CMS Super Session: CAR-T & Cellular Therapy Coverage, Coding, Reimbursement & Policy Updates

TCT Meeting
February 19, 2020

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ASBMT Policy, Coding, and Reimbursement Advisor
2019: Medicare Year In Review
(or, “why you felt so tired last year”)

February/March
- Wild speculation at TCT meeting
- NCA comment period
- ICD-10 toxicity code presentation postponed
- CMS cell processing transmittal 😊

April
- IPPS proposed rule
- NUBC meeting to discuss new CAR-T revenue codes
- Revenue code 891 goes live

May
- HCPCS Q-code meeting déjà vu
- Transmittal corrected! (kind of)
- NCD decision delayed

June/July
- IPPS comments due
- Hill advocacy and CMS meetings
- OPPS/MPFS issued – no changes proposed

August
- IPPS Final Rule: NTAP cap upped to 65%
- Outpatient hospital advisory panel meeting
- Final CAR-T NCD released!

September/October
- NCD significant cost decision made in September and transmittal released (finally) in October
- ICD-10-CM public presentation of toxicity code request
- Medicare Advantage CAR-T questions begin

November
- CMS deadline to request a New CAR-T MS-DRG for FY 2021
- Massive advocacy to make the final push for CAR-T toxicity codes

December
- PACT Act Passed!
- CMS Leadership/Staff Meetings
- ICD-10-CM final deadline for new codes for FY 2021
- Follow up request for more info on toxicity codes from NCHS – good sign!

Jan/Feb 2020
- CMS meetings & political level discussions
- ICD-10-CM CRS toxicity diagnosis codes finalized for FY 2021
- Annual Support Group Meeting (aka TCT!)
### CAR-T Coverage Overview

<table>
<thead>
<tr>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Most commercially insured patients have coverage for Yescarta and/or Kymriah</td>
<td>• State-by-state decisions</td>
<td>• National Coverage Decision announced <strong>August 7, 2019</strong></td>
</tr>
<tr>
<td>• Some limitations from specific plans may exist</td>
<td>• No uniformity = high variability</td>
<td>• Nationwide coverage when:</td>
</tr>
<tr>
<td>• Experimental or investigational denials may be attempted</td>
<td>• Approved vs. actually paid</td>
<td>• Product is FDA-approved, and administered at healthcare facilities enrolled in the FDA REMS and used for a medically accepted indication</td>
</tr>
<tr>
<td></td>
<td>• Covered in-state vs. out?</td>
<td>• September 9, 2019, CMS announces “Significant Cost Determination (SCD)” for MA plans</td>
</tr>
<tr>
<td></td>
<td>• Covered inpatient vs. outpatient</td>
<td></td>
</tr>
</tbody>
</table>
Examples of KYMRIAH® (tisagenlecleucel) Medicaid FFS Policies with site-of-care requirements as of January 2020:

**Inpatient:** Colorado, Florida, Minnesota, Missouri, Pennsylvania

**Outpatient:** Texas, West Virginia

**Not Specified:** California, New York, Oklahoma, Minnesota, Maine, Virginia, Arizona, Montana, Utah, Washington, Wisconsin and Iowa
Medicare’s Final Decision Memo: Better Late than CED

Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)

What does this mean for Medicare Advantage (MA) beneficiaries?
CAR-T NCD and Significant Cost

• About a month later, on September 9, 2019 CMS announced that CAR-T was determined to be a significant additional and unplanned cost for MA Plans.

• Medicare Advantage (MA) plans required to provide the same benefits as Medicare Fee-for-Service (FFS)
  • Reference in Chapter 4, Section 10.2 of the Medicare Managed Care Manual

• Billing guidance released October 24th, 2019 explaining providers will be paid by regular fee-for-service Medicare for Medicare Advantage enrollees during calendar years 2019 and 2020

• Medicare Advantage Plans to account for CAR-T products and services in their contract year 2021 bids
Poll: Your Real-World Experience with the SCD Billing Guidance

What has your center’s experience been with addressing Medicare Advantage for CAR-T since the significant cost decision transmittal?

– **Option 1:** Annoying but clear – few significant issues
– **Option 2:** Very frustrating – lots of rework, claw backs, and problems
– **Option 3:** Business as usual…our MA Plan doesn’t seem to know there was a change
Top Questions We Are Hearing about Medicare Advantage

• Since the significant cost transmittal states “…for 2019 and 2020”, doesn’t that mean all 2019 patients have to be paid under regular FFS Medicare?

• Should we bill Medicare FFS for the CAR-T product and MA for the inpatient stay?

• Do we still need to enter into single case agreement with MA plans?

• Who should we bill for cell collection and cell processing? Will MA pay for this separately from the CAR-T product and infusion?

• Does my Center have to treat Medicare Advantage patients?
Today’s Topics

- Reimbursement
- Coding and Billing
- Coverage
1-Slide Coding Summary

- Reporting cell administration is easy and follows normal coding and billing convention
  - Two inpatient ICD-10-PCS codes for facility reporting: XW033C3 or XW043C3
  - One hospital outpatient and physician billing infusion code: 0540T

- Reporting cell collection and cell processing does not follow normal coding convention; providers will see rejections from Medicare when these services are billed on outpatient claims but have options for billing
  - 0537T: collection
  - 0538T: outbound processing
  - 0539T: inbound processing

- Reporting the cellular therapy product follows normal billing convention but the charge set up may vary depending on how cell collection and processing are set up
  - Q2040
  - Q2042
  - [https://www.astct.org/practice/practice-resources/car-t-therapy-reimbursement-resources](https://www.astct.org/practice/practice-resources/car-t-therapy-reimbursement-resources)
Reminder: The National Uniform Billing Committee (NUBC) Finalized New Codes to Increase Billing Transparency

087x  Cell/Gene Therapy
Charges for procedures performed by staff for the acquisition and infusion/injection of genetically modified cells.

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

089x  Pharmacy - Extension of 025x and 063x
The category is an extension of 025x and 063x for reporting additional breakdown where needed.

<table>
<thead>
<tr>
<th>SubC</th>
<th>Subcategory Definition</th>
<th>Standard Abbreviation</th>
<th>Unit</th>
<th>HCPCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>RESERVED (Use 0250 for General Classification)</td>
<td>DRUGS/CELL THERAPY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Special Processed Drugs - FDA Approved Cell Therapy(^{\dagger})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-9</td>
<td>RESERVED</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{\dagger}\) Charges for drugs and biologies 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

But more changes are around the corner!

http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf
More Changes to Value and Revenue Codes Effective April 1, 2020

New Value Codes

a. Value: 87
   Categorization: Monetary
   Title: Gene Therapy Invoice Cost
   Definition: Invoice/acquisition cost of modified biologics. For use with Revenue Category 0892.
   Effective Date: 4/1/20

b. Value: 90
   Categorization: Monetary
   Title: Cell Therapy Invoice Cost
   Definition: Invoice/acquisition cost of modified biologics. For use with Revenue Category 0891.
   Effective Date: 4/1/20 (Replaces discontinued Value Code 86)

New Revenue Code

Value: 0892
Title: Special Processed Drugs - FDA Approved Gene Therapy
Definition: Charges for drugs and biologics for gene 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.
Standard Abbreviation: DRUGS/GENE THERAPY
Effective Date: 4/1/20

Changes due to separating cell from gene therapy in terms of acquisition cost (reported with the value code) and in reporting billed charges (reported with the revenue code)

Value code 86 for CAR-T will change to value code 90!
Why All the Controversy With Cell Collection and Cell Processing?

<table>
<thead>
<tr>
<th>US</th>
<th>THEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not sure</td>
<td>Variety of “unclear” reasons</td>
</tr>
<tr>
<td>- AMA approved and released CPT codes</td>
<td>- These services are part of the manufacture process</td>
</tr>
<tr>
<td>- Cell collection and cell processing are hospital services rendered to registered patients</td>
<td>- Isn’t this just like Provenge? Can’t we follow the Provenge model?</td>
</tr>
<tr>
<td>- No one is paying for these…not Medicare and not the manufacturer</td>
<td>- No benefit category exists…but if that’s true then why not also reject when reported on inpatient claims?</td>
</tr>
<tr>
<td></td>
<td>- Price of the product</td>
</tr>
</tbody>
</table>

How important is this issue to providers today vs. tomorrow?
What Are Providers To Do?

• Ignore cell collection and cell processing reporting since these costs are inconsequential relative to the product cost

• Report cell processing and cell collection separately even if rejections occur because at least CMS receives the data

• Build the dollars for these services into the charge for the CAR-T product Q-codes

• Drop outpatient charges for these services and report them on the inpatient administration claim (options exist on how)
And Now for Some GREAT News on Complication Codes for Cytokine Release Syndrome

The proposal for **Cytokine release syndrome** will be included in the October 1, 2020 addenda as follows:

<table>
<thead>
<tr>
<th>New subcategory</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>D89.83 Cytokine release syndrome</td>
<td>Code first underlying cause, such as: complications of transplanted organs and tissue (T86.89-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use additional code to identify associated manifestations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D89.831</td>
<td>Cytokine release syndrome, grade 1</td>
</tr>
<tr>
<td>D89.832</td>
<td>Cytokine release syndrome, grade 2</td>
</tr>
<tr>
<td>D89.833</td>
<td>Cytokine release syndrome, grade 3</td>
</tr>
<tr>
<td>D89.834</td>
<td>Cytokine release syndrome, grade 4</td>
</tr>
<tr>
<td>D89.835</td>
<td>Cytokine release syndrome, grade 5</td>
</tr>
<tr>
<td>D89.839</td>
<td>Cytokine release syndrome, grade unspecified</td>
</tr>
</tbody>
</table>

**Round II Begins:**
March 17-18, 2020 at the ICD-10-CM Coding Meeting in Baltimore

**Codes Won’t Be Available for Reporting Until October 1, 2020**
Looking Under the Medicare Claims Hood: Coding and Billing Feedback – 2018-2019

How we’re doing right now…

How we need to be doing…

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Medicare CAR-T Data: 368 cases from 59 providers
Source: Standard Analytic File; Oct 1, 2018 – June 30, 2019

Type of Case Breakdown
- Non-Trial Case: 67%
- Clinical Trial Case: 33%

Type of Hospital Breakdown
- Exempt Hospitals: 7 Providers (42%)
- PPS Hospitals: 52 Providers (58%)
Trendline: Decrease in Total Trial Cases Reported

Clinical Trend or Reporting Issue?

<table>
<thead>
<tr>
<th></th>
<th>Q4 2017</th>
<th>Q1 2018</th>
<th>Q2 2018</th>
<th>Q3 2018</th>
<th>Q4 2018</th>
<th>Q1 2019</th>
<th>Q2 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAF Non-Clinical Trial</td>
<td>13</td>
<td>28</td>
<td>40</td>
<td>64</td>
<td>58</td>
<td>87</td>
<td>103</td>
</tr>
<tr>
<td>SAF Clinical Trial</td>
<td>15</td>
<td>30</td>
<td>40</td>
<td>70</td>
<td>48</td>
<td>34</td>
<td>38</td>
</tr>
<tr>
<td>SAF Total</td>
<td>28</td>
<td>58</td>
<td>80</td>
<td>134</td>
<td>106</td>
<td>121</td>
<td>141</td>
</tr>
</tbody>
</table>
Poll: Your Real-World Experience with Billing Clinical Trials

How confident are you in your Center’s knowledge/ability on when to report the clinical trials Z00.6 diagnosis code?

–Option 1: Very confident
–Option 2: Not so confident
–Option 3: I have no idea
Poll: Your Real-World Experience Reporting Cases With No CAR-T Product Cost

How does your Center report a case where no CAR-T product cost has been incurred because of cell viability/manufacturing issues (also known as an “out of spec” product)?

– Option 1: As a clinical trial case using diagnosis code Z00.6
– Option 2: As a non-clinical trial case because this patient isn’t enrolled in a clinical trial per se
– Option 3: I have no idea
Further Breakdown of the FY 2019 SAF Data

- 42% of cases from 7 PPS-Exempt Cancer Centers
- 58% of cases from 52 PPS hospitals
- 33% of cases are clinical trials

*Note: revenue code 0891 charges from claims after April 1 not included in the charge averages since it's unclear how CMS will treat this information for FY 2021 rate-setting*
Non-Trial Pharmacy Charge Breakdown: Cases from Preliminary (3Qs) FY 2019 SAF

• Grading Curve: CMS multiples the $$$ submitted by 0.191 (national cost center for pharmacy)

• Honor Roll: 26% have charges of more than $1.5M!  
  – Change from last year

• Needs Improvement:  
  – 23% have drug charges below $100,000  
  – 63% have drug charges below $1M

Charge statistics for drugs in non-clinical cases of CAR-T DRAFT -- based on SAF data  
Adding revenue center 0891

The FREQ Procedure

<table>
<thead>
<tr>
<th>Revenue Center Total Charge Amount</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative Frequency</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0-$100,000</td>
<td>57</td>
<td>22.98</td>
<td>57</td>
<td>22.98</td>
</tr>
<tr>
<td>$100,000-$500,000</td>
<td>41</td>
<td>16.53</td>
<td>98</td>
<td>39.52</td>
</tr>
<tr>
<td>$500,000-$1,000,000</td>
<td>58</td>
<td>23.39</td>
<td>156</td>
<td>62.90</td>
</tr>
<tr>
<td>$1,000,000-$1,500,000</td>
<td>27</td>
<td>10.89</td>
<td>183</td>
<td>73.79</td>
</tr>
<tr>
<td>More than $1,500,000</td>
<td>65</td>
<td>26.21</td>
<td>248</td>
<td>100.00</td>
</tr>
</tbody>
</table>
The $8,950 reported in revenue code 891 is likely due to the holding and reporting of outpatient cell collection and processing charges.

<table>
<thead>
<tr>
<th></th>
<th>Number of Claims</th>
<th>Minimum Revenue Charges</th>
<th>Mean Revenue Charges</th>
<th>Median Revenue Charges</th>
<th>Max Revenue Charges</th>
<th>Standard Deviation of Revenue Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPS Hospital, Clinical Trial</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PPS Hospital, Non Clinical Trial</td>
<td>16</td>
<td>$ 8,950</td>
<td>$ 1,497,670</td>
<td>$ 1,495,547</td>
<td>$ 2,611,000</td>
<td>$ 849,235</td>
</tr>
<tr>
<td>PPS Exempt, Clinical Trial</td>
<td>*</td>
<td>*</td>
<td>$ 373,000</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>PPS Exempt, Non Clinical Trial</td>
<td>21</td>
<td>$ 373,000</td>
<td>$ 758,427</td>
<td>$ 932,500</td>
<td>$ 1,187,500</td>
<td>$ 254,142</td>
</tr>
</tbody>
</table>
Poll: Your Real-World Experience on Reporting CAR-T Product Charges

Did your Center utilize an appropriate CCR-based mark-up to develop its CAR-T product charge?

– Option 1: Yes, we know this is allowed and that it is important
– Option 2: Yes, but it’s not as high as it should be given how CMS uses the data in rate-setting
– Option 3: No, we continue to struggle with this
– Option 4: I have no idea
Poll: Your Real-World Experience on Reporting CAR-T Product Charges

Are you using revenue code 0891 to report your CAR-T product charge?

– Option 1: Yes
– Option 2: No, we use revenue code 25x or 63x
– Option 3: I have no idea
### ICU Days and % of Charges

MedPAR FY 2018 Final Rule data has **43%** of cases (152 out of 356) with reported ICU days

<table>
<thead>
<tr>
<th>Number of Cases with ICU Days</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU Days</td>
<td>152</td>
</tr>
<tr>
<td>ICU Care Charges</td>
<td>152</td>
</tr>
<tr>
<td>ICU Charges as a Percentage of Total Charges (Excluding Drugs)</td>
<td></td>
</tr>
</tbody>
</table>

3 Quarters of FY 2019 SAF Data has **41%** of cases (152 out of 368) with reported days in ICU

<table>
<thead>
<tr>
<th>Number of Cases with ICU Days</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU Days</td>
<td>152</td>
</tr>
<tr>
<td>ICU Care Charges</td>
<td>152</td>
</tr>
<tr>
<td>ICU Charges as a Percentage of Total Charges (Excluding Drugs)</td>
<td></td>
</tr>
</tbody>
</table>
Today’s Topics

- Reimbursement (Medicare focus)
- Coding and Billing
- Coverage
FY 2020 Final Medicare MS-DRG Assignment and National CAR-T Payment Rate

- Inpatient CAR-T cases assigned to MS-DRG 016 based on the presence of one of two CAR-T ICD-10-PCS codes (XW033C3 and XW043C3) which are also required for the NTAP calculation

<table>
<thead>
<tr>
<th>MS-DRG 016 Title</th>
<th>National Unadjusted PPS Payment*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy</td>
<td>$43,127** (~$3,100 higher than FY 2019)</td>
</tr>
</tbody>
</table>

- National unadjusted PPS payment = payment before hospital specific adjustments are applied
- In addition to the MS-DRG payment, hospitals may receive additional payment in NTAP and outlier dollars
  - Remember both NTAP and outlier dollars 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. Charges are the prices for each service and drug in the chargemaster.

* PPS-exempt hospitals have a different payment mechanism
** CMS used clinical trial cases in setting the payment rate which results in a lower rate than would have been calculated otherwise
30,000 Foot Overview of Medicare Inpatient Payment System Specifics

Adjusted by one or more hospital specific factors such as the wage index, Indirect Medical Education (IME), and/or Disproportionate Share (DSH) as applicable

* 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
Big News for FY 2020! NTAP Formula Change

NTAP Cap Changes from 50% to 65%*

Nothing special for CAR-T

So What Does This Really Mean?

* One exception: qualified designated infectious products (QDIP) have a cap of 75%
Poll: Your Real-World Experience on Medicare Reimbursement

Is Your Hospital Receiving the Maximum NTAP of $242,500?

–Option 1: Yes, for sure!
–Option 2: No
–Option 3: I have no idea
Remind Me – Why Not Infuse in the Outpatient Setting Given the Poor Medicare Inpatient Payment

Reminder: outpatient services related to inpatient admission within a set period of time are paid under the inpatient rate

- Infusion occurs outpatient…but complications necessitate an inpatient stay…then what?
  - If Within 3 days: Inpatient Stay
  - If Within 1 day: Inpatient Stay

Medicare Has Paid for Very Few Outpatient Cases:
Less than 35 cases from 9 providers from January 1, 2018 – March 31, 2019
Facility CAR-T Service CPT Codes and CY 2019 and CY 2020 OPPS Final Payments

- New codes have been in effect since January 1st, 2019
- CMS only pays separately for 0504T; all other codes are assigned status “B”
  - CMS’ rationale for status “B”: 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)

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>SI</th>
<th>APC</th>
<th>Payment Rate</th>
<th>CI</th>
<th>SI</th>
<th>APC</th>
<th>Payment Rate</th>
<th>$ Chg in Pmt Rte</th>
<th>% Chg in Pmt Rte</th>
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</thead>
<tbody>
<tr>
<td>0537T</td>
<td>Bld drv t lymphcyt car-t cll</td>
<td>B</td>
<td></td>
<td>$0.00</td>
<td>B</td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>0538T</td>
<td>Bld drv t lymphcyt prep trns</td>
<td>B</td>
<td></td>
<td>$0.00</td>
<td>B</td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>0539T</td>
<td>Receipt&amp;prep car-t cll admn</td>
<td>B</td>
<td></td>
<td>$0.00</td>
<td>B</td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>0540T</td>
<td>Car-t cll admn autologous</td>
<td>S</td>
<td>5694</td>
<td>$288.38</td>
<td>S</td>
<td>5694</td>
<td></td>
<td>$309.56</td>
<td>$21.18</td>
<td>7.3%</td>
</tr>
</tbody>
</table>

**Bottom Line:** CMS has not yet recognized that these codes describe hospital services and should be separately reportable, recognizable, and ideally payable!
CAR-T Product Codes and Payment Rates for CY 2019 and CY 2020 Final

- Q-codes remain inclusive of clinical services despite significant advocacy for separation
- Separate product payment continues based on ASP +6%
- CMS has stated Q-codes function as J-codes; therefore no need to change

### Reminder: Patient co-payment is capped at the inpatient deductible amount which for 2020 is ~$1,400
2020 Physician Office Payment

- In the MPFS, CMS recognizes the CAR-T administration code by assigning a status “C” which means payment is determined by the carrier.

- CMS assigned the remaining three codes status “B” indicating they are bundled into some other service presumably provided on the same day.

<table>
<thead>
<tr>
<th>CPT / HCPCS</th>
<th>Description</th>
<th>Status</th>
<th>Work RVUs²</th>
<th>Non-Facility PE RVUs²</th>
<th>Facility PE RVUs²</th>
<th>Mal-Practice RVUs²</th>
<th>Total Non-Facility RVUs²</th>
<th>Total Facility RVUs²</th>
<th>Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>0537T</td>
<td>Bld drv t lymphcyt car-t cll</td>
<td>B</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>XXX</td>
</tr>
<tr>
<td>0538T</td>
<td>Bld drv t lymphcyt prep trns</td>
<td>B</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>XXX</td>
</tr>
<tr>
<td>0539T</td>
<td>Receipt&amp;prep car-t cll admn</td>
<td>B</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>XXX</td>
</tr>
<tr>
<td>0540T</td>
<td>Car-t cll admn autologous</td>
<td>C</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>YYY</td>
</tr>
</tbody>
</table>

From MPFS: B = Bundled code; C = Carrier priced code

No changes finalized for CY 2020

- For ‘carrier priced’ prices the physician must contact the MAC and provide information describing the service and what it is similar to in terms of resource use in order to receive payment.

- Line items/services with status “B” will be denied but the entire claim will not. It is considered a best practice to report these codes to let CMS and AMA/CPT know the frequency of the service.
Poll: Your Real-World Experience on Receiving Physician Reimbursement

My Center has submitted a letter to our Medicare Administrative Contractor (MAC) to obtain separate physician reimbursement for CPT code 0540T for the infusion of CAR-T

– Option 1: Yes, we wrote the letter and are getting payment
– Option 2: No, it’s not worth the hassle for the low reimbursement
– Option 3: I have no idea
SELF AUDIT SUGGESTIONS

- Are we reporting the clinical trials diagnosis code Z00.6 accurately and consistently?
  *Ask your Health Information Management Department*

- Are we posting charges for cell collection and processing at the time it is provided?
  *Ask your Chargemaster Manager*

- Are we adding cell collection and processing charges to the CAR-T product charge line for Medicare/Medicare Advantage accounts?
  *Ask your Patient Accounting Manager*

- Are we seeking physician reimbursement from the MAC for CAR-T administration code 0540T?
  *Ask your Finance Director*

- Do we report our CAR-T product charge in revenue code 0891?
  *Ask your Chargemaster Manager*

- Am I receiving the maximum NTAP payment possible from CMS?
  *Ask your Finance Director or Chief Financial Officer*

- Are MA plans paying us correctly?
  *Ask your Managed Care Director*

- Have we analyzed whether payment from early single case agreements with commercial payers appropriately cover our case cost?
  *Ask your Managed Care Director*
The Path Ahead: How Will Medicare Pay for Inpatient CAR-T in FY 2021?

- NTAP to expire – September 30, 2020
  - Will CMS extend NTAP for another year?

- Will CMS create a new MS-DRG for CAR-T?
  - What will it look like?
  - Which cases/claims data will CMS use?
  - Will it facilitate or hamper patient access?

- What do we know about CMS’ early thinking for FY 2021?
What CMS Requested Comments on for FY 2021:

<table>
<thead>
<tr>
<th>The most appropriate way to develop the relative weight for a new MS–DRG</th>
<th>How to address the significant number of cases involving clinical trials</th>
<th>Other approaches for setting the relative weight if it were to finalize a new MS–DRG</th>
<th>Whether to geographically adjust the payment for any new MS–DRG or apply adjustments to a lower proportion of payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whether to use IME and DSH payments or whether a reduced applicable percentages should be used</td>
<td>Ability to use its exceptions and adjustments authority to implement various changes (this could be good or bad)</td>
<td>Payment alternatives and how these payment alternatives would affect access to care/affect incentives to encourage lower drug prices</td>
<td></td>
</tr>
</tbody>
</table>
## What Commenters Told CMS:

**Should:**
- Create a new MS-DRG for FY 2021
- Apply the usual adjustments
- Exclude clinical trial cases from rate-setting
- Carve out the product payment from patient care costs
- Extend NTAP until enough data is available to establish new, adequately paying MS-DRG

**Should NOT:**
- Eliminate NTAP without figuring out proper payment for inpatient CAR-T
- Keep CAR-T cases in MS-DRG 016
- Follow usual rate-setting methodology given variability in provider charging practices
- Eliminate the use of adjustments such as wage index, IME, and DSH
Hope? (Or Nope?)

“I’m equally frustrated about the challenges that we’ve had with figuring out how to pay for CAR-T,” Verma said. “CAR-T came out and it was available in the fall of 2017, and here we are — almost two years later and we’re struggling to figure out what the reimbursement should be.”

Verma insists her agency is hamstrung by existing laws that required a certain level of data before CMS can set reimbursement rules specific to CAR-T. That data doesn’t currently exist, she said, partially because the therapies are so new. She also insists some hospitals are making the existing system work — negotiating hard and cobbling together payments from CMS to make sure they’re not losing money.
Reasons CMS’ Might Be Resistance to Change

**Typical CMS’ Constraints**
- Part A Trust Fund and pipeline concerns
- Questions about care setting
- Statutory authority
- Regulatory processes and timelines
- PPS is a system of averages
- Opening the floodgates for more “unique/one-off requests if it extends NTAP or changes rate-setting method
- Political environment around drug pricing

**Cards CMS Has Played**
- Granted NTAP to CAR-T
- Increased NTAP cap from 50 to 65%
- Finalized an NCD with few requirements
- Outpatient product payment “robust” at ASP+6%
- Considering new MS-DRG for 2021
- Significant staff time and resources spent on CAR-T discussions
The View From CMS’ Seat: Bracing for the Tsunami

By 2027, nearly half of U.S. health spending, or 47%, will be financed by federal, state and local governments as baby boomers age into Medicare, which will remain a key driver of overall healthcare outlays. In 2017, federal, state and local governments financed 45% of national health spending.

“Medicare spending growth is projected to average 7.4% over 2018-2017, the fastest rate among the major payers,” the CMS report said.
The View From CMS’ Seat: Bracing for the Tsunami (Cont.)

Figure 31

Number of Medicare Beneficiaries and Number of Workers Per Beneficiary, 2000-2050

In millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of beneficiaries (in millions)</th>
<th>Number of workers per beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>4.0</td>
<td>39.7</td>
</tr>
<tr>
<td>2010</td>
<td>3.4</td>
<td>47.7</td>
</tr>
<tr>
<td>2020</td>
<td>2.8</td>
<td>64.4</td>
</tr>
<tr>
<td>2030</td>
<td>2.3</td>
<td>81.8</td>
</tr>
<tr>
<td>2040</td>
<td>2.2</td>
<td>89.2</td>
</tr>
<tr>
<td>2050</td>
<td>2.3</td>
<td>92.8</td>
</tr>
</tbody>
</table>


Bottom Line: More Beneficiaries But Less Money At the Same Time The Tsunami is Coming
## Summary of Stakeholder Concerns

### Medicare Concerns
- **Funding**
  - Constrained by statues around funding pools, NTAP; CMS looks at the program overall

- **Lack of data**
  - Clinical & outcomes data, access data, cost off-sets, efficacy, durability

- **Infrastructure**
  - Existing infrastructure will not support new models; new investments and new ways of thinking along with new laws required

### Provider Concerns
- **Upfront costs**
  - Large purchase prices will cause cash flow problems; consider replacing buy and bill

- **Unsustainable Losses**
  - Private payer rates on current CARs are not able to offset Medicare’s poor reimbursement

- **Alternative Care Options**
  - Clinical trials, move to outpatient; in-house development; non-payment for cell collection/processing likely to become a bigger issue

### Industry Concerns
- **Value vs $$$**
  - High value therapies that patients need, costs to develop are high, our price is “right”

- **Long-Term Costs Lower**
  - Upfront costs are high, but downstream costs are averted; different analyses needed by payers

- **Patient Access**
  - Approvals coming but these therapies are only as useful as patients can access them and questions about price vs. access goals being asked
Can we convince CMS that it needs to change its 35+ year old inpatient payment system given the “new branch of medicine”? And that it needs to begin now before the full force of the cell and gene therapy pipeline hits?
Final Poll: What’s Your Gut Telling You?

For FY 2021, CMS will…

–Option 1: Extend NTAP because it needs time to figure things out
–Option 2: Create a new CAR-T MS-DRG that pays ~$250-400k?
–Option 3: Create a new CAR-T MS-DRG that pays well but eliminates application of all adjustments
–Option 4: Ignore us and go to the beach 😊 (i.e., rate-setting as usual)