Achieving Sustainable Market and Patient Access: Medicare and Medicaid Coverage, Reimbursement, and Coding Issues for CAR-T

Jugna Shah, MPH
President and Founder, Nimitt Consulting
ASGCT Meeting
April 28th, 2019
Washington, DC

“Straight roads are for fast cars; turns are for fast drivers.”

- *Colin McRae, British Rally Car Champion*

Today's Topics

Current State of CAR-T Coverage, Reimbursement, and Coding

Lessons Learned

Medicare Reimbursement Proposals for FY 2020 and Beyond

Implications For Other Therapies

CURRENT STATE:

CAR-T COVERAGE, REIMBURSEMENT, AND CODING ISSUES

Two Approved CAR-T Products

Kymriah™ (Novartis)

- August 2017: FDA Approval for Precursor B-cell Acute Lymphoblastic Leukemia (ALL)
  - Refractory or in second or later relapse
  - "Up to 25 years of age" (i.e. 25 &, 364 days)
- May 2018: FDA Approval for Adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma & DLBCL arising from follicular lymphoma
- About 85+ certified centers
- $475,000 for pediatric and $373,000 for adult indication
- Q2040 was effective from January 1 – December 31, 2018 but has now changed to Q2042 as of January 1, 2019 and there is a description change

Yescarta™ (Kite/Gilead)

- October 2017 FDA Approval for Relapsed/Refractory Large B-Cell Lymphoma
  - No age restrictions
  - Median age of Dx = 70
  - After failing 2+ systemic lines of therapy
- About 70+ Centers
- $373,000
- Q2041; Effective Date: April 1, 2018 with a slight description change as of January 1, 2019

Population Notes: High percentage of government payers in each indication:
- Pediatric population = 35-45% Medicaid
- DLBCL median age of Dx = 70 (Medicare age = 65)

CAR-T = The Perfect Storm

- High cost drug provided primarily in the inpatient setting
- Inadequate inpatient reimbursement
- Limited number of hospitals providing care
- Commercial payer reimbursement not enough able to cross-subsidize Medicare short-falls
- Significant operational challenges
- Current Administration's focus on drug pricing seems to have stymied any sympathy for provider challenges and patient access
- Unexpected coverage analysis from CMS

COVERAGE

Is CAR-T Covered?

Commercial

- Most commercially insured patients have coverage for Yescarta and/or Kymriah
- Some limitations for specific plans and/or employer-sponsored groups may exist
  - Experimental/investigational denial may be attempted

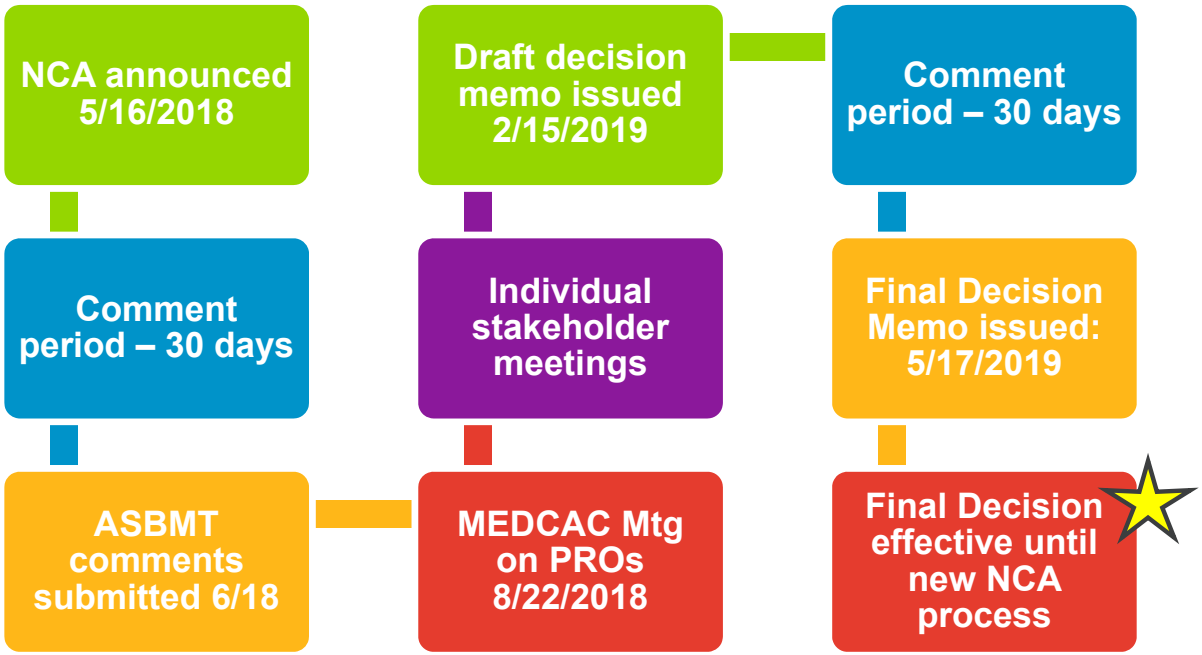
CMS

- National Coverage Decision expected May 2019
  - In the meantime, "medically accepted indications" appear to be covered, *i.e.*, labeled indication, and indications supported by compendia
  - For inpatients, it is a drug used in a covered episode of care – i.e. treatment of lymphoma
  - Payment assigned under the outpatient setting; have not heard of rejected claims

Medicaid

- State-by-state decisions
  - Payment ranges from cost-based "carve out" to no separate product payment to what appears to be no coverage at all
- Medicaid managed care
- Covered in-state vs. out?
- Approved vs. actually paid

CMS/Medicare NCA for CAR-T: Process Flow



Follow the issue by visiting: https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=291 or Visit www.CMS.gov – enter "chimeric" in the main search box at top of page

CMS Proposed Decision Overview: CED

CMS proposes to cover autologous treatment with T-cells expressing at least one CAR through coverage with evidence development (CED)

- Patient must have:
  - Relapsed or refractory cancer; and
  - Not currently experiencing any comorbidity that would preclude patient benefit
- Covered Indications:
  - FDA-approved indication furnished in a hospital that participates in a qualifying registry; OR
  - FDA-approved biological for use in the NCCN Drugs & Biologicals Compendium with grade 2 or after August 17 when patient enrolled in a CMS-approved clinical study
- Site of Service Requirements - Service can be performed in the hospital inpatient or outpatient as long as the following conditions are met:
  - Has a Cellular Therapy Program
  - Has a designated care area
  - Written guidelines for patient communication, monitoring, and transfer to a ICU

CED Translation: What does it really mean?

CMS proposes to cover autologous treatment with T-cells expressing at least one CAR through coverage with evidence development (CED).

Would not include Allo products

- Patient must have:
  - **Relapsed or refractory** cancer; and
  - Not currently experiencing **any comorbidity that would preclude patient benefit**

Limits scope for new products

Says who? MD or MAC?

- Covered Indications:
  - FDA-approved indication furnished in a hospital that participates in a qualifying registry; OR
  - FDA-approved biological for use in the NCCN Drugs & Biologicals Compendium with grade 2 or after August 17 when patient enrolled in a CMS-approved clinical study

No MD offices or clinics

- Site of Service Requirements - Service can be performed in the **hospital inpatient** or **outpatient** as long as the following conditions are met:
  - Has a Cellular Therapy Program
  - Has a designated care area
  - Written guidelines for patient communication, monitoring, and transfer to a ICU

i.e. FACT accredited

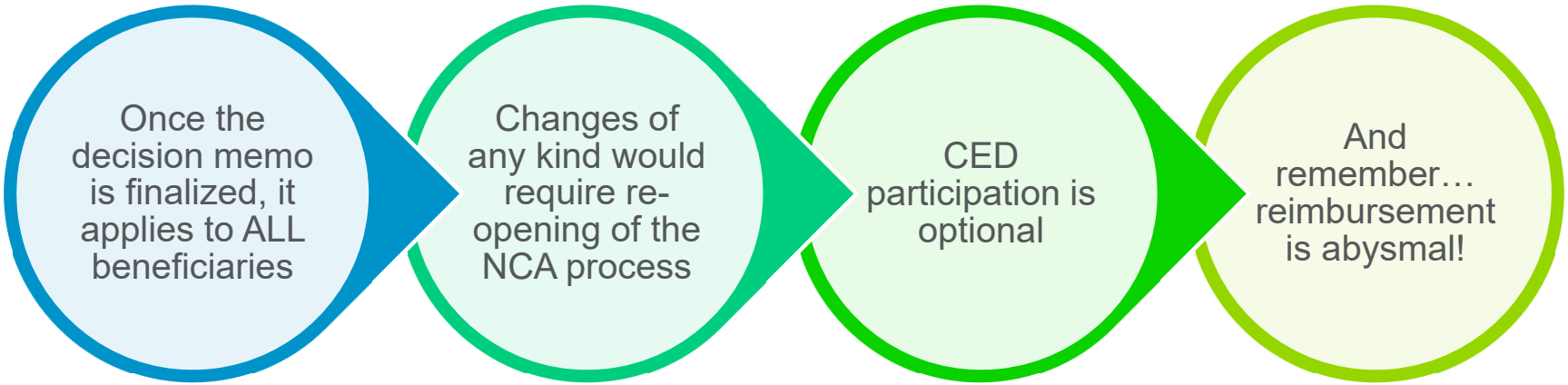
CED Framework Details: Registry Driven Study

Registry Requirements

- Prospective, National, Audited
- Accepts all manufactured products
- Follows patients for 2+ years
- Has PRO QOL capabilities
- Must be reviewed and approved by CMS

CIBMTR is likely the only entity currently capable and is already managing data for Kite and Novartis.

The Big Picture: Will it Impact Access?



- FFS and Medicare Advantage

- Would have to petition for changes, 6+ months process if accepted
- CED will likely be open for at least 5-10 years based on data timeline

- Facilities are not mandated to participate (to the best of our knowledge)

Medicaid: No Uniformity

Pediatric ALL eligible population (r/r) is 1-2 cases per million

- Same clinical evidence, yet high variability
  - Covered or not and if not, why not?
  - Available policy or not; easy to find or not?
  - Site of care requirements
  - Product payment
  - Prior authorization
  - Requirements beyond the label
  - Other

Institute for Clinical and Economic Review Report Finds Costs of Approved CAR-T Therapies Align with Clinical Benefit

– Report will be subject to public deliberation during CTAF meeting on March 2, 2018 –

BOSTON, February 15, 2018 – The Institute for Clinical and Economic Review (ICER) today released an Evidence Report assessing the comparative clinical effectiveness and value of tisagenlecleucel (Kymriah™, Novartis) and axicabtagene ciloleucel (Yescarta™, Kite Pharma/Gilead). The report found that both therapies provided improvements in response rates and survival for patients who have exhausted most other treatment options, and that the drugs are priced in alignment with their clinical value.

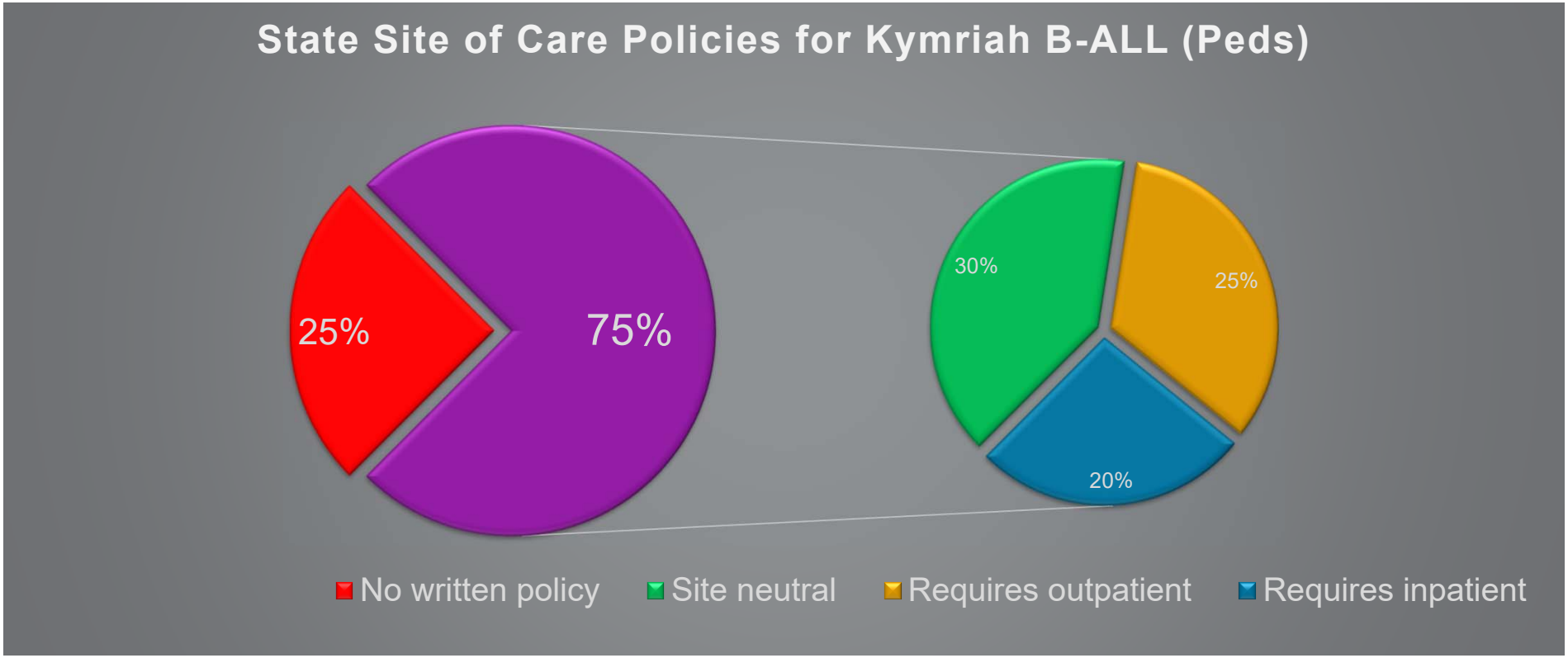
RECENT ANNOUNCEMENTS

Institute for Clinical and Economic Review to Assess Treatments for Amyloidosis, Prostate Cancer in Upcoming Reports

NCCN National Comprehensive Cancer Network®

Guideline Name:	Acute Lymphoblastic Leukemia 1.2018
Disease:	Acute Lymphoblastic Leukemia
Agent:	Tisagenlecleucel
FDA Indication:	Tisagenlecleucel is indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse.
Brand:	Kymriah™
Category of Evidence:	2A ○ **Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate;
Pharmacologic Class:	CD19-directed genetically modified autologous T cell immunotherapy
Route:	IV
Recommended:	Single-agent therapy for • relapsed/refractory Philadelphia chromosome-positive B-ALL in patients < 26 years and with refractory disease or ≥ 2 relapses and failure of 2 TKIs • relapsed/refractory Philadelphia chromosome-negative B-ALL in patients < 26 years and with refractory disease or ≥ 2 relapses
ICD10:	C91.00, C91.02
Billing Code:	Q2042

Site of Care Coverage Policy Breakdown



Just Because a Policy Exists, Doesn't Mean there is Clear or Adequate Product Coverage

All Providers

New York State Medicaid Will Begin Covering Tisagenlecleucel

New York State (NYS) Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) will begin covering tisagenlecleucel (brand name KYMRIAH™) for members who have a diagnosis of acute lymphoblastic leukemia (ALL) when the member meets the criteria outlined in this policy. This coverage policy is effective December 1, 2017 for FFS and February 15, 2018 for MMC.

Tisagenlecleucel is a chimeric antigen receptor T cell (CAR-T) therapy for the treatment of patients twenty-five years of age or younger with B-cell precursor ALL that is refractory or in second or later relapse. Tisagenlecleucel is a one-time treatment that uses a patient's own T cells to fight cancer. Tisagenlecleucel is the first therapy based on gene transfer that has been approved by the FDA.

Coverage Policy:
In accordance with FDA indications, Medicaid reimburses for tisagenlecleucel when the following criteria are met:

- The patient must have a diagnosis of B-cell precursor ALL;
- The patient must be 25 years of age (up to the end of the 25th year) or younger; and
- The ALL must be refractory or in second or later relapse.

NY, MA, WA providing product cost pass-through

State "X"

Outpatient = ASP+ ?%

Inpatient = $XXXX per day and no payment for the product cost

Q-codes listed as being reimbursed outpatient and requires a prior authorization

[Revised] Injectable Medication (* indicates more information after table)	[Revised] Procedure Code(s)	[Revised] Reimbursable Place of Service and Other Limitations or Restrictions
Tisagenlecleucel (Kymriah)*	Q2042	Place of Service: Office, Outpatient Hospital Prior Authorization Required

Policy Implications

Clinicians

- Talk directly to Medicaid contacts
- Revisit frequently
- Offer assistance with clinical information review

States

- There may be local political backlash if formal “greenlight” given to costly therapies
- Watching neighboring states and CMS for how to proceed
- Some states filing requests to modify their benefits to allow for milestone-based contracts – Oklahoma first to implement, several more in process
- How to reach agreement with an out-of-state treatment center quickly?

Policy Makers

- Considering how to handle high-cost specialty drugs (medical benefit)
- Reviewing perverse incentives for site of care with high-cost drugs, especially with rebate potential

CURRENT MEDICARE REIMBURSEMENT

On Average, Are Providers Receiving Sufficient Medicare Reimbursement for CAR-T in the Inpatient Setting?

A. Yes, because it's a designated breakthrough therapy

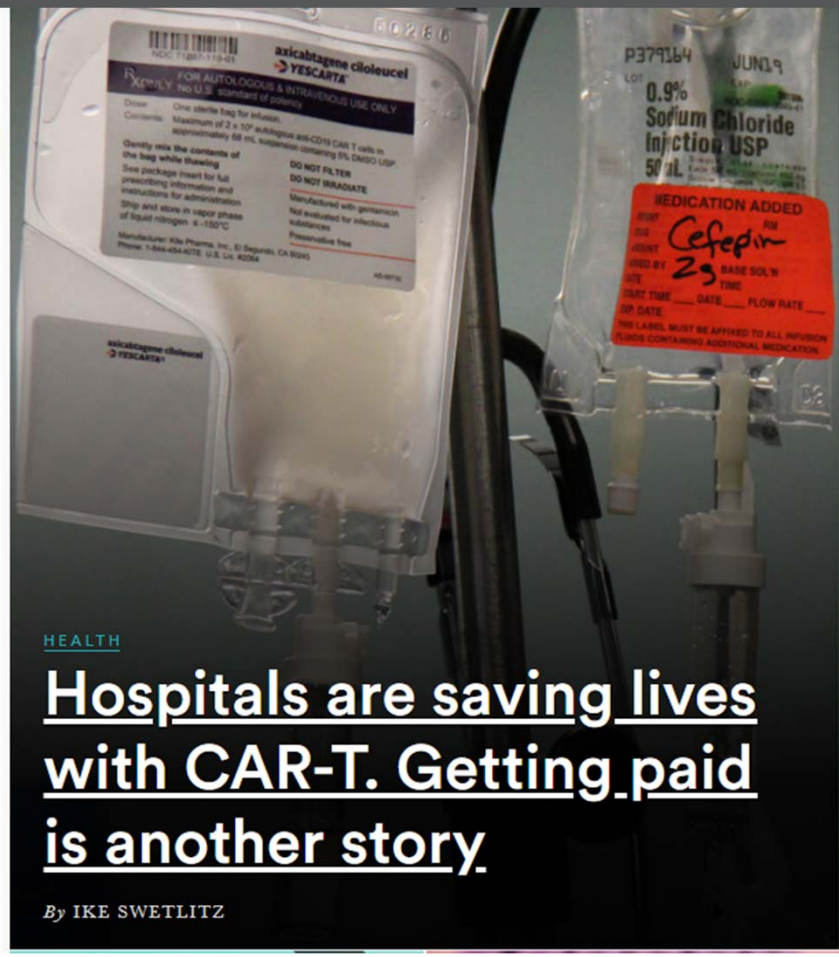
B. Yes, because Medicare approved a new technology add-on payment (NTAP)

C. Maybe, it depends on charging practices

D. No way, not even close!

In a recent speech, CMS Administrator Seema Verma acknowledged that Medicare's payment system for CAR-T isn't working.

"The CAR-T story is an example of how government programs often fail to keep pace with innovation," Verma said on March 4.



Current FY 2019 Medicare Inpatient CAR-T Payment

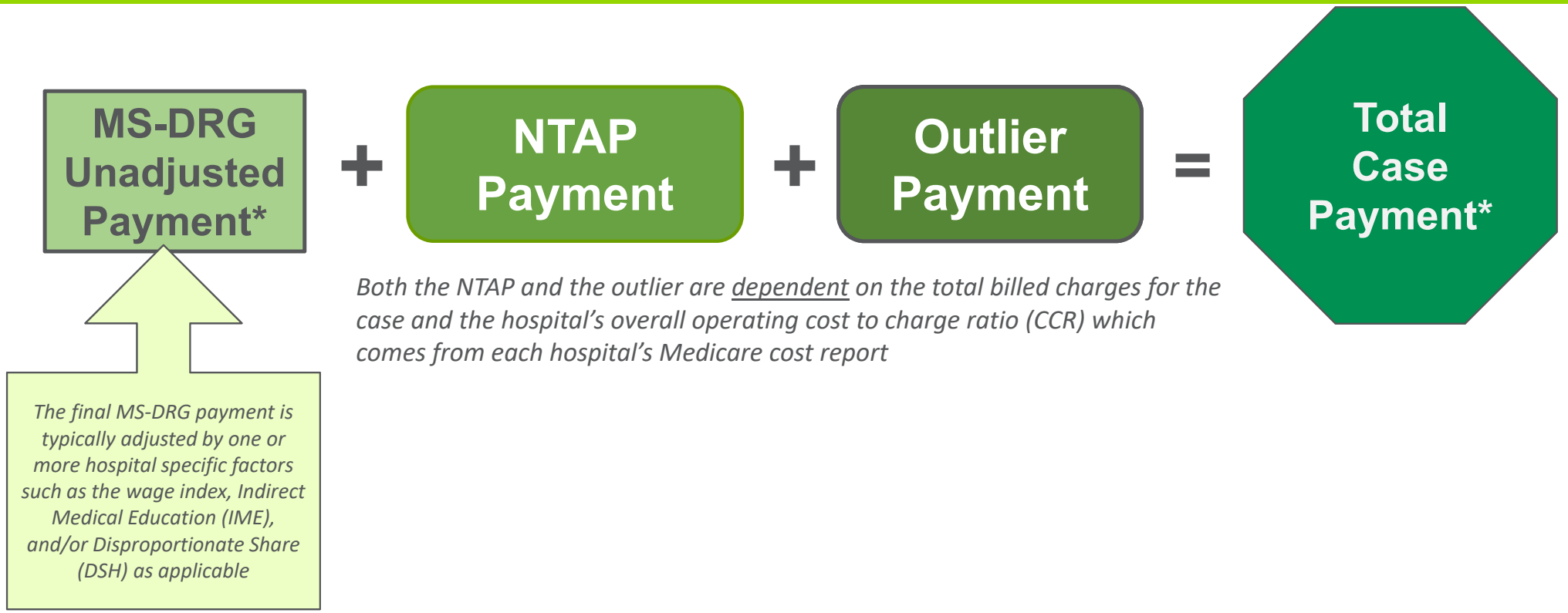
- Inpatient CAR-T cases are grouped to MS-DRG 016 based on the presence of one of two CAR-T ICD-10-PCS codes (XW033C3 and XW043C3)

MS-DRG O16 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 can receive additional payments through either the new technology add-on payment and the outlier payment mechanism

** PPS-exempt hospitals have a different payment mechanism*

High-level Overview of IPPS Payment

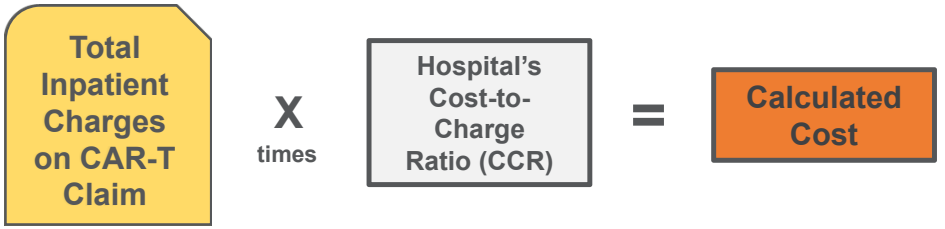


Both the NTAP and the outlier are dependent on the total billed charges for the case and the hospital's overall operating cost to charge ratio (CCR) which comes from each hospital's Medicare cost report

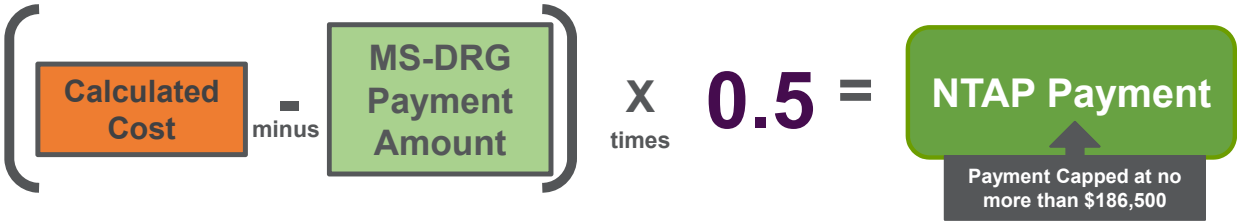
FY 2019 IPPS Hospital NTAP Formula

- 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 "**calculated cost"** by taking total inpatient billed charges multiplied by the hospital's operating CCR and if this exceeds the MS-DRG payment, then an NTAP (the lesser of 50% of the remaining cost or the NTAP cap) payment is made

Step 1: Get "Calculated Cost"

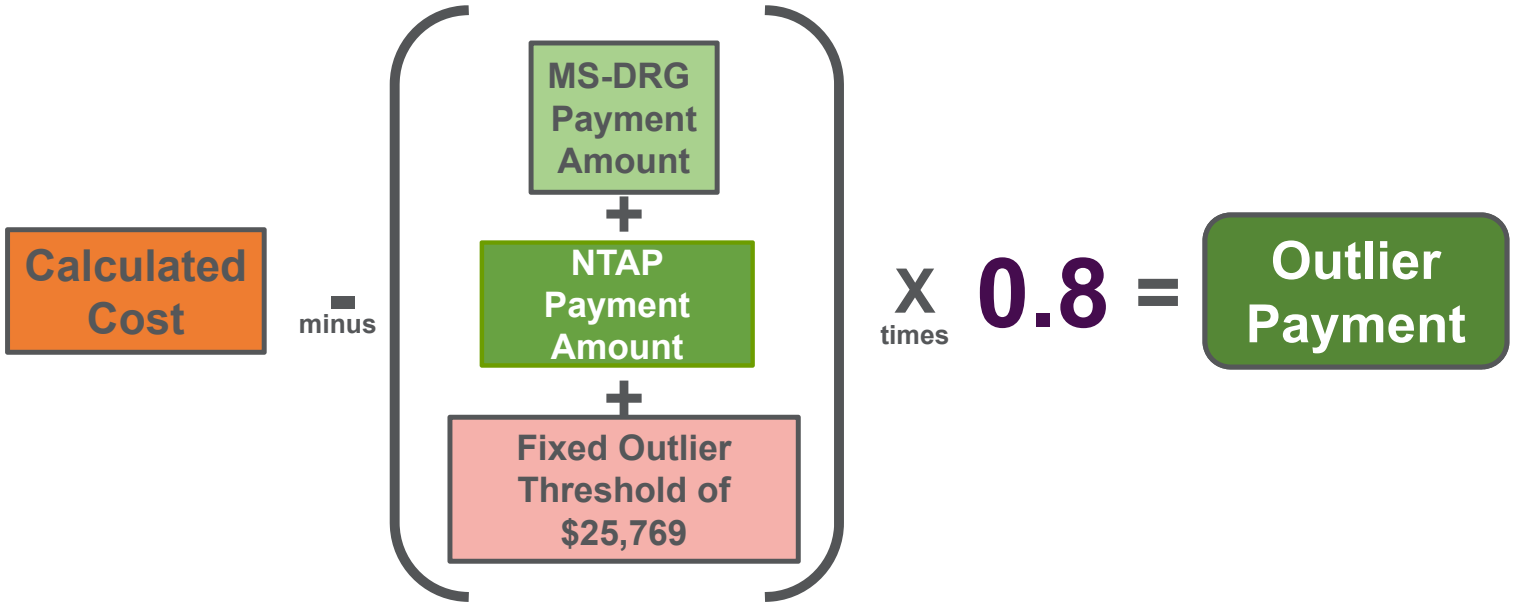


Step 2: Use Calculated Cost to Get NTAP Payment Amount



FY 2019 IPPS Hospital Outlier Formula

- CMS computes a **calculated cost** 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 if there is remaining cost CMS makes an outlier payment equal to 80% of it



Summary of the Order of Operations

Hospital Case Study

- **Hospital and Patient Characteristics**

  Both hospitals A and B:

  - Are certified to provide CAR-T therapy
  - Pay the manufacturer $373,000
  - Have a wage-index of 1.0 and no other adjustments
  - Have an overall operating cost-to-charge ratio of 0.25
  - Treat the same type of patient

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

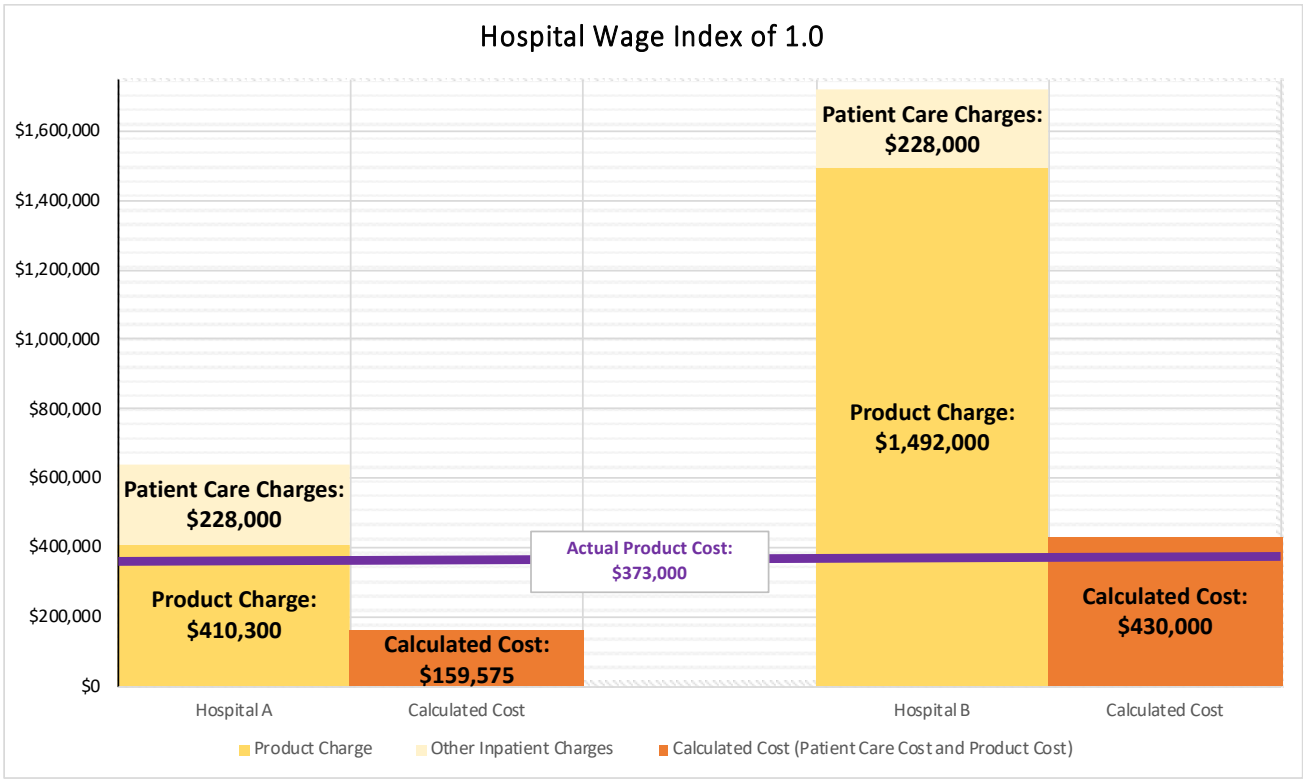
Hospital A Example Inpatient Hospital Claim		
Description	Units	Total Charges
Room & Board	14	$63,000
Pharmacy	100	$45,000
Supplies	20	$13,000
Laboratory	520	$32,000
All other	50	$75,000
CAR-T Drug*	1	$410,300
Total Charges		$638,300

Hospital B Example Inpatient Hospital Claim		
Description	Units	Total Charges
Room & Board	14	$63,000
Pharmacy	100	$45,000
Supplies	20	$13,000
Laboratory	520	$32,000
All other	50	$75,000
CAR-T Drug*	1	$1,492,000
Total Charges		$1,720,000

** In the claims examples shown, the CAR-T product charge is split out from other pharmacy charges for illustrative purposes to demonstrate how reporting of the CAR-T product can occur. This would require explicit instructions from CMS.*

Differences in Hospital Charging Practices Impact Total Reimbursement

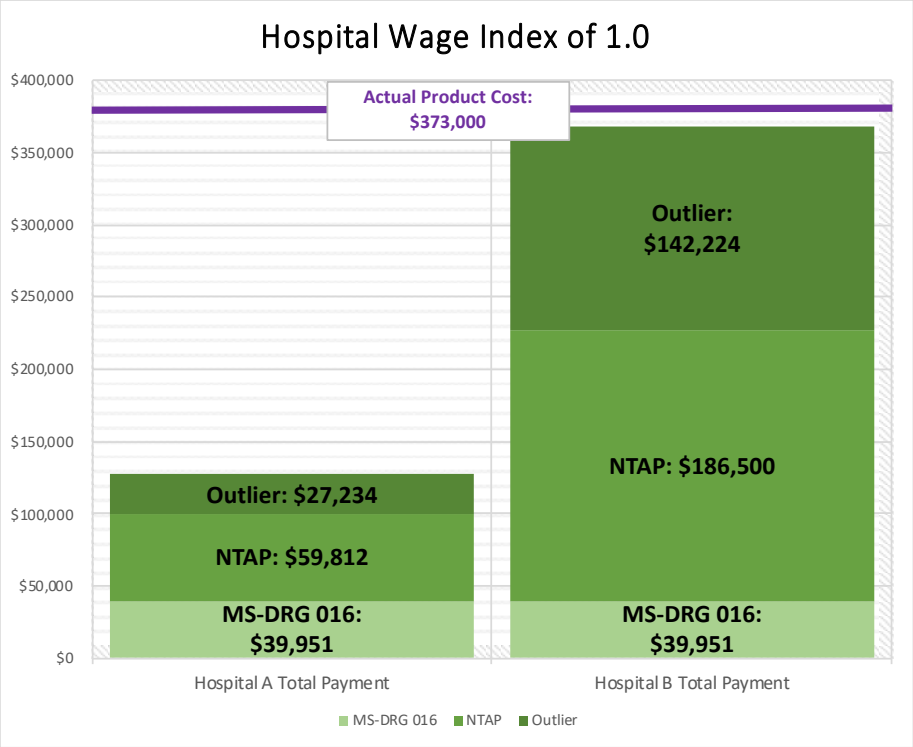
- Hospital A and B have different total charges
- CMS determines the "calculated cost" by multiplying the total billed charges by the hospital's overall CCR which in our example is 0.25 for both hospitals
- Because of the difference in total charges between Hospital A and B, CMS' calculated cost for 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 NTAP and outlier payment, but these payments plus the MS-DRG payment do NOT cover even the cost of the CAR-T product let alone any patient care costs



CY 2019 CAR-T Product Codes and Payment Rates

- No J-codes assigned despite manufacturer and provider requests
- CMS elected to retain Q-codes "as is" which means they still include "leukapheresis and other dose preparation procedures" and the descriptions now reflect "per therapeutic dose"
- Kymriah code Q2040 deleted and replaced with Q2042 which encompasses the cell dosage for both the pediatric and adult indications (…up to 600 million car-positive viable cells…)
- Separate payment continues based on ASP + 6%

2nd Quarter CY 2019 OPPS/Addendum B							
HCPCS Code	**Short Descriptor**	**SI**	**APC**	**Payment Rate**	**Minimum Unadjusted Copayment**	**Note: Actual copayments would be lower due to the cap on copayments at the Inpatient Deductible of $1,364.00**	*** Indicates a Change**
Q2041	Axicabtagene ciloleucel car+	G	9035	$395,380	$79,076	#	*
Q2042	Tisagenlecleucel car-pos t	G	9194	$449,128	$89,826	#	*

CODING AND OTHER CHALLENGES

But At Least the Coding is Straightforward, Right?

Product Q-codes include cell collection and processing which has caused many issues

CPT codes did NOT exist until January 1, 2019

Now codes exist but CMS does NOT recognize all of them

No specific codes (until recently) to isolate product cost & charge info on inpatient claims

National Uniform Billing Committee (NUBC) created codes, but there are issues with CMS recognizing them as created…though they should be; NUBC is challenging CMS on this

CY 2019 OPPS Payments for Facility Reporting of New Category III CAR-T Service CPT Codes

- Four new CAR-T Category III CPT codes were released in July for use starting January 1st, 2019 but only one recognized for payment (0504T); the other codes are assigned status "B" which means report a "better/different code" but CMS does not specify or discuss what code(s) that would be…
  - *CMS' rationale: The procedures described by CPT codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T-cells, and Medicare **does not generally pay separately** for each step used to manufacture a drug or biological." (pg. 271 of the 2019 OPPS rule)*

	CY 2019 Final Rule Payment					
HCPCS Code	Short Descriptor	CI	SI	APC	Payment Rate	Minimum Unadjusted Copayment
0537T	Bld drv t lymphcyt car-t cll	NC	B		$0.00	
0538T	Bld drv t lymphcyt prep trns	NC	B		$0.00	
0539T	Receipt&prep car-t cll admn	NC	B		$0.00	
0540T	Car-t cll admn autologous	NC	S	5694	$288.38	$57.68

National Uniform Billing Committee (NUBC) Approved New Revenue Codes and a New Value Code for April 1, 2019 Implementation

087x Cell/Gene Therapy

Charges for procedures performed by staff for the acquisition and infusion/injection of genetically modified cells.

SubC	Subcategory Definition	Standard Abbreviation	Unit	HCPCS
0	General Classification	CELL/GENE		
1	Cell Collection	CELL/GENE CELL COLL		
2	Specialized Biologic Processing and Storage - Prior to Transport	CELL/GENE TRANS PRIOR		
3	Storage and Processing after Receipt of Cells from Manufacturer	CELL/GENE STOR PROC AFT		
4	Infusion of Modified Cells	CELL/GENE INFUSION		
5	Injection of Modified Cells	CELL/GENE INJECTION		
6-9	RESERVED			

NEW Category

089x Pharmacy - Extension of 025x and 063x

The category is an extension of 025x and 063 x for reporting additional breakdown where needed.

SubC	Subcategory Definition	Standard Abbreviation	Unit	HCPCS
0	RESERVED (Use 0250 for General Classification)			
1	Special Processed Drugs - FDA Approved Cell Therapy[a]	DRUGS/CELL THERAPY		
2-9	RESERVED			

NEW Category

[a] Charges for drugs and biologics for modified cell therapy requiring specific identification as required by the payer. If using a HCPCS to describe the drug, enter the HCPCS code in the appropriate HCPCS column.

Effective Dates:
UB-04: July 1, 2018, April 1, 2019
837: Upon Implementation of Post 5010 HIPAA Standard
Meeting Date: 3/3/15, 8/4/15, 4/6/16, 8/9/17 8/7/18

Form Locators 39-41
Page 14 of 19

NEW value code for reporting cell acquisition cost

86	Cell/Gene Therapy Invoice Cost (Effective 4/1/19)	$	Invoice/acquisition cost of modified biologics. For use with Revenue Category 089x.

- Robust discussion about having more detailed reporting of cell and gene therapy services and products at the August 7-8, 2018 meeting
  - Unanimous agreement around these new transaction code set data elements!

http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf

CMS' April 2019 OPPS Update Transmittal Goes Against the New NUBC Requirements

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4255	Date: March 15, 2019
	Change Request 11216

SUBJECT: April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)

6. Chimeric Antigen Receptor (CAR) T- Cell Therapy

(CAR) T-cell therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention.

As stated in the CY 2019 OPPS/ASC final rule, CMS is continuing OPPS pass-through payment status for CAR T HCPCS codes Q2041 (Yescarta) and Q2042 (Kymriah) (see long descriptors in Table 5, Attachment A). The OPPS pass-through payment rate is determined following the standard ASP methodology, updated on a quarterly basis if applicable information indicates that adjustments to the payment rates are necessary.

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11216.pdf

- NUBC is one of the HIPAA designated maintenance organizations that defines requirements for institutional claims submission
- NUBC requirements cover **all payers and providers including government payers**.
- Payer cannot disregard or be in conflict with NUBC requirements; there is an enforcement process if a HIPAA-covered entity is believed to be non-compliant with Administrative Simplification

It's the Law

Health care providers, health plans, payers, and other HIPAA-covered entities must comply with Administrative Simplification.

The **requirements apply to all providers who conduct electronic transactions**, not just providers who accept Medicare or Medicaid.

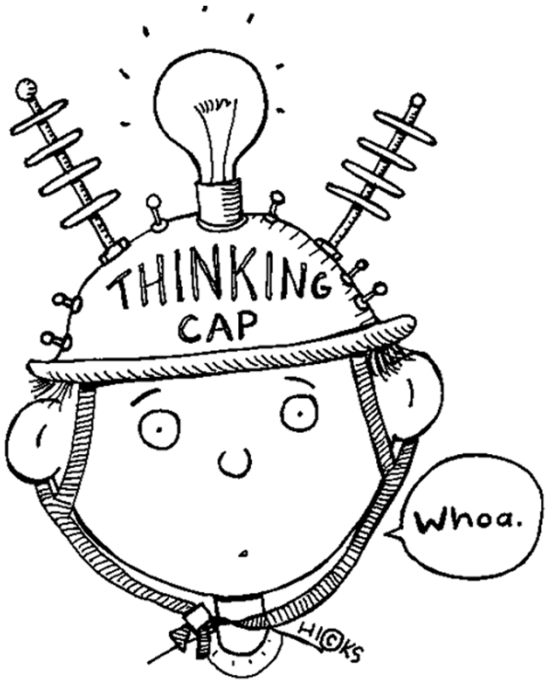
Highlights from the April 9th NUBC Meeting

- **Many Questions Raised by Providers About CMS' Transmittal Guidance**
  - How can the same services (cell collection and cell processing) be called non-covered when reported on outpatient claims but considered covered when on inpatient claims?
  - Doesn't the "non-covered" mean this becomes a patient liability?
  - How can CMS ask hospitals to report outpatient charges on inpatient claims that occur outside the IPPS 3-day payment window?
  - Won't providers have to change dates of service on their claims and manipulate them to get them processed?

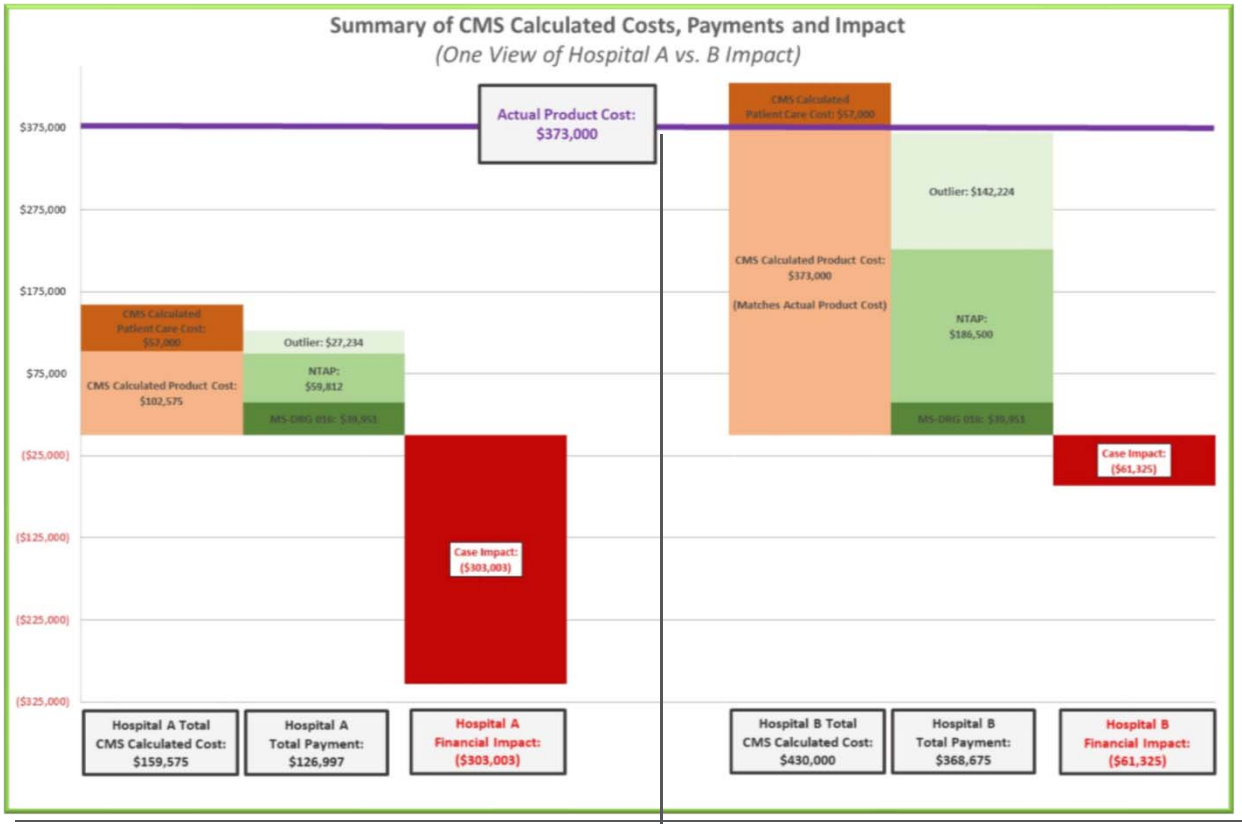
- **CMS' Perspective: There is a "benefit category issues"**
  - Because the CAR-T products were FDA approved as biologics everything associated with producing the biologic, even the hospital services of cell collection and processing, are considered part of the biologic and CMS appears to believe the average sales price reported by the manufacturers (the basis for outpatient payment) is inclusive of "everything" involved in creating the drug, even hospital services – even though neither *CAR-T manufacturer pays hospitals for these services*

- **NUBC's Perspective: CMS is in violation and should address it's issues separately!**
  - CMS instructions should not contradict claim submission rules which are for all providers and all payers to follow

Lessons Learned



Lesson 1: Change is Hard



- CAR-T is currently a buy-and-bill model
- Providers may not be able/willing to adjust their financial systems in order to buy-and-bill this as needed for reimbursement
- Providers are assuming large amounts of risk along with operational difficulties
- Might be easier to “just say no” or seek alternative products or methods

Lesson 2: OBAs IRL - 2G2BT?

Outcomes Based Agreements = “Only pay if it works, otherwise manufacturer absorbs cost”

- Model where hospitals opt in for all payers/patients for certain diseases
- If patient doesn’t achieve certain outcome during a certain interval, hospital wouldn’t pay for the product and the payer wouldn’t be charged

In Real Life:

- Not all hospitals appear to have signed up but most appear to have
- Some are frustrated to hold all charges to Day 28+; say there could be violations or issues with payer contract
- Small #s/lack of understanding if program is primarily focused on adult DLBCL
- Payer lack of understanding about the contract – asking for OBA for both/all indications or do not want to modify standard contract; creates provider burden/frustration

Too Good to Be True?

- Definitely does not solve all issues with the price of the product
- Future comparison of OBAs in the buy-and-bill world vs. direct-to-payer contract may be needed
- OBAs with longer time frames could be more complicated to implement – may cross payer types and entities

Lesson 3: CMS Was Not Impressed (Enough)

Tremendous number of requests:

- Specialty societies
- Industry
- BIO, ARM, PhRMA
- Patient groups
- Providers
- Congress

Stakeholders were flexible as to the solution

- Pass-through based on invoice/acquisition
- New MS-DRG
- CCR of 1.0
- Higher NTAP

And yet – CMS did **not** modify payment or utilize any innovative route or propose its own alternative

*"Given the relative newness of CAR T-cell therapy, the potential model, and our request for feedback on this model approach, we believe it would be **premature to adopt changes** to our existing payment mechanisms for FY 2019"*

Lesson 4: Clarity Elusive but Necessary…

A master plan from CMS or what??

- Lots of breadcrumbs and tea leaves with confusion and chaos at every turn…
- By design...some stealth strategy or
- Uncoordinated actions across offices within the agency

Between Stakeholder groups

- Various viewpoints between patient advocacy groups, physician societies, hospital groups, industry, payers

Within stakeholder groups

- Multiple opinions and strategies amongst specialty organizations and providers; may be hard to get to “the best” idea for all to agree upon

FUTURE MEDICARE REIMBURSEMENT PROPOSALS: FY 2020 AND BEYOND

FY 2020 IPPS Proposed Rule – Progress or Not?

The Proposals

(1) CAR-T cases to remain in MS-DRG 016

(2) Increase the new tech add-on payment from **50% to 65%** for all NTAPs (would mean a max of $242,450 for the two CAR-T products)

(3) Continue the NTAP for FY 2020

Seeking Comment

(1) How best to create a new MS-DRG for CAR-T? Lots of questions being asked…

(2) Eliminate the use of the CCR in calculating the NTAP for Kymriah and Yescarta by making **a uniform add-on payment** that equals the proposed maximum add-on payment of $242,450

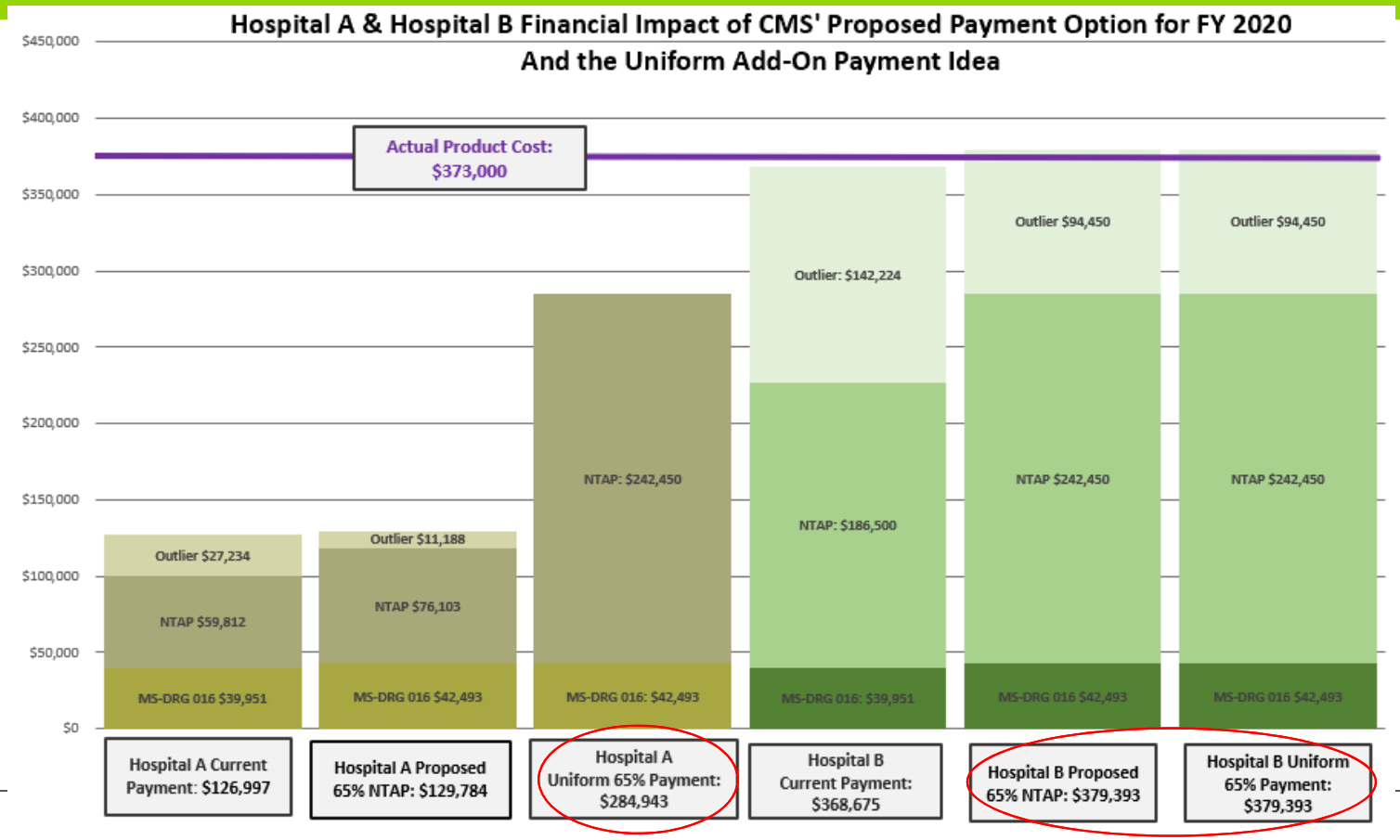
(3) Use a higher percentage than the proposed 65% to calculate the maximum new technology add-on payment amount (related to the proposal item on increasing the NTAP)

More Tea Leaves

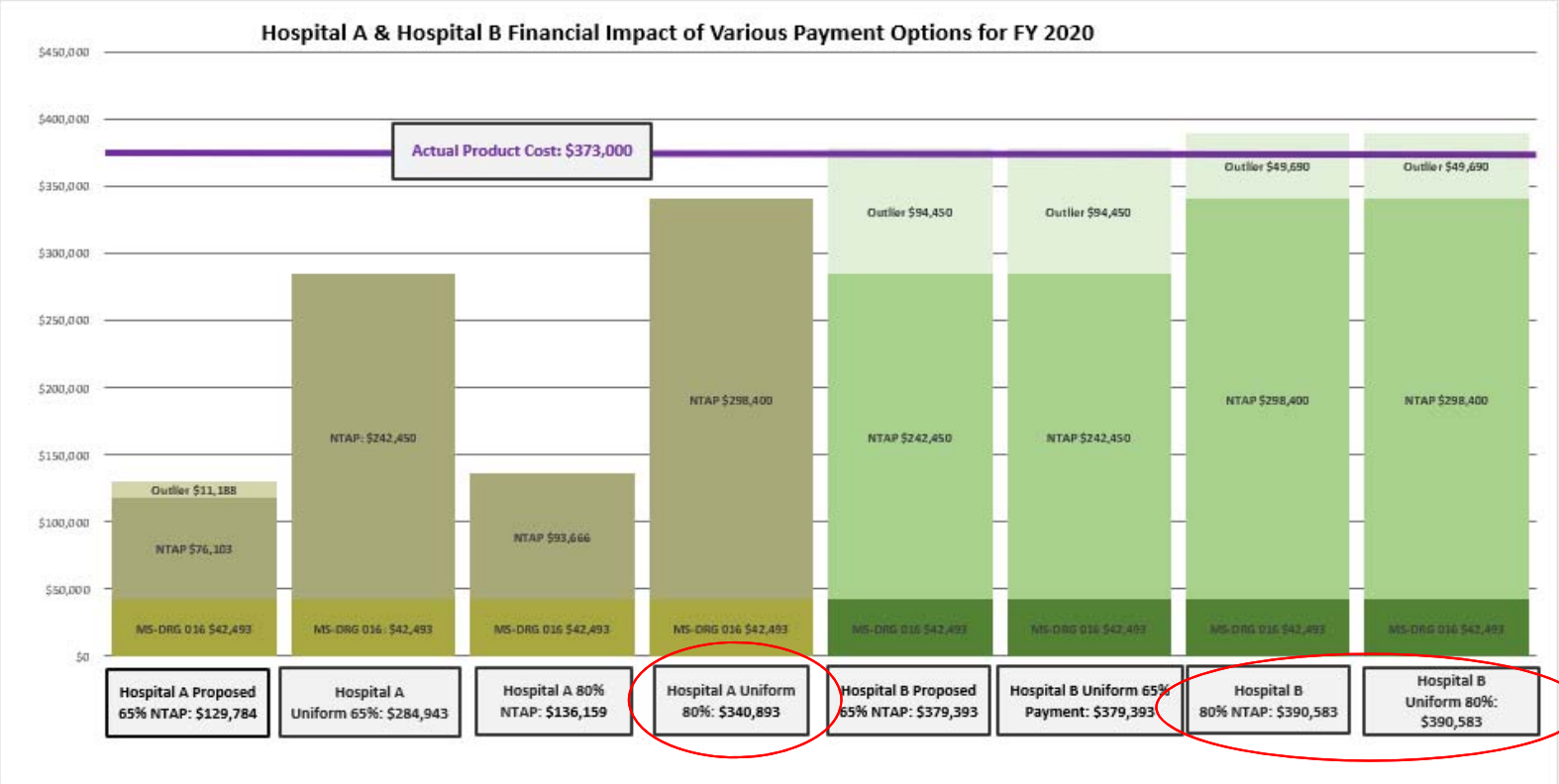
(1) Revisit the use of a CCR of 1.0 for certain aspects like the outlier, NTAP, and exempt providers

(2) Soliciting comments on how the effective dates of any potential payment methodology alternatives, if any were to be adopted, may intersect and affect future participation in such alternative approaches.

Comparing Current Hospital Financial Realities to Some Specific Options for FY 2020



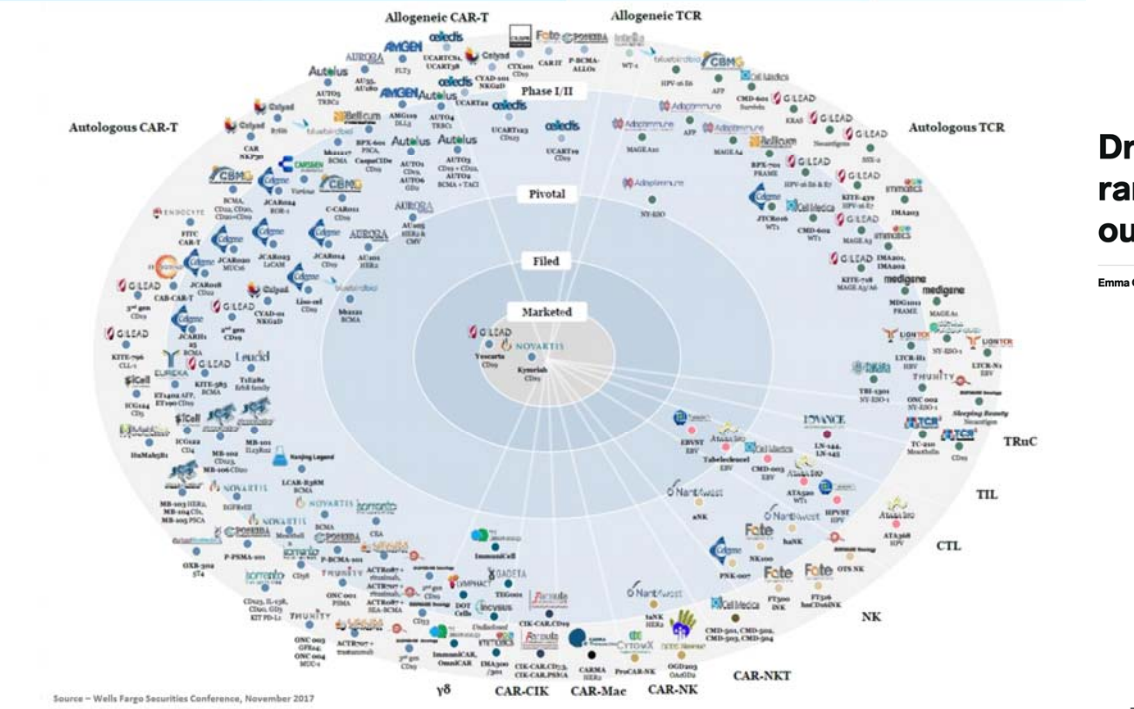
Improving Upon CMS' Basic 65% Proposal…



Implications for Future Cell and Gene Therapy Products

The Future is Now…Whatever CMS Does With Coverage, Coding/Billing, and Reimbursement is Precedent-Setting

Adoptive Cellular Therapy: Immuno-Oncology Landscape



COMMENTARY

We Need to Be Realistic About Gene Therapy

IDEAS

When a Treatment Costs $450,000 or More, It Had Better Work

Some biotech companies are offering a new way to soften the shock of drug prices: Insurers pay only if the patient improves.

APR 22, 2019

Drugs that cost as much as a house are on the way to treat rare and devastating diseases. The US is scrambling to figure out how to pay for them.

Emma Court Mar. 4,

How Are Gene Therapies Going To Get Paid For?

Joshua Cohen Contributor

Healthcare

THE PHARMALOT VIEW

If the states don't treat pharma as a utility, it may be 'lights out' for too many patients

By ED SILVERMAN @Pharmalot / APRIL 25, 2019

Understand the Ecosystem

Providers

- Important to be seen as cutting edge, but cannot risk organizational insolvency on a single product or therapeutic class
- Under greater pressure for price transparency
- A new therapy will be one of many providers need to be able to choose from – difficult ones may be ruled out of their arsenal until easier and/or more affordable

Payers

- Concerned about the influx of high cost new therapies;
- Risk of "opening up the floodgates" if they modify payment policy
- Payers = companies. 90% of large companies are self-funded. What is their value proposition for these bills?
- CMS outpatient payment (ASP+6%) is in the crosshairs – active attempts to reduce that will continue
- Coverage policies may be used to limit spend on these therapies
- Medicaid remains a wildcard

System & Political

- New era of high-cost therapies is highlighting structural issues around healthcare
- Congressional intervention?
- Dramatic provider decisions or new collaborations?

Implications for Future Therapies

Significant Initial Scrutiny

- ICER assessments likely
- All payer types will pay close attention to each step in the process – prior authorizations, slow claims adjudication, challenges from stop-loss payers
- Payment policy precedent may be hard to shake

Medicare Coverage and Payment

- Do not assume magic solution via NTAP, new DRG or the Innovation Center
- Factor in strong potential for CED – long timeline, indications may be narrower than label, variable outcome at the end
- Benefit category questions may impact FDA pathway/process

Provider Partnerships Essential

- Facility qualifications – accreditations, reporting capability, Centers of Excellence
- Long-term follow-up – at high prices, payers want data (registries, PROs)
- Clear and specific coding – large dollar amounts, claims scrutiny a must
- Outcome/milestone models – TBD on if they are useful and can be operationalized

Important Dates in 2019

- CMS' release of a revision to the April 1st Transmittal
- IPI/Drug Pricing – Spring 2019
- Final coverage decision – May 17th
- CY 2020 OPPS Proposed Rule – July 2019
- *FY 2020 IPPS Final Rule – August 2019*
- CY 2020 OPPS Final Rule – November 2019
- The next FDA approved products

Questions/Discussion

Thank you!

Presented by Jugna Shah, MPH
Nimitt Consulting, Inc.
www.nimitt.com

Special Thanks To:
- Valerie Rinkle, Principal, Nimitt Consulting Inc.
- Amy Rinkle, Policy Analyst, Nimitt Consulting Inc.