CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule Updates and Operationalizing New Technologies

Presented to LA HFMA August 29, 2022

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Health Policy Partners

Agenda

- Part I: CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule updates
- Part II: Operationalizing new technologies

Part I: CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule updates

- Key topics
 - Financial updates
 - 340B
 - Inpatient only (IPO) list
 - Remote behavioral health services
 - Pass-through payment
 - Prior authorization
 - Non-opioid pain management
 - Others...

OPPS proposed rule financial updates

- CMS proposed an increase of 2.7% for OPPS payment rates in CY 2023
 - This is based on a market basket update of 3.1%, reduced by a productivity adjustment of 0.4%
- CMS will increase the fixed-dollar threshold for outliers to \$8,350; a large increase over the current CY 2022 threshold of \$6,175
- Limit on wage index reduction to 5% (similar to IPPS) year over year

TABLE 84: ESTIMATED IMPACT OF THE CY 2023 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Numbe r of Hospit als	APC Recalibrat ion (all changes)	New Wage Index and Provider Adjustme nts	All Budget Neutral Change s (combin ed cols 2 and 3) with Market Basket Update	Propose d Rural SCH Exceptio n to Off Campus Provider Based Departm ent Visits Policy	All Chang es
ALL PROVIDERS		3,502	0.0	0.1	2.9	0.1	2.9
ALL HOSPITALS		3,411	0.1	0.2	2.9	0.1	3.0
	(excludes hospitals held harmless and CMHCs)						

The 340B case and OPPS

In 2018, CMS finalized a payment reduction for 340B-purchased drugs to -22.5% of ASP, from the ASP +6% that was previously in place;

•The AHA, among other entities, brought litigation for this change

In 2019, the court sided with hospitals in the lawsuit indicating that the Secretary had exceeded his authority and required CMS to cease and remedy harm to hospital

•CMS appealed the case but continued with the 340B payment reduction in CY 2020

On July 31, 2020, a higher court ruled that CMS' 340B payment reduction is legal, striking down the lower court's decision

•AHA appealed, and on July 2nd, 2021, the US Supreme Court agreed to review the circuit court's decision

On June 15, 2022, the Supreme Court held that absent a survey of hospitals' drug acquisition costs, CMS may not vary the reimbursement rates for 340B hospitals and CMS' 2018 and 2019 340B rates were unlawful

• Recall in the CY 2021 rule, as a result of a survey sent to hospitals, CMS considered an even larger reduction in 340B payments (-28.7%) but in the end finalized staying with -22.5%

The 340B case and OPPS (Cont.)

- While the focus of the SCOTUS decision was the 2018 and 2019 payment rates, it also will impact the CY 2023 rates
 - In the proposed rule, CMS stated that due to the timing of the SCOTUS decision they were unable to adjust their proposed payment rates in the OPPS proposed rule in response
 - Therefore, while CMS formally proposes a continued ASP -22.5% rate for 340B-purchased drugs/biologicals, in the final OPPS rule, CMS will finalize ASP +6%
- CMS states that the OPPS conversation factor will need to be decreased to account for any 340B payment increases (estimated to be about \$1.96 billion) to maintain budget neutrality
- CMS asked for comment on how to apply SCOTUS's ruling to address remedies for CY 2018-2022 payment rates
- Providers need to submit comments by September 13th to CMS to ensure an appropriate remedy is implemented

Inpatient Only (IPO) list

- Recap: in CY 2021, CMS reversed its longstanding IPO policy and decided to eliminate the IPO list, in a staggered way, over three years
 - However, in the CY 2022 OPPS final rule, CMS reversed its previous CY 2021 decision and reinstated the IPO list and codified five longstanding criteria that it uses to determine whether a service/procedure should be removed from the IPO list
- For CY 2023, CMS proposes to remove 10 services from the IPO list, and to add 8 services to the list that were recently created by the AMA CPT editorial panel for CY 2023
 - These services, if finalized, would be effective January 1, 2023

Remote behavioral health services

- Due to the COVID-19 Public Health Emergency (PHE), CMS issued numerous waivers, including one that has allowed patients to receive remote behavioral health services from hospital outpatient department clinical staff
 - This is for services performed by clinical staff of a hospital using telecommunication technology, originating from the hospital location to beneficiaries in their homes
- CMS is proposing to pay these services under OPPS as covered outpatient services, after the PHE expires
 - To accomplish this, CMS is proposing OPPS-specific coding to describe the services
- To qualify, patients would need to receive an in-person service 6 months or less before the first remote visit, and every 12 months after the remote visit
 - CMS proposes to permit providing these services via audio-only technology, to improve health equity
- This proposal reflects longstanding desires from providers for coverage/payment under OPPS for remote services

Prior authorization updates

- In the CY 2020 OPPS final rule, CMS finalized that hospitals must seek provisional affirmation of coverage before performing select outpatient services, and before a claim can be submitted
 - This initially applied only to five categories of services and then in CY 2021 CMS added two new categories of services
- For CY 2023, CMS is proposing to add the category of facet joint interventions
 - This would consist of facet joint injections, medial branch blocks, and facet joint nerve destruction

Rural Emergency Hospitals (REHs)

- New hospital type created as of 2022
- Provides emergency services, observation services and other outpatient services
 (designated by CMS) but no inpatient services and patient stays are limited to 24 hours
- May provide skilled nursing facility services in a distinct part unit
- Paid OPPS rates +5% and \$268,294 per month (updated by the hospital market basket) and rates for non-OPPS services without 5% bonus
- To qualify, must have been a CAH or rural hospital under 50 beds as of 12/27/2020
- CMS proposed to subject REHs to CAH conditions of participation (with proposed amendments)

Refund for drug wastage

- Section 90004 of the Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for discarded amounts from administration of single dose vials over 10 percent of the drug's cost
- This will be calculated from provider reporting JW modifier that is used to bill for wastage
- CMS is concerned that providers do not accurately report wastage (as they are currently paid the same without or without any wastage), so proposes a new modifier JZ that attests to no wastage
- CMS will be initiating audits on drug wastage.

Payments for domestic manufactured N95 masks

- Domestic manufactured National Institute of Occupational Safety and Health (NIOSH) approved N95 masks are more expensive than other masks and were in high demand during the PHE
- CMS proposes a subsidy through the Medicare cost report based on the marginal cost of domestic NIOSH approved N95 masks relative to non-domestic NIOSH approved N95 masks
- Complex methodology to determine OPPS and IPPS shares of the cost
- Made budget neutral under the OPPS consistent with statutory authority and not budget neutral under the IPPS as no budget neutrality is mandated
- New supplemental cost report form for reporting cost
- May rely on a written statement from the manufacturer that the N95 is domestically manufactured

Round up of other proposals

- G0463-PO 60% Reduction
 - CMS proposes not to apply the reduction to rural sole community hospitals
- Additional payment proposals
 - CMS proposes to pay for "software as a service" when used to evaluate existing images
 - CMS proposes to not count organs used in research in Medicare share of organ acquisition costs
- ASCs
 - CMS proposes an analog to a complexity adjusted C-APC for ASCs that relies on specific HCPCS level II codes
 - CMS proposes to maintain its current separate payment policy for non-opioid pain management drugs and biologics that function as supplies in the ASC setting for FDA approved products that are indicated for pain management or that serve as an analgesic

Part II

- Taking Stock: How well do you operationalize new technologies?
 - Cost-based reimbursement and stem cell transplant
 - Novel high-cost therapies like CAR-T approved for new technology add-on payment (NTAP)
 - New high-cost devices
 - Future therapies, including \$2M gene therapies

Is your institution maximizing its reimbursement for stem cell transplant as well as new technologies that have been approved for NTAP from Medicare?

Medicare

Cost or Cost Passthrough (Regardless of Care Setting)

Best for providers, but not unlikely to happen

- Given high cost of new technologies and therapies, and how it would set a precedent, unlikely CMS would set up costbased reimbursement
- Requires Congress to act; which we saw occur for the payment of donor search and cell acquisition costs for allogeneic stem cell transplant

Inpatient

New Technology Add-on Payment (NTAP)

- Regular pathway to request separate additional payment for a period of 2-3 years
- Granted to most drugs, biologicals, and cell therapies that meet the newness, significant cost, and substantial clinical improvement criteria
- Capped at 65% of product cost

New MS-DRG

• **Not likely** from the outset

Outpatient

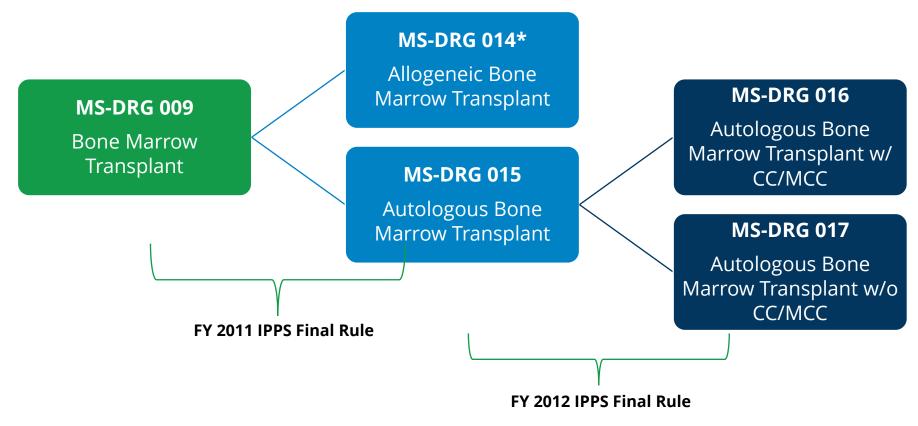
Pass through payment

- Regular pathway to request separate additional payment for a period of 2-3 years
- Granted to all drugs, biologicals, and cell therapies with payment based on the average sales price (ASP) plus 6% for all hospitals

New Technology APC

 Can be created from the outset for truly new technologies Do you provide allogeneic stem cell transplant? If yes, are you aware of the cost reimbursement mechanism CMS has implemented?

Medicare's bone marrow/stem cell transplant payment groups (MS-DRGs)



^{*}MS-DRG 014 <u>includes</u> payment for donor search & cell acquisition (i.e., NMDP invoices, labs/HLA testing of recipient, donor, siblings, etc.) through FY 2021

BACKGROUND: PAYMENT FIX

Legislation fixed the low reimbursement for alloHSCT

Key issues raised with Congress:



TCs lose hundreds of thousands of dollars treating Medicare patients, primarily due to Medicare's flawed methodology of accounting for donor search and cell acquisition



Financial losses are unsustainable and threaten patient access



Donor search and cell acquisition costs should be reimbursed separately at reasonable cost (somewhat like solid organ)

Successful Result!

The Patient Access to Cellular Transplant (PACT) Act language was introduced first in 2018 and again in 2019

The legislation called for Medicare to reimburse donor search and cell acquisition costs on a <u>reasonable cost</u> <u>basis</u>, <u>separate from the MS-DRG payment</u>

Section 108 of the Further Consolidations Appropriations Act (FCAA) was signed into law 12/20/19.

Understanding the specifics of Section 108

Effective for PPS hospitals starting with cost reporting periods beginning on or after October 1, 2020 for inpatient discharges

MS-DRG 014 + interim biweekly payments based on historical data reported in the Provider Statistical and Reimbursement (PS&R) report reduced to cost & divided by 26; updates can be requested quarterly

No change to the definition of donor search and cell acquisition costs charges as defined in Pub 100-04, Ch. 3, Section 90.3.3.A & Ch. 4 Section 231.11

Hospitals to maintain itemized statements; estimated payments will be reconciled at cost report settlement with actual acquisition costs incurred

Hospitals must continue reporting donor search and cell acquisition charges in revenue code 0815 on the recipient's transplant claim

Utilization of cost report line 0077 along with the implementation of new cost reporting worksheet D-6 (final instructions still pending) necessary for cost reimbursement

STATUTE REQUIRES MEDICARE TO REIMBURSE DONOR SEARCH AND CELL ACQUISITION AT COST

Cost reimbursement is a HUGE reimbursement opportunity...

But what will qualify for cost reimbursement under Section 108 Section 108 of the Further Consolidations Appropriations Act (FCAA) was signed into law 12/20/19.

And who will decide? When?

Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended--

(1) <<NOTE: Effective date.>> in subsection (a)(4), in the second sentence, by inserting `for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for

[[Page 133 STAT. 3103]]

the purpose of an allogeneic hematopoietic stem cell transplant (as described in subsection (d)(5)(M)),'' after ``October 1, 1987),'';

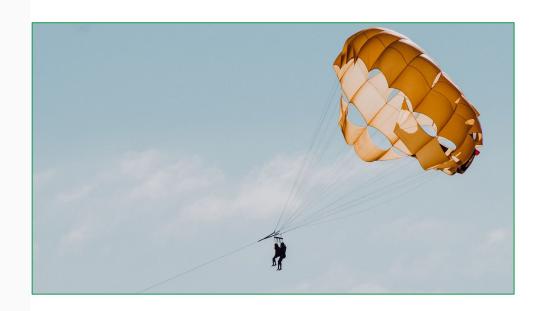
- (2) in subsection (d) --
 - (A) in paragraph (4)(C)(iii)--
 - (i) by inserting ``or payments under paragraph
 (5)(M) (beginning with fiscal year 2021)'' after
 ``fiscal year 1991)''; and
 - (ii) by inserting ``or payments under paragraph (5) (M)'' before the period at the end; and
 - (B) in paragraph (5), by adding at the end the following new subparagraph:

``(M)(i) <<NOTE: Effective date.>> For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual during such a period, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis. The items included in such hematopoietic stem cell acquisition shall be specified by the Secretary through rulemaking.

``(ii) <<NOTE: Definition.>> For purposes of this subparagraph, the term `allogeneic hematopoietic stem cell transplant' means, with respect to an individual, the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.''.

Medicare Codification of Donor Search and Cell Acquisition Costs*

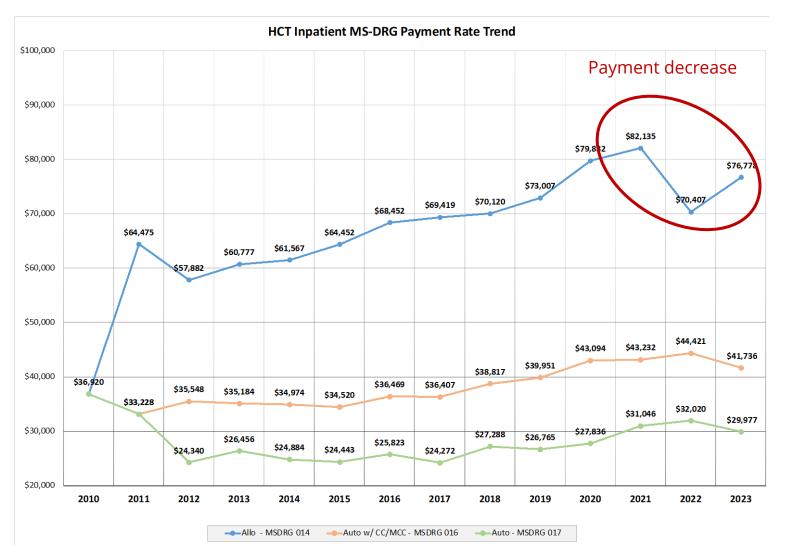
- (e) Allogeneic hematopoietic stem cell acquisition. For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis.
 - (1) An allogeneic hematopoietic stem cell transplant is the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.
 - (2) Allogeneic hematopoietic stem cell acquisition costs recognized under this paragraph (e) are costs of acquiring hematopoietic stem cells from a donor. These costs are as follows:
 - (i) Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.
 - (ii) Tissue typing of donor and recipient.
 - (iii) Donor evaluation.
 - (iv) Physician pre-admission/pre-procedure donor evaluation services.
 - (v) Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services), and transportation costs of stem cells if the recipient hospital incurred or paid such costs.
 - (vi) Post-operative/post-procedure evaluation of donor.
 - (vii) Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).



30,000 ft question... what new cell therapy/donor sources will qualify for cost reimbursement under Section 108 and who will decide

FY 2022 and beyond: the new payment reality

- MS-DRG 014 only covers patient care costs since donor search and cell acquisition are now being paid separately through interim payments and cost settlement
- Given the new opportunity for cost reimbursement, what else might fit under Section 108?



Taking stock: where does your transplant center stand?

- ✓ Is revenue code 0815 being used?
- Are all actual related and unrelated charges being captured and reported in revenue code 0815?
- Is standard cost center (line 77) for "Allogeneic Stem Cell Acquisition" in the cost report?
- Does the Medicare Administrative Contractor (MAC) need to be asked to update the interim payment amount?
- Can donor expenses and revenue be matched up?

- Is there a process in place to review accounts to ensure everything is flowing the way it should be?
- Is there a system in place to retain itemized department charges for related donor services?
- Have Medicare Advantage contracts been reviewed and/or adjusted?
- Does everyone in the organization understand

 what is required in terms of coding, billing,
 charging, and utilization of the new cost reporting
 instructions?

SUMMARY

Implications of not being ready

- If revenue code 0815 is not being used, transplant centers will not receive the correct interim payment
- If cost report line 0077 and worksheet D-6 are not used completely and correctly, cost reimbursement will be compromised
- Overall decrease in reimbursement will be experienced if only MS-DRG 014 is received along with low or no interim payments or cost settlement
- Medicare Advantage (MA) rates are likely to decrease unless providers renegotiate their contracts
- Medicaid rates may be impacted so need to review

Do you provide novel cell and gene therapies such as Chimeric Antigen Receptor T-cell (CAR-T) therapy, or are you planning to?

Cost concerns and misunderstandings

Study Finds Total Cost of Care for CAR-T, Post-Treatment

Events Can Exceed \$1 Million

April 13, 2021

Aislinn Antrim, Associate Editor

NOVEMBER 16, 2021

Hospitals Still Grappling With \$1 M+ Price Tag for CAR-T Rx

Improving Outcomes and Mitigating Costs Associated With

CAR T-Cell Therapy

August 18, 2021

Rebecca Borgert, PharmD, BCOP

Supplements and Featured Publications, Optimizing the Value of CAR T-Cell Therapy: Managements

Recent Clinical Findings, Volume 27, Issue 13

SEPTEMBER 20, 2021

Cost, Response Rates a Mixed Bag in CAR T-Cell Rx

October 28, 2021 4 min read

Earlier CAR-T treatment possible

if price comes down, FDA official

says

New technologies for many indications

- The product pipeline of costly cell and gene therapies will explode over the next three to five years, with price tags unlike what the provider community has ever seen.
- What does this mean in terms of coverage, coding, and reimbursement?
- Learning from how providers
 have operationalized CAR-T
 today may help streamline and
 maximize reimbursement in the
 future.

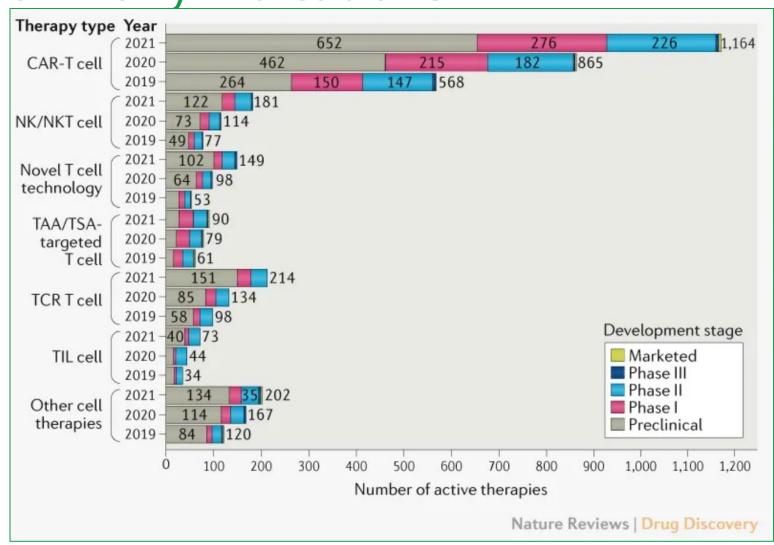


Image source: https://www.creative-biolabs.com/blog/car-t/overview-of-global-pipelines-of-cell-therapy-for-cancer/

BLAST FROM THE PAST

CAR-T approvals raised lots of questions initially

- The first FDA-approved CAR-T product was tisagenlecleucel (KYMRIAH®; Novartis) was approved in August 2017
 - Indicated for pediatric patients with relapsed/refractory (r/r) Acute Lymphoblastic Leukemia (ALL)
 - A panelist during the pre-approval Oncologic Drugs Advisory Committee (ODAC) meeting was quoted as saying CAR-T was "the most exciting thing I've seen in my lifetime"
- An approval for r/r Diffuse Large B-Cell Lymphoma (DLBCL) followed in October 2017
 - Axicabtagene ciloleucel (YESCARTA®; Kite Gilead)
 - DLBCL is typically diagnosed in older adults, of which a large proportion are Medicare beneficiaries
- The price for both therapies generated questions in the press about value, cost, effectiveness, and concern from hospitals about appropriate payment
- Questions began: What is CAR-T? And does the CAR-T biologic, along with its ancillary services of cell collection and processing fit, under existing coverage policies?

It's not a typical biologic: it is made from patient-specific T-cells

It's not a typical anti-neoplastic drug: it cannot be pulled "off-the-shelf"

It's not a typical transplant: it only contains a subset of immune

effector cells

SIGNIFICANT COST DETERMINATION

Significant cost determination announcement

On August 7, 2019, CMS released the NCD for CAR-T with coverage to label

7 Aug. 2019

Billing guidance released October 24th, 2019, explaining providers will be paid by regular fee-for-service Medicare for MA enrollees during calendar years 2019 and 2020; retroactive to NCD issue date

As of January 1, 2021, hospitals must bill MA plans directly

6 Sep. 2019

24 Oct. 2019

1 Jan. 2021

On September 6, 2019, CMS announced CAR-T was a significant additional and unplanned cost for Medicare Advantage (MA) Plans

MA Plans had 2020 to adjust their CY 2021 bids

2020

KNOWLEDGE · RESOURCES · TRAINING Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N MLN Matters Number: SE19024 Related Change Request (CR) Number: N/A Article Release Date: October 24, 2019 Effective Date: August 7, 2019 Related CR Transmittal Number: N/A Implementation Date: August 7, 2019 PROVIDER TYPE AFFECTED

Image source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19024.pdf

https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems[...]PMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2019-Week1-Sept-2-6

CMS made a "significant cost determination" for this NCD which meant from August 7, 2019 - December 31, 2020, Medicare FFS paid CAR-T claims rather than billing the MA plan

FUTURE THERAPIES AND COVERAGE

What can we expect for future CAR therapies?

- The current NCD for CAR-T is limited to:
 - Autologous CAR-T therapy
 - For cancer treatment
- The current NCD does not include the following which means it is silent:
 - <u>Allogeneic</u> CAR-T therapy for cancer
 - CAR-T for <u>indications other than treating cancer</u>
 - Other types of CAR immune effector cell therapies, such as CAR-NK, CAR-M products
 - Non-CAR cell therapies (TIL, iPSC, etc.)

Response: We appreciate the comment and recognize that CAR T-cell therapies are evolving with limited patient uses. This NCD is limited in scope to treatment with autologous T-cells. Allogeneic T-cell therapy is outside the scope of this final decision. CAR NK cells are outside the scope of this final decision. We are making this NCD in response to a formal request for an NCD from an outside party. We believe that a uniform national policy will be helpful to Medicare beneficiaries.

Image source: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=291

Working assumption: The more complex and high-cost a therapy is, the more attention it will draw and likely result in a NCA

CODING SUMMARY

CAR-T therapy: coding history

At time of launch

- Complication diagnosis codes lacking
- Non-product specific ICD-10-PCS codes used to report two different products; no visibility in the data of what products were administered
- Unlisted codes reported for cell collection, processing, and administration (if outpatient and physician reporting)

Visit the ASTCT website for free coding and billing resources, including a detailed coding and billing guide: https://www.astct.org/advocate/car-t-coding-and-billing-guide

1-3 years in

- New revenue codes released
- Value code released for reporting the cell therapy product cost
- Request for new diagnosis codes and request to streamline ICD-10-PCS codes
 lengthy process begun
- CPT codes released for the outpatient services of cell collection (0537T), processing (0538T and 0539T), and administration (0540T); payment separate issues altogether
 - Physician payment requires a letter to MAC
- CMS agreed to name all products
- Cost report line 78 exists but instructions unclear

3+ years to current

- Complication codes exist
- ICD-10-PCS codes streamlined
- Resolution achieved on most, but not all fronts
- Modifier –KX reporting required to indicate REMS certification
- Cost report line 78 instructions clarified to include product costs and cell collection and processing costs
- CMS finalized using condition code 90 instead of the remarks field to report a CAR-T expanded access case

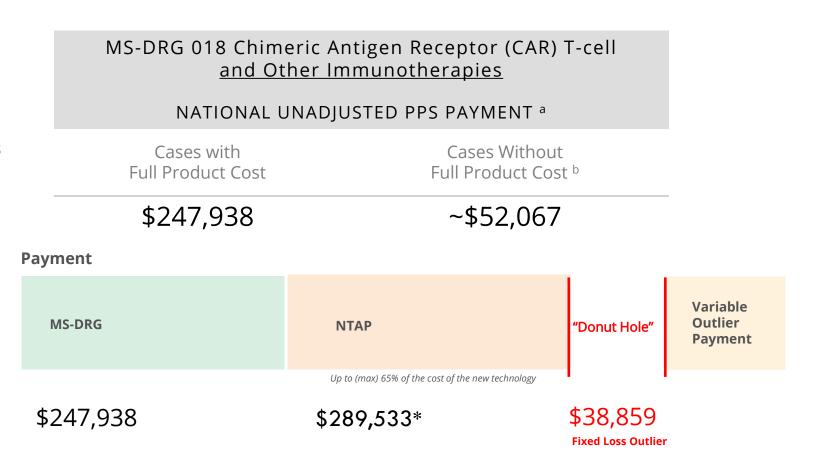
Medicare CAR-T inpatient & outpatient summary

FY 2018 FY 2019 FY 2020 FY 2021 FY 2022 FY 2023 (October 1, 2022 (Oct 1, 2017 -(Oct 1, 2018 -(Oct 1, 2019 -(Oct 1, 2020 -(October 1, 2021 - Sept 30, 2023) Sept 30, 2018) Sept 30, 2020) Sept 30, 2019) Sept 30, 2021) - Sept 30, 2022) MS-DRG 018 with a NFW CAR-T Non-Specific MS-MS-DRG 018 MS-DRG 016 MS-DRG 016 name change DRGs (\$7,000-**MS-DRG 018** INPATIENT (\$40,000)(\$43,127)(\$247,938)(\$242,500)\$18,000) (\$246,958) NTAP Approved at 1 new product NTAP Approved at 2 new NTAPs NO NTAP 50% cap of 65% cap of No NTAP granted; with merged into 1 \$186,500 \$242,500 various caps NTAP Outlier Outlier Outlier Outlier Outlier Outlier ASP + 6% (non-340B) Once pass through expires for a product, Pass-Through the payment varies based on whether the Payment = **OUTPATIENT** hospital is a 340B purchasing provider ASP + 6% ASP- 22.5% (340B)

FY 2023 IPPS FINAL RULE

MS-DRG 018

- CMS continues to exclude clinical trial claims and claims with pharmacy charges < \$373,000 from rate-setting
- Payment adjuster will increase to 0.21 for cases without product cost
- National unadjusted payment rate increases slightly due to overall payment system updates, but the relative weight decreases
 - FY 2022 weight = 37.4501
 - FY 2023 weight = 36.1452
- Expanded access cases to be billed with condition code 90 instead of remarks field
- Three CAR-T products that map to MS-DRG
 018 are eligible for NTAP
 - Tecartus
 - Abecma
 - Carvykti

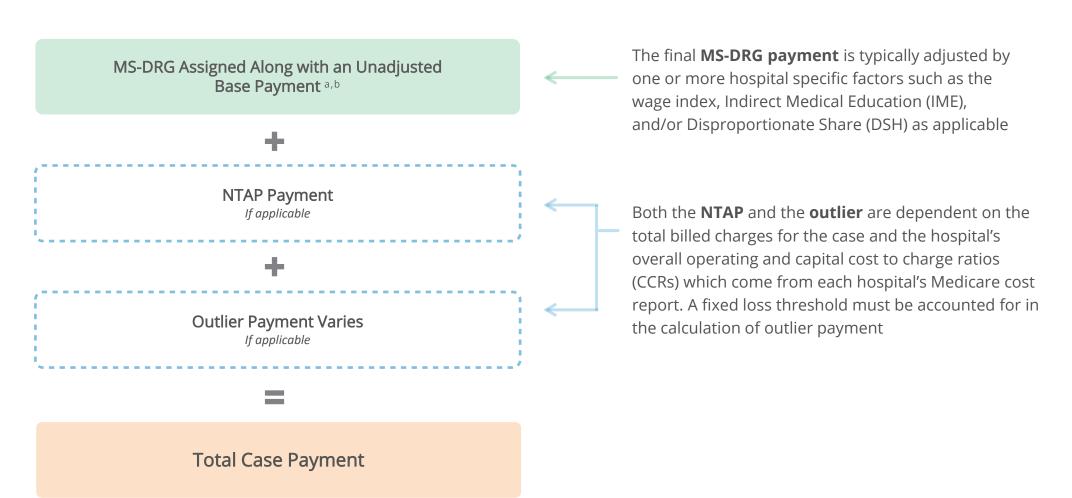


^{*} Amount shown is 65% of the list price of two CAR-T products with NTAP, which CMS finalized for FY 2023

#1 Question I am asked:

"How are hospitals doing with inpatient Medicare CAR-T reimbursement?"

Payment components of the IPPS



^a Also called a national rate since it's before hospital-specific adjustments are applied, such as wage index, indirect medical education (IME) & disproportionate share hospital (DSH). The outlier calculation is also hospital-specific.

^B Certain hospitals such as PPS-exempt cancer hospitals (PCHs), children's hospitals, and critical access hospitals (CAHs) are paid differently

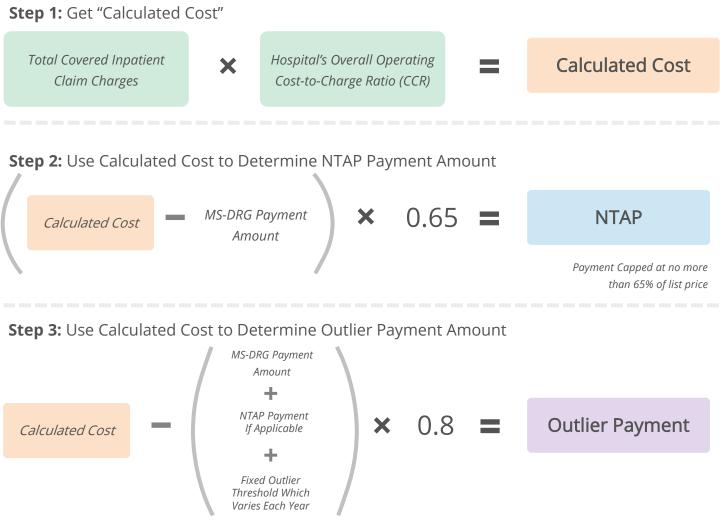
REVIEW OF THE FORMULAS

NTAP and outlier

Step 1: For both formulas CMS computes
 "calculated cost" by taking total inpatient billed
 charges multiplied by the hospital's operating CCR

 Step 2: NTAP is a separate additional payment for 2-3 years of no more than 65% of the cost of the new technology which is pre-determined by CMS

 Step 3: CMS' computed calculated cost for the case is compared 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



Variation in two hospital's charging practices

Both hospitals:

- Are certified to provide Chimeric Antigen Receptor T-cell (CAR-T) therapy
- Pay the manufacturer \$445,435
- Have a wage-index of 1.0 and no other adjustments*
- Have an overall operating CCR of 0.25
- Have the same patient care charges
- Have different CAR-T product charge due to their mark-up practices

Example Inpatient Hospital CAR-T Claims

Hospital A						
Markup 110%						
FL 42 Revenue Code	FL 43 Description	FL 46 Units	FL 47 Total Charges			
0121	Room & Board	14	\$63,000			
0250	Pharmacy	100	\$45,000			
0270	Supplies	20	\$13,000			
0300	Laboratory	520	\$32,000			
All other dept. charges (radiology, etc.)	All other	50	\$75,000			
0891* Detailed drugs		1	\$489,979			
0001	Total charges		\$717,979			

Hospital B							
Markup 400%							
FL 42 Revenue Code	FL 43 Description	FL 46 Units	FL 47 Total Charges				
0121	Room & Board	14	\$63,000				
0250	Pharmacy	100	\$45,000				
0270	Supplies	20	\$13,000				
0300	Laboratory	520	\$32,000				
All other dept. charges (radiology, etc.)	All other	50	\$75,000				
0891*	Detailed drugs	1	\$1,781,740				
0001	Total charges		\$2,009,740				

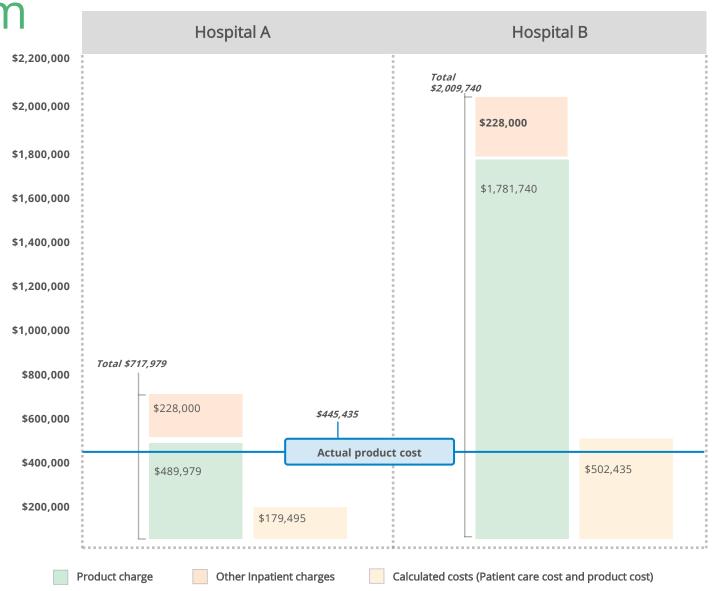
^{*}Hospital adjustments (WI, IME, DSH) were not utilized in this example but are important to account for when calculating hospital-specific reimbursement estimates.

CASE EXAMPLE 1

Calculated cost from billed charges

- Hospital A and B have different total charges
- CMS determines the "calculated cost" by multiplying the total billed charges by the hospital's overall operating CCR, which, is 0.25 for both hospitals in this example
- Because of the difference in total charges between Hospital A and B, CMS calculates a VERY different cost for each hospital

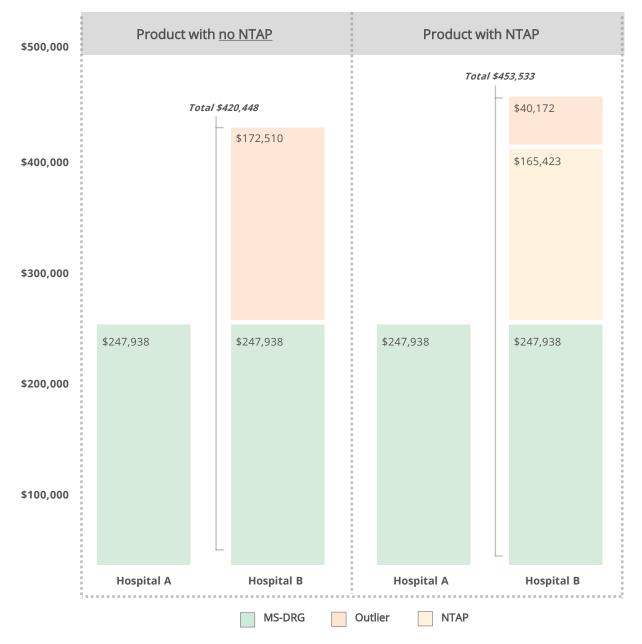
Note: "calculated cost" does not equal "actual cost;" yet this is the information used in determining Medicare payment



Payment impact with and without NTAP

Adjustments and charging practices matter

- Graphs show that appropriate charging is the key to getting outlier payment and NTAP
- MS-DRG 018 for CAR-T and other immunotherapies has been assigned
- Adjustments such as IME and DSH are applied if applicable for each hospital and these can have a significant impact on the final hospital payment amount as can the adjusted outlier payment



Most recent guidance from CMS from the FY 2021 and FY 2022 rules?



"[w]ith respect to the commenters who expressed concerns about hospital charging practices, we note that there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs."

(CMS reiterated this again in the FY 2022 IPPS Final Rule)

LOOKING AHEAD

Some reasons why providers still do not set charges appropriately

- Lack of understanding of what Medicare's PRM guidance that all payers have to be charged the same price ("gross charge") means in terms of what is billed to the payer
- Lack of knowledge about how:
 - Medicare's NTAP and outlier calculations work
 - Today's claims data is used to set future Medicare payment
 - Commercial contracts do not have to be negatively impacted since discount deductions can be taken
 - CMS allows charges to be set in accordance with CCRs which means mark-ups are allowed
- Staff turnover
- Manual work steps often required may feel "too hard"
- Concern around optics of marking-up already high-cost items
- Local market competitive pricing concerns

CHARGES IMPACT NTAP AND OUTLIER FOR NEW TECHNOLOGIES

Decoding CMS long-standing views on setting charges

In the 2006 OPPS Final Rule (70 Federal Register 68654), CMS stated:

"...We believe that hospitals have the ability to set charges for items properly so that <u>charges converted to costs can appropriately account fully for their acquisition and overhead costs....</u>"

From the Provider Reimbursement Manual, Part 1, Chapter 22

Section 2203: "[E]ach facility should have an established charge structure which is <u>applied uniformly to each patient</u> as services are furnished to the patient and which is <u>reasonably and consistently related to the cost of providing the services</u>"

Section 2202.4: "Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients' charges used in the development of apportionment ratios should be recorded at the gross value; (i.e., charges before the application of allowances and discount deductions)"

- The language from the 2006 OPPS final rule gives providers permission to mark-up appropriately
- CMS' language <u>requires</u> "the same" gross charge (i.e., CDM "list price") be posted for all patients receiving the same service
- CMS' language <u>allows</u> for contractual adjustments either pre-or-post billing, which means providers can apply an appropriate mark-up to each purchased item/service, etc. in order to get full reimbursement from Medicare—while <u>also</u> meeting commercial payers' contractual requirements related to carveouts, invoice cost, or other provisions

What does the future hold?

- Recall that MS-DRG relative weights in general are impacted by a number of factors including the following:
 - Volume and types of cases from providers
 - Provider charging practices
 - Composition of the MS-DRG including what new things are added to the DRG
 - With the case of MS-DRG 018, CMS' unprecedented rate-setting methodology
- MS-DRG 018 also impacted by CMS' unprecedented rate-setting methodology

As these things change, so too will the relative weight...

HOMEWORK

Provider Checklist for CAR-T

- Are you more like Hospital A or B? Do your charges need updating?
- Is the CAR-T product charge being reported in revenue code 0891?
- What methodology is being used to report cell collection and processing given CMS' multiple options on how this can be handled?
- Is there a process in place to review accounts?
- Are complications being captured?
- Are the new ICD-10-PCS codes being used?

- Is physician reimbursement being sought from the MAC for CAR-T administration?
- Are CMS instructions being followed on reporting cases correctly when there is no cell therapy product cost incurred (expanded access and clinical trials)?
- How is your payer contracting department structuring commercial contracts, Medicare Advantage, Medicaid, etc.?
- Are you reporting modifier –KX?
- Are you seeing denials?

Given providers struggle to charge appropriately today, what will happen with the pipeline of novel cell and gene therapies that will have prices over \$2M?

With \$2.8M gene therapy, Bluebird sets new bar for US drug pricing

The company will offer an up to 80% refund if the treatment, sold as Zynteglo, doesn't work as expected.

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Questions and Discussion