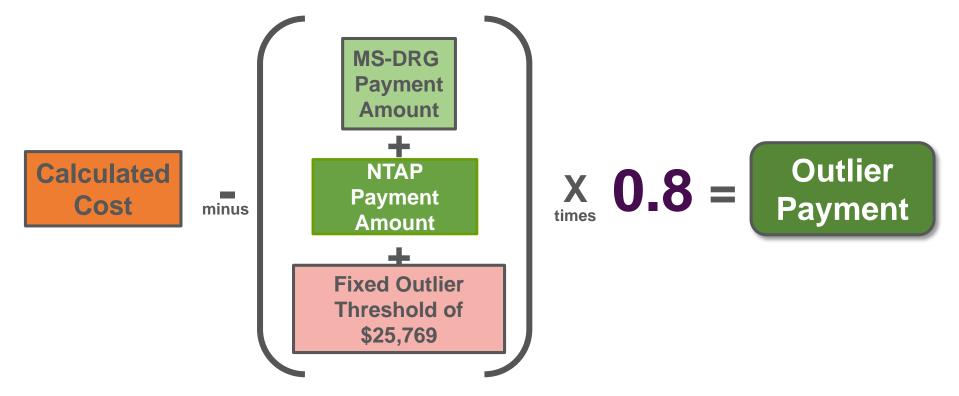
FY 2019 IPPS Hospital NTAP Formula

- NTAP = separate additional payment for 2-3 years of no more than 50% of the cost of the new technology which is pre-determined by CMS which for CAR-T is capped at \$186,500 (50% of the product cost of \$373,00)
 - CMS computes "<u>calculated cost</u>" by taking total inpatient billed charges multiplied by the hospital's operating CCR and if this exceeds the MS-DRG payment, then an NTAP (<u>the lesser of</u> 50% of the remaining cost or the NTAP cap) payment is made



FY 2019 IPPS Hospital Outlier Formula

• CMS computes a <u>calculated cost</u> for the case by taking total inpatient billed charges multiplied by the hospital's operating CCR and compares it to the sum of the MS-DRG payment + NTAP + the fixed loss outlier and <u>if</u> there is remaining cost CMS makes an outlier payment equal to 80% of it



NTAP and Outlier Both Available for FY 2019

Order of Operations

- Step 1: CAR-T cases are assigned to MS-DRG 016 (national unadjusted payment rate = \$39,951)
- **Step 2:** The NTAP payment amount for the case is computed; capped at a maximum of \$186,500
- **Step 3:** The outlier payment calculation is computed to see if any additional dollars are warranted after CMS compares the calculated cost of the case to the sum of the MS-DRG payment + the NTAP + the fixed loss outlier threshold

MS-DRG 016, \$39,951	NTAP up to \$186,500	"Donut Hole" Fixed Loss Outlier \$25,769	Variable Outlier Payment
MS-DRGs NTAP	"Donut Hole" Fixed Loss	Outlier Threshold	Variable Outlier Payment

Clinical Example to Demonstrate Current Payment Calculations Using Sample Claims

• Hospital and Patient Characteristics

- -Hospital A and B are both certified to provide CAR-T therapy
- -Both hospitals pay the manufacturer \$373,000
- -Both hospitals have a wage-index of 1.0 and no other adjustments to their MS-DRG payment rate
- -Both hospitals have an overall operating cost-to-charge ratio of .25
- -Both hospitals treat the same type of simple CAR-T patient (i.e., no complications arising)

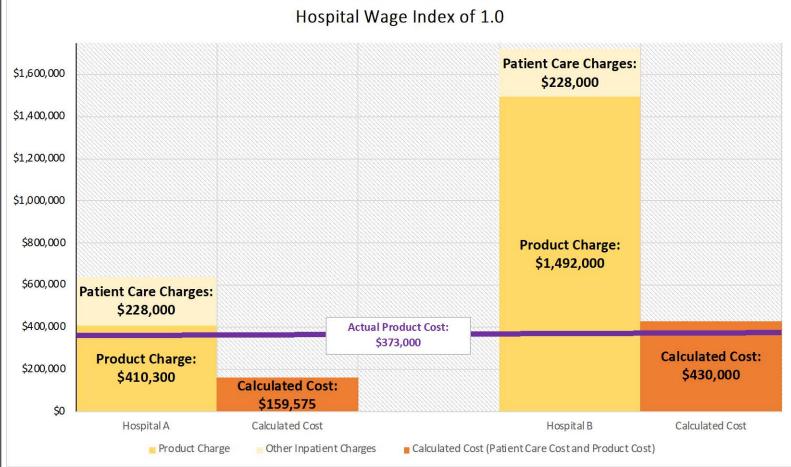
Example of CAR-T Patient Claims from Two Different Hospitals

- The only difference between Hospital A and B is the amount of the CAR-T product charge billed on the claim
 - Hospital's B charge is reflective of its operating CCR of .25, but Hospital A's is not

•	Hospital A Example Inpatient Hospital Claim		Hospital B Example Inpatient Hospital Claim					
		Total						
Description	Units	Charges		Description	Units	Total Charges		
Room & Board	14	\$63,000		Room & Board	14	\$63,000		
Pharmacy	100	\$45,000		Pharmacy	100	\$45,000		
Supplies	20	\$13,000		Supplies	20	\$13,000		
Laboratory	520	\$32,000		Laboratory	520	\$32,000		
All other	50	\$75 <i>,</i> 000		All other	50	\$75,000		
CAR-T Drug*	1	\$410,300		CAR-T Drug*	1	\$1,492,000		
Total Charges		\$638 <i>,</i> 300		Total Charges		\$1,720,000		
* In the claims examples shown, the CAR-T product charge is split out from other								
pharmacy charge	pharmacy charges for illustrative purposes to demonstrate how reporting of the							
CAR-T product can occur. This would require explicit instructions from CMS.								

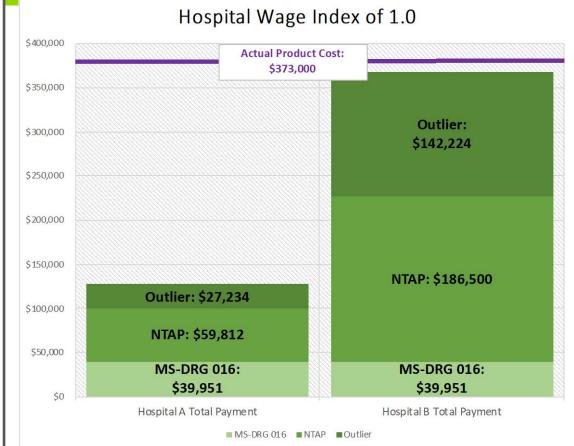
Charge and Calculated Cost Variations for Hospital A and B

- Hospital A and B have different total charges
- CMS determines the "calculated cost" by multiplying the total billed charges by the hospital's overall CCR which in our example is 0.25 for both hospitals
- Because of the difference in total charges between Hospital A and B, CMS' calculated cost for each hospital is very different
- Note: "calculated cost" does not equal "actual cost"; yet this is the information used in determining Medicare payment

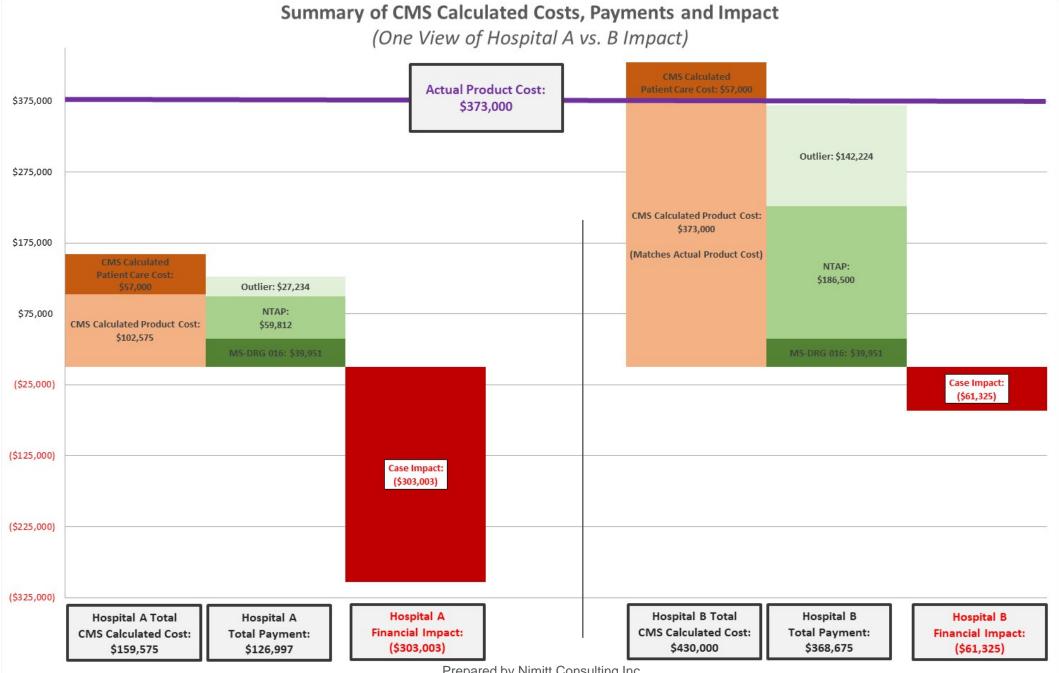


Calculated Cost for Each Hospital Impacts the NTAP and Outlier Payment Amounts Received

- Calculated cost (patient care + product cost)
 Hospital A = \$159,575
 Hospital B = \$430,000
- Payment components
- –MS-DRG 016 payment is the same for Hospital A and B since we haven't applied any adjustments in our example
- NTAP payment varies because total charges and calculated costs vary
- Outlier payment varies because total charges and calculated costs vary



Both hospitals receive the MS-DRG payment + NTAP + Outlier, but these payments do not cover the cost of the CAR-T product let alone any of the patient care costs associated with the hospitalization or other services provided to the patient



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Summary

- Each inpatient case starts with a base MS-DRG or per case payment
- If there is a product eligible for NTAP during the inpatient admission, the NTAP formula gets applied and is based on total charges and has a cap
- Outlier payment may available but it too is based on total charges
- Hospital financial impact will vary due to things like:
 - Patient care factors such as complications that may arise resulting in days in the intensive care unit (ICU), use of additional drugs, etc.
 - Hospital adjustment factors (i.e., wage-index, DSH, and IME)
 - Hospital charging practices and the operating CCR

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