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

TCT Meeting, Houston Texas - February 22, 2019

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Disclosures

- Jugna Shah
  - Has received consulting income in support of providing coding and reimbursement support and education to Novartis, Bellicum, Actinium, Miltenyi, and NOHLA

- Erika Miller
  - No disclosures
# Today’s Topics

## Part 1: Coverage and Advocacy (15-18 min)
- Ongoing Advocacy Initiatives and the Latest from CMSCAR-TNCA

## Part II: Coding, Billing, and Reimbursement Updates (30-35 min)
- Payments: FY 2019 IPPS and CY 2019 OPPS
- Coding and Reporting Conundrum
- Charge Description Master (CDM) and Billing Issues
- Changes on the Horizon and Creating Your To Do List!

## Part III: Payer Updates & Discussion (15-20 min)
- Hearing from 2-3 payers on key issues/considerations
PART I: COVERAGE AND ADVOCACY

- Advocacy Updates
- Medicare’s NCA Explanation
- NCA Advocacy and Next Steps
Review of the 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 84 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 68 Centers
- $373,000
- Q2041; Effective Date: April 1, 2018 with a slight description change as of January 1, 2019

**NEWS:** Novartis rescinded its fair market value contracting with providers for cell collection
Advocacy Update

Meetings and Events:
- CMS meeting on January 30, 2019
- Ongoing conversations with CMS Administrator’s office
- Meetings with majority and minority staff of Congressional committees of jurisdiction
- Journalism Briefing - Friday, Nov 16th
- Senate Finance Briefing - Tuesday, Nov 13th

Correspondence:
- Joint ASBMT/ASH letter submitted to CMS with short-and-long term proposals for CAR-T payment and coverage
- Joint ASBMT/ASH letter supporting new ICD-10-CM diagnosis complication codes for CAR-T
- Joint ASBMT/ASH/ASCO/CAP letter to MACs to ensure CAR-TCategory III codes are added to their existing local policy or article

What’s Next?
- Submission of appropriations report language on CAR-T
- Potential Congressional sign-on letter re: improving CAR-T reimbursement
The Latest Proposals Provided to CMS in a Nutshell

**IPPS Payment**: For FY 2020, implement a CCR of 1.0 to allow centers to receive maximum NTAP without markup and increase the NTAP amount available.

**Technical/Coding Changes**: CMS to adopt changes approved by the National Uniform Billing Committee (NUBC) for implementation April 1, 2019 and to use the data in its payment calculations.

**OPPS Payment**: Remove patient clinical services from CAR-T product Q-codes and recognize and pay for three new Category III CPT codes that describe these services.

**CMMI**: Consider 1) Case rate or episode payment, 2) Shared learning model or 3) Outcomes-based payment (after much more evidence is gathered).

**Coverage**: DO NOT create a prospective, comparative CED trial with a high provider data burden.
Additional News...

- ASBMT has formed a Government Relations Committee and has a new Director of Government Relations

- Other ongoing activities:
  - Continued engagement with CMS re: CAR-T reimbursement
  - RUC survey on evaluation & management services
  - Developing comments on multiple proposed rules and guidances from CMS and FDA respectively
  - FY 2020 Appropriations process kicking off
  - PCORI reauthorization
### Is CAR-T Covered?

<table>
<thead>
<tr>
<th><strong>Commercial</strong></th>
<th><strong>CMS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Most commercially insured patients have coverage for Yescarta and/or Kymriah</td>
<td>- No indication of non-coverage nationally</td>
</tr>
<tr>
<td>- May be limitations for specific plans and/or employer-sponsored groups</td>
<td>- Q codes and payment rates assigned under the outpatient setting; have not heard of rejected claims but MAC policies vary</td>
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<tr>
<td>- Experimental/investigational denial may be attempted</td>
<td>- In IPPS, it is a drug used in a part of a covered episode of care – i.e. treatment of lymphoma</td>
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</table>
Medicare NCA for CAR-T

CMS opened a National Coverage Analysis in May 2018

- Proposed decision available on February 15
- 30 day comment period
- Final decision will be issued in May 2019
  - If final decision retains CED, there may be an access delay while registry approval occurs and study protocol is developed, approved and center enrollment begins

ASBMT/CIBMTR/NMDP Comments – June 2018

- National coverage process initiation premature
- Will create barriers to patient access
- Concerns about CED

COMMENTS DUE MARCH 17!!!

CMS Coverage Proposal

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 NCCA 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
Coverage with Evidence Development

Requirements

- Registries must be reviewed and approved by CMS
- Prospective, national, and audited
- Accepts all manufactured products
- Follows patients for at least 2 years
- Answers specific questions with PRO for QOL and functional status for outpatients

Initial Reactions

- Less burdensome version of CED than what could have been implemented, but concerns exist about patient reported outcomes (PROs)
- CIBMTR likely to qualify as a registry
- Need to evaluate if coverage policy is broad enough re: types of CARs and patient condition
- Determining impact on patient access

Questions and Next Steps

**Questions**

- Should policy be expanded to cover allogeneic CARs?
- Should indications be expanded beyond relapsed or refractory cancer?
- Will CIBMTR qualify as a registry? Will CIBMTR need to make changes to qualify?
- Is it less burdensome to report PROs for inpatients and outpatients rather than just outpatients?
- Are there concerns about coverage for homebrew CARs?
- Others...

**Next Steps**

- ASBMT is working with stakeholders to answer these questions.
- Will be developing talking points and a response to be shared with members before March 17 deadline.

PART II: Coding, Billing, and Reimbursement Updates

- FY 2019 Medicare Inpatient Reimbursement
- CY 2019 Outpatient Reimbursement and the Coding Conundrum
- Charge Description Master (CDM) Set-Up and Billing Issues
- Changes on the Horizon
- Your Operational and Advocacy “To-Do” List
Question: Patients receiving CAR-T for Lymphoma in my Center are treated in:

A. Only the inpatient setting
B. Only the outpatient setting
C. Both care settings
D. Don’t know
Question: Medicare CAR-T cases are assigned to MS-DRG 016 based on:

A. ICD-10-CM diagnosis codes
B. ICD-10-CM procedure codes
C. CPT codes
D. HCPCS Q-codes for the CAR-T product
FY 2019 Final 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).

<table>
<thead>
<tr>
<th>MS-DRG O16 Title</th>
<th>National Unadjusted PPS Payment*</th>
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</thead>
<tbody>
<tr>
<td>Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy</td>
<td>$39,951</td>
</tr>
</tbody>
</table>

- 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.

- 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.

* PPS-exempt hospitals have a different payment mechanism.
Question: The new technology add-on payment, along with outlier payment provides our hospital with adequate Medicare payment

A. True
B. False
C. Don’t Know
The final MS-DRG payment is typically adjusted by one or more hospital specific factors such as the wage index, Indirect Medical Education (IME), and/or Disproportionate Share (DSH) as applicable and is also impacted by hospital charging practices and the operating cost-to-charge ratio (CCR) from the most recently filed 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”

\[
\text{Total Inpatient Charges on CAR-T Claim} \times \frac{\text{Hospital’s Cost-to-Charge Ratio (CCR)}}{X} = \text{Calculated Cost}
\]

**Step 2:** Use Calculated Cost to Get NTAP Payment Amount

\[
\frac{\text{Calculated Cost} - \text{MS-DRG Payment Amount}}{X} \times 0.5 = \text{NTAP Payment}
\]

Payment Capped at no more than $186,500
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.

\[
\text{Calculated Cost} = \text{MS-DRG Payment Amount} + \text{NTAP Payment Amount} + \text{Fixed Outlier Threshold of} \quad \text{\$25,769} \times 0.8 = \text{Outlier Payment}
\]
NTAP and Outlier Both Available for FY 2019

Summary of the Order of Operations

- **Step 1**: CAR-T cases are assigned to MS-DRG 016 (national unadjusted payment rate = $39,951)
- **Step 2**: The NTAP payment amount for the case is computed; capped at a maximum of $186,500
- **Step 3**: The outlier payment calculation is computed to see if any additional dollars are warranted after CMS compares the calculated cost of the case to the sum of the MS-DRG payment + the NTAP + the fixed loss outlier threshold
Question: We mark-up our CAR-T product charge in a manner consistent with CMS’ cost-estimation methodology of reducing billed charges to costs?

A. Yes
B. No because it would not be appropriate to charge patients so much
C. No, because managed care contracting won’t agree since it can impact our contracts
D. No, because it is wrong from a Medicare compliance perspective since all payers have to be charged the same
E. No, because we do not want to be on the front page of our local paper
F. No idea what you are talking about
Clinical Example to Demonstrate Current Payment Calculations Using Sample Claims

• Hospital and Patient Characteristics

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

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

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<thead>
<tr>
<th>Description</th>
<th>Units</th>
<th>Total Charges</th>
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<td>Pharmacy</td>
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<td>CAR-T Drug*</td>
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<td><strong>Total Charges</strong></td>
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<td><strong>$638,300</strong></td>
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<th>Description</th>
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<td><strong>Total Charges</strong></td>
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*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.*
Charge and Calculated Cost Variations for Hospital A and B

- Hospital A and B have different total charges
- CMS determines the “calculated cost” by multiplying the total billed charges by the hospital’s overall CCR which in our example is 0.25 for both hospitals
- Because of the difference in total charges between Hospital A and B, CMS’ calculated cost for each hospital is very different
- Note: “calculated cost” does not equal “actual cost”; yet this is the information used in determining Medicare payment
Calculated Cost for Each Hospital Impacts the NTAP and Outlier Payment Amounts Received

- **Calculated cost (patient care + product cost)**
  - Hospital A = $159,575
  - Hospital B = $430,000

- **Payment components**
  - MS-DRG 016 payment is the same for Hospital A and B since we haven’t applied any adjustments in our example
  - NTAP payment varies because total charges and calculated costs vary
  - Outlier payment varies because total charges and calculated costs vary

Both hospitals receive the an NTAP and Outlier payment, but these payments along with the MS-DRG payment do not cover even the cost of the CAR-T product let alone any patient care costs.
FY 2018 Medicare CAR-T Claims Data: What is Medicare Seeing?

- **N = 166 cases**
  - 53 with ICD-10 PCS Code: XW033C3
  - 113 with ICD-10 PCS Code: XW043C3
  - Average Length of Stay: 16.26

- **Non Clinical Trial Cases**
  - N = 81
  - Average LOS: 17.14

- **Clinical Trial Cases**
  - N = 85
  - Average LOS: 15.42

- **Averages**: Pharmacy Rev Code 250 Charges: $797,285
  - Total Charges: $1,031,593

- **Averages**: Pharmacy Rev Code 250 Charges: $95,962
  - Total Charges: $284,173
### CAR-T Product Charges

**Posted Publicly as of February 20th, 2019 for Hospitals with Medicare CAR-T Case Volume from Oct 1, 2017 – June 30, 2018**

<table>
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<tr>
<th>Number of CAR-T cases by PPS Hospital</th>
<th>Number of Clinical Trial cases</th>
<th>Q2040 CDM Posted Charge</th>
<th>Q2041 CDM Posted Charge</th>
<th>Q2042 CDM Posted Charge</th>
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</tbody>
</table>

*Prepared by ASBMT*
Outpatient and Physician Coding and Reimbursement Updates
Final 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%

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>APC</th>
<th>Payment Rate</th>
<th>Minimum Unadjusted Copayment</th>
<th>Note: Actual copayments would be lower due to the cap on copayments at the Inpatient Deductible of $1,364.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2041</td>
<td>Axicabtagene ciloleucel car+</td>
<td>9035</td>
<td>$395,380.00</td>
<td>$79,076.00</td>
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<td>Q2042</td>
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<td>9194</td>
<td>$489,764.13</td>
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</table>

CPT codes and descriptions only are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply. Dental codes (D codes) are copyright 2018 American Dental Association. All Rights Reserved.
Question: Which of the following should be reported for the administration of CAR-T cell therapy in the outpatient setting:

A. 38999
B. 96413
C. Only the CAR-T product Q-code
D. 0540T
E. Depends on the payer
F. Not sure
Four new CAR-T Category III CPT codes were released in July for use starting January 1st, 2019.

CMS agreed CAR-T should not be reported as chemo or transplant and assigned payment to the new CAR-T administration CPT code but did not recognize the other 3 codes and assigned status “B” which means report a “better/different code” but did not specify what to report.

CMS clarified the therapeutic apheresis CPT code and the associated National Coverage Decision (NCD 110.14) does not apply for CAR-T.
CMS MAC Coverage of Category III CPT Codes

- Category III CPT codes are generally not covered by the Medicare Administrative Contractors (MACs), unless a separate LCD or exception is sought or a specific reference is made in their policies to allow coverage.

- Check your MAC policy and reach out to your MAC Medical Director to have the CAR-T Category III codes added to their existing local policy or article – at a minimum the infusion code should be added!

- If your MAC does not have a favorable policy, then you’ll have to appeal and/or send in additional documentation.
Question: For Medicare patients, who is reimbursing hospitals for T-cell collection and cell processing?

A. Medicare
B. Novartis
C. KITE
D. No one
E. Not sure
Part of CMS’ Rationale...

- “The existing CAR T-cell therapies on the market were approved as biologics and, therefore, provisions of the Medicare statute providing for payment for biologicals apply.

- 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)
  

Yes...CMS expects to collect data on these services...but how?
CMS Expects to Receive Data on Cell Collection and Cell Processing…But How?

- In the CY 2019 OPPS Final Rule CMS states, “...there is no separate payment by Medicare for these steps in the manufacturing process. However, it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for codes reported for services in which no separate payment is made.”

**How? Given the Assignment of Status Indicator “B”?**

- CMS must resolve the disconnect between its policy statement and its assignment of status indicator “B” since that indicator never allows codes to come in to CMS

**Answer:** Assign status indicator “N” through the release of a correction notice  

**Better Answer:** Assign status indicator “S” and make separate payment for these services and remove any references to them from the product Q-codes
Question: On the day of T-cell collection, the following service also typically occurs:

A. Full evaluation and management of the patient
B. Central line placement
C. Some other separately payable procedure
D. No other service/procedure is provided
E. Not sure
Question: Physicians can get paid for their involvement/work effort associated with cell collection and cell infusion

A. True
B. True but only for the cell infusion
C. False, there is no payment for either of these Category III CPT codes by the MAC
D. Not sure
**Physician Coding and Reimbursement Questions**

- Physicians can get reimbursed for CAR-T administration by reporting the new Category III CPT code 0540T but since this is carrier priced, physicians will have to send a letter to their MACs describing the service provided and what it is similar to in terms of work effort.

- What about physicians being able to get reimbursed for T-cell collection?
  - *Status B here under the PFS means the service is bundled into something else. So the question is what is the “something else” that the physician is able to get paid for?*

- Even though T-cell collection has a status “B” and is considered bundled, should we still report it to let CMS know what service was provided?
  - *Great question! If codes with status “B” are reported, they will be denied but the claim will not. It is important to report the code to let CMS and AMA/CPT know the frequency of the service.*

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**Addendum B – Relative Value Units and Related Information Used in CY 2019 Final Rule**

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<th>CPT(^1)/HCPCS</th>
<th>Description</th>
<th>Status</th>
<th>Work RVUs(^2)</th>
<th>Non-Facility PE RVUs(^2)</th>
<th>Facility PE RVUs(^2)</th>
<th>Mal-Practice RVUs(^2)</th>
<th>Total Non-Facility RVUs(^2)</th>
<th>Total Facility RVUs(^2)</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>
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<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>
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</table>

*From MPFS: B = Bundled code; C = Carrier priced code*
PART III: CAR-T - What’s on the Horizon and What Do You Need to Do...
CAR-T Reporting Changes on the Horizon for April 1, 2019

The National Uniform Billing Committee (NUBC) finalized new revenue codes to capture CAR-T services and products so additional CDM changes required for providers and payers.

From the CY 2019 OPPS Rule, CMS states, “The CAR T-cell related revenue codes and value code established by the NUBC will be reportable on HOPD claims, and will be available for tracking utilization and cost data, effective for claims received on or after April 1, 2019.”

http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf
Setting up your Charge Description Master (CDM)

- Update the Q-codes

- Add the new Category III CAR-T CPT codes and appropriate revenue codes to report services to Medicare and determine whether commercial payers will accept all of the new Category III codes

- Convene a work group to create a mini CAR-T CDM structure and prepare simple claims examples that illustrate the flow of outpatient and inpatient services and the CAR-T administration

- Have the work group think about Jan 1st and April 1st as more changes are coming
### Example CDM Set-Up - Prices are Illustrative Only

#### Codes Effective January 1 to March 31, 2019

<table>
<thead>
<tr>
<th>Hospital Department</th>
<th>Charge Description</th>
<th>Revenue Code</th>
<th>HCPCS Code</th>
<th>Example CDM Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy*</td>
<td>Yescarta only excluding leukapheresis and cell processing**</td>
<td>0250 (inpatient) 0636 Outpatient</td>
<td>Q2041****</td>
<td>$746,000</td>
</tr>
<tr>
<td>Pharmacy*</td>
<td>Kymriah (adult indication) only excluding leukapheresis and cell processing**</td>
<td>0250 (inpatient) 0636 Outpatient</td>
<td>Q2042****</td>
<td>$746,000</td>
</tr>
<tr>
<td>Pharmacy*</td>
<td>Kymriah (pediatric indication) only excluding leukapheresis and cell processing**</td>
<td>0250 (inpatient) 0636 Outpatient</td>
<td>Q2042****</td>
<td>$950,000</td>
</tr>
<tr>
<td>Cell Transplant Department</td>
<td>Cell Collection/ Harvesting</td>
<td>0940 (inpatient) 0760 Outpatient</td>
<td>0537T****</td>
<td>$2,500</td>
</tr>
<tr>
<td>Cell Transplant Lab</td>
<td>Cell Processing Outbound</td>
<td>0310 (inpatient) 0760 Outpatient</td>
<td>0538T****</td>
<td>$5,000</td>
</tr>
<tr>
<td>Cell Transplant Lab</td>
<td>Cell Processing Inbound</td>
<td>0310 (inpatient) 0760 Outpatient</td>
<td>0539T****</td>
<td>$5,000</td>
</tr>
<tr>
<td>Cell Transplant Department</td>
<td>CAR-T IV Administration</td>
<td>0260 (inpatient and outpatient)</td>
<td>0540T</td>
<td>$3,000</td>
</tr>
<tr>
<td>Cell Transplant Department</td>
<td>Pre-T-Cell Collection E/M Visit</td>
<td>0510 (inpatient and outpatient)</td>
<td>G0463</td>
<td>$250</td>
</tr>
<tr>
<td>Cell Transplant Department</td>
<td>Peripherally Inserted Central Catheter-Adult</td>
<td>0361 (inpatient and outpatient)</td>
<td>36571</td>
<td>$1,500</td>
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</tbody>
</table>

#### After April 1, 2019^:

<table>
<thead>
<tr>
<th>Hospital Department</th>
<th>Charge Description</th>
<th>Revenue Code</th>
<th>HCPCS Code</th>
<th>Example CDM Price</th>
</tr>
</thead>
<tbody>
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<tr>
<td>Pharmacy*</td>
<td>Kymriah (adult indication) only excluding leukapheresis and cell processing**</td>
<td>0891</td>
<td>Q2042****</td>
<td>$746,000</td>
</tr>
<tr>
<td>Pharmacy*</td>
<td>Kymriah (pediatric indication) only excluding leukapheresis and cell processing**</td>
<td>0891</td>
<td>Q2042****</td>
<td>$950,000</td>
</tr>
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<td>Cell Processing Outbound</td>
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<tr>
<td>Cell Transplant Department</td>
<td>CAR-T Infusion Administration</td>
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<td>0540T</td>
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<td>CAR-T Injection Administration</td>
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<tr>
<td>Cell Transplant Department</td>
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<td>0510</td>
<td>G0463</td>
<td>$250</td>
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<tr>
<td>Cell Transplant Department</td>
<td>Peripherally Inserted Central Catheter-Adult</td>
<td>0361 (inpatient and outpatient)</td>
<td>36571</td>
<td>$1,500</td>
</tr>
</tbody>
</table>

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Summary and Looking Towards 2019…

- Hospital charging practices critical as they impact current and future reimbursement
- Inpatient Medicare reimbursement still problematic
- Outpatient Medicare reimbursement far better but most cases are inpatient
- Category III codes useful but coverage and payment concerns exist
- Commercial payer and Medicaid reimbursement less problematic
- Access issues being raised
- Hospitals need to address operational issues and continue advocating for change!
Creating Your Operational To-Do List

- Evaluate/re-evaluate your CAR-T product charge in light of CMS’ formulas for NTAP and outlier payment
- Address CDM set-up issues with respect to reporting cell collection and cell processing
- Contact your MAC and request the CAR-T Category III CPT codes be recognized
- Prepare a Carrier letter for physicians to submit and receive payment for administration of CAR-T
- Determine if your physicians will report the bundled cell collection service code
- Contact commercial payers regarding acceptance of the Category III CPT codes and new revenue codes going live April 1st
- Be ready to make NUBC updates for April 1st
- Continue asking operational coding, billing, and charging questions to CMS
- Conduct a self-audit
Creating Your Advocacy To-Do List...

- Continue advocating that CMS remove patient care services from CAR-T product Q-codes
- Continue and instead recognize the Category III CAR-T CPT codes for payment
- Continue advocating for appropriate inpatient reimbursement for CAR-T administration
- Continue advocating for separate payment for outpatient Category III CAR-T CPT codes
- Prepare to submit comments on:
  - The proposed NCA (March 2019)
  - New ICD-10-CM diagnosis CAR-T complication codes if discussed/proposed (March/April 2019)
  - The next inpatient rule (April/May 2019)
  - The next outpatient and physician fee schedule rule (July/August 2019)
Appendix: Reporting CAR-T Services to Medicare and Sample Claims Examples
### Sample Claims for Outpatient and Inpatient Services

**Codes Effective January 1 to March 31, 2019**

#### Inpatient Medicare CAR-T Administration Claim

<table>
<thead>
<tr>
<th>Rev Code</th>
<th>Detail Statement</th>
<th>HCPCS</th>
<th>Example Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>0250***</td>
<td>Yescarta only excluding leukapheresis and cell processing</td>
<td>NA</td>
<td>$746,000</td>
</tr>
<tr>
<td>0260</td>
<td>CAR-T Infusion Administration</td>
<td>NA</td>
<td>$3,000</td>
</tr>
<tr>
<td>0310</td>
<td>Cell Processing Inbound</td>
<td>NA</td>
<td>$5,000</td>
</tr>
</tbody>
</table>

**Outpatient Medicare T-Cell Collection Claim**

<table>
<thead>
<tr>
<th>Rev Code</th>
<th>Detail Statement</th>
<th>HCPCS</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>0510</td>
<td>Pre-T-Cell Collection E/M Visit</td>
<td>G0463</td>
<td>$250</td>
</tr>
<tr>
<td>0760</td>
<td>Cell Collection/Harvesting</td>
<td></td>
<td>$2,500*</td>
</tr>
<tr>
<td>0760</td>
<td>Cell Processing Outbound</td>
<td></td>
<td>$5,000*</td>
</tr>
</tbody>
</table>

*Revenue code 0760 line will sum to $7,500 on actual claims

**Outpatient Medicare CAR-T Administration Claim**

<table>
<thead>
<tr>
<th>Rev Code</th>
<th>Detail Statement</th>
<th>HCPCS</th>
<th>Example Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>0636</td>
<td>Yescarta only excluding leukapheresis and cell processing</td>
<td>Q2041</td>
<td>$746,000</td>
</tr>
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<td>0260</td>
<td>CAR-T Infusion Administration</td>
<td>0540T</td>
<td>$3,000</td>
</tr>
<tr>
<td>0760</td>
<td>Cell Processing Inbound</td>
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<td>$5,000</td>
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</table>

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# Reporting Collection and Cell Processing

<table>
<thead>
<tr>
<th>Autologous CART Cell Collection and Cell Processing Coding Options</th>
<th>Outpatient Facility Reporting</th>
<th>Physician Reporting</th>
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<tr>
<td><strong>COLLECTION</strong></td>
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<tr>
<td>6A550Z1</td>
<td>Pheresis of Leukocytes, Single</td>
<td>CPT or HCPCS Codes</td>
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<tr>
<td>6A551Z1</td>
<td>Pheresis of Leukocytes, Multiple</td>
<td>CPTSS Status Indicator “B” assigned. Meaning of this code is reported on outpatient hospital claims, the line item will be returned to the provider (HIP) per the outpatient code editor. The dollars associated with the service can be reported with a procedure revenue code and no CPT code to account for facility resources expended.</td>
</tr>
<tr>
<td><strong>CELL PROCESSING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Charges reported using revenue codes</td>
<td>CPTSS Status Indicator “B” assigned. Meaning of this code is reported on outpatient hospital claims, the line item will be returned to the provider (HIP) per the outpatient code editor. The dollars associated with the service can be reported with a procedure revenue code and no CPT code to account for facility resources expended.</td>
</tr>
<tr>
<td></td>
<td>CPTSS Status Indicator “B” assigned. Meaning of this code is reported on outpatient hospital claims, the line item will be returned to the provider (HIP) per the outpatient code editor. The dollars associated with the service can be reported with a procedure revenue code and no CPT code to account for facility resources expended.</td>
<td>Medical and Commercial Payment Implications</td>
</tr>
</tbody>
</table>

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### Reporting Cell Administration

<table>
<thead>
<tr>
<th>Coding Options for Reporting Administration of Autologous CAR-T</th>
<th>Inpatient Facility Reporting*</th>
<th>Outpatient Facility Reporting</th>
<th>Physician Reporting</th>
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<tr>
<td>CD10-PCS Codes</td>
<td>Description</td>
<td>CPT/HCPCS Codes</td>
<td>Description</td>
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<td>ICD-10-PCS Codes</td>
<td>Description</td>
<td>CPT/HCPCS Codes</td>
<td>Description</td>
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<td>Introduction, Peripheral Vein Engineered Autologous Chimeric Antigen Receptor T Cell Immunotherapy</td>
<td>054OT</td>
<td>Chimeric antigen receptor T-cell (CAR-T) therapy, CAR-T cell administration, autologous</td>
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<tr>
<td>XW043C3</td>
<td>Introduction, Central Vein Engineered Autologous Chimeric Antigen Receptor T Cell Immunotherapy</td>
<td>S2107</td>
<td>Adaptive immunotherapy, i.e., development of specific anti-tumor reactivity (e.g., tumor-infiltrating lymphocyte therapy) per course of treatment</td>
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</tbody>
</table>

Full sheet with references at: [https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/Print_version_-_1-7-2019_ASBMT_CAR-T_Administration_Coding_Options.pdf](https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/Print_version_-_1-7-2019_ASBMT_CAR-T_Administration_Coding_Options.pdf)
## Reporting Product Q-Codes

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<tr>
<th>Inpatient Facility Reporting</th>
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<tbody>
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<td><strong>Autologous CAR-T Product Reporting Options</strong></td>
<td><strong>HCPCS Code</strong>*</td>
</tr>
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<td>- <strong>PRODUCT REPORTING TO MEDICARE</strong></td>
<td>Q2041</td>
</tr>
<tr>
<td><strong>PRODUCT REPORTING TO MEDICAID</strong>*</td>
<td>Q2041</td>
</tr>
<tr>
<td><strong>PRODUCT REPORTING TO COMMERCIAL PAYERS</strong></td>
<td>Q2041</td>
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</tbody>
</table>

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Full sheet with references at: [https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/Print_version_-_1-7-2019_ASBMT_CAR-T_Product_Coding_Options.pdf](https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/Print_version_-_1-7-2019_ASBMT_CAR-T_Product_Coding_Options.pdf)