CAR-T & Cellular Therapy: Reimbursement Policy and Coverage Updates

Presented by: Nimitt Consulting, Inc.
April 24, 2022

Health Policy Partners
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Disclosures

Speakers have the following to disclose:

Novartis, bluebird bio, Gamida Cell, Jasper Therapeutics, Vor Biopharma, eGenesis Bio, Vertex Pharmaceuticals, AlloVir, Legend Biotech, Biogen, Cabaletta Bio, Neurocrine Biosciences, Moderna Therapeutics, Miltenyi Biotech, NECTx, NuPulse, CSL Behring, Immunogen
Agenda

Media and Advocacy

Medicare inpatient reimbursement and implications of provider charging practices

Medicare outpatient and physician reimbursement

Coding and billing updates

Looking ahead

Prepared by Nimitt Consulting Inc.
Media and advocacy
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

Improving Outcomes and Mitigating Costs Associated With CAR T-Cell Therapy

August 18, 2021
Rebecca Borgert, PharmD, BCOP

Earlier CAR-T treatment possible if price comes down, FDA official says

September 20, 2021

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

November 16, 2021

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

Prepared by Nimitt Consulting Inc.
KEY DRIVER OF CHANGE

Provider advocacy

2017

Predicted payment concerns shared with CMS

+ Requests:
  • Mitigate charge compression on CAR-T product
  • Different NTAP and outlier computation
  • Alternative payment model
  • New cost tracking

Post-approval payment issues grow; advocacy increases

2018

CMS began making changes:
  • New revenue & value codes (4/1)
  • NTAP cap change to 65% (10/1)
  • No CED; NCD to FDA label (8/7)

+ Requests:
  • Mitigation of charge compression
  • Claims transparency (CMS instructions to use value code)
  • Billing and coding specificity
  • Creation of a new MS-DRG
  • NDC reporting on claims

2019

Changes continue being made:
  • New MS-DRG 018 (10/1)
  • Differential payment for cases based on paid product cost
  • Instruction to hospitals to charge appropriately
  • Implementation of CRS dx codes

+ Requests:
  • Billing and coding specificity
  • Claims transparency
  • More granular coding
  • Dismissal of CED proposal

2020

Changes continue being made:
  • Implementation of Dx codes for ICANS (10/1)
  • All CAR-T products named and placed in the XW0 table and generic auto and allo codes for CAR-T added to the table
  • Creation of cost report line 78 to collect CAR-T cost data

+ Requests:
  • Creating new/different types of MS-DRGs for cell and gene therapies
  • Publishing examples of claims billing

2021

Predicted payment concerns shared with CMS

+ Requests:
  • Mitigate charge compression on CAR-T product
  • Different NTAP and outlier computation
  • Alternative payment model
  • New cost tracking

Post-approval payment issues grow; advocacy increases

Prepared by Nimitt Consulting Inc.
Review of Medicare FFS reimbursement, and implications of provider charging practices
5 YEAR VIEW

Medicare CAR-T payment summary

INPATIENT

**FY 2018** (Oct 1, 2017 – Sept 30, 2018)
- Non-Specific MS-DRGs ($8,000-$18,000)
- NO NTAP
- Outlier

**FY 2019** (Oct 1, 2018 – Sept 30, 2019)
- MS-DRG 016 ($40,000)
- NTAP Approved at 50% cap of $186,500
- Outlier

**FY 2020** (Oct 1, 2019 – Sept 30, 2020)
- MS-DRG 016 ($43,127)
- NTAP Approved at 65% cap of $242,500
- Outlier

**FY 2021** (Oct 1, 2020 – Sept 30, 2021)
- NEW CAR-T MS-DRG 018 ($242,500)
- No NTAP

**FY 2022** (October 1, 2021 – Sept 30, 2022)
- MS-DRG 018 with a name change ($246,958)
- 2 new NTAPs granted; with various caps

OUTPATIENT

**Pass-Through Payment = ASP + 6%**

**Once pass through expires for a product, the payment varies based on whether the hospital is a 340B purchasing provider**

**ASP + 6% (non-340B)**

**ASP- 22.5% (340B)**

Prepared by Nimitt Consulting Inc.
**Unprecedented methodology used for CAR-T**

- **All Inpatient Claims**
  - PPS provider non-CAR-T claims
  - Medicare's normal rate-setting process assigns MS-DRGs and creates relative weights
  - 766 MS-DRGs

- **CAR-T inpatient PPS claims**
  - PPS provider CAR-T claims data
  - Claims are filtered into two buckets:
    - Non-clinical trial cases:
      - No Z00.6 code on claims
      - Pharmacy charges >$373K
      - Cases go through rate-setting
      - MS-DRG 018
    - Clinical trial cases (as defined by CMS):
      - Z00.6 code on claims
      - Pharmacy charges <$373K
      - Claims excluded from rate-setting

*Prepared by Nimit Consulting Inc.*
MS-DRG 018

Key Information:
• MS-DRG 018 name change
• Clinical trial claims and claims with pharmacy charges < $373,000 continue to be excluded from rate-setting
• Still one MS-DRG and two payment rates (claims without a product cost are paid a lower rate using a 0.17 adjustor)
• ICD-10-PCS code for Tumor Infiltrating Lymphocyte (TILs) product assigned to MS-DRG 018
• New CAR-T allogeneic ICD-10-PCS codes assigned to 018
• Fixed loss outlier threshold higher
• NTAP payment available for two products (up to 65%); maximum depends on the specific CAR-T product

**MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies**

**NATIONAL UNADJUSTED PPS PAYMENT**

<table>
<thead>
<tr>
<th>Payment</th>
<th>Cases with Full Product Cost</th>
<th>Cases Without Full Product Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS-DRG</td>
<td>$246,955</td>
<td>~$42,000</td>
</tr>
<tr>
<td>NTAP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Donut Hole&quot;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fixed Loss Outlier Payment**

- $246,955
- $272,675*
- $30,988 Fixed Loss Outlier

*Amount shown is 65% of the list price of a CAR'T product, approved for NTAP for FY 2022.*

Prepared by Nimitt Consulting Inc.
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.

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. A fixed loss threshold must be accounted for in the calculation of outlier payment.

**Inpatient FFS payment overview for FY 2022**

**MS-DRG 018 National Unadjusted Base Payment = $246,955**

*(based on a relative weight of 37.4501)*

**NTAP Payment**

*if applicable*

**Outlier Payment Varies**

*if applicable*

**Total Case Payment**
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.

**Step 1:** Get “Calculated Cost”

\[
\text{Total Covered Inpatient Claim Charges} \times \text{Hospital’s Overall Operating Cost-to-Charge Ratio (CCR)} = \text{Calculated Cost}
\]

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

\[
\frac{\text{Calculated Cost} - \text{MS-DRG Payment Amount}}{0.65} = \text{NTAP}
\]

**Step 3:** Use Calculated Cost to Determine Outlier Payment Amount

\[
\frac{\text{Calculated Cost} - (\text{MS-DRG Payment Amount} + \frac{\text{NTAP Payment If Applicable}}{0.8} + \frac{\text{Fixed Outlier Threshold Which Varies Each Year}}{0.8})}{0.8} = \text{Outlier Payment}
\]
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 charges converted to costs can appropriately account fully for their acquisition and overhead costs....”

From the Provider Reimbursement Manual, Part 1, Chapter 22
Section 2203: “[E]ach facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services”

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 requires “the same” gross charge (i.e., CDM “list price”) be posted for all patients receiving the same service
- CMS’ language allows 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 also meeting commercial payers’ contractual requirements related to carve-outs, invoice cost, or other provisions

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The impact of charging practices

Hospital and patient characteristics

Both hospitals
- Are certified to provide CAR-T
- Pay the manufacturer $419,500
- 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

*To isolate the impact of charging practices we do not include variables such as hospital adjustments, but these adjustments are important to account for when calculating hospital-specific estimated reimbursement.*

### Example: Inpatient Hospital Claim

<table>
<thead>
<tr>
<th>FL 42 Revenue Code</th>
<th>FL 43 Description</th>
<th>FL 46 Units</th>
<th>FL 47 Total Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>0121</td>
<td>Room &amp; Board</td>
<td>14</td>
<td>$63,000</td>
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<tr>
<td>0205</td>
<td>Pharmacy</td>
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<tr>
<td>0270</td>
<td>Supplies</td>
<td>20</td>
<td>$13,000</td>
</tr>
<tr>
<td>0300</td>
<td>Laboratory</td>
<td>520</td>
<td>$32,000</td>
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<tr>
<td>0891*</td>
<td>Detailed drugs</td>
<td>1</td>
<td>$461,450</td>
</tr>
<tr>
<td>0001</td>
<td>Total charges</td>
<td></td>
<td>$589,450</td>
</tr>
</tbody>
</table>

**Hospital A**
- Markup 110%

<table>
<thead>
<tr>
<th>FL 42 Revenue Code</th>
<th>FL 43 Description</th>
<th>FL 46 Units</th>
<th>FL 47 Total Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>0121</td>
<td>Room &amp; Board</td>
<td>14</td>
<td>$63,000</td>
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<td>0270</td>
<td>Supplies</td>
<td>20</td>
<td>$13,000</td>
</tr>
<tr>
<td>0300</td>
<td>Laboratory</td>
<td>520</td>
<td>$32,000</td>
</tr>
<tr>
<td>All other dept. charges (radiology, etc.)</td>
<td>All other</td>
<td>50</td>
<td>$75,000</td>
</tr>
<tr>
<td>0891*</td>
<td>Detailed drugs</td>
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</tr>
<tr>
<td>0001</td>
<td>Total charges</td>
<td></td>
<td>$1,906,000</td>
</tr>
</tbody>
</table>

**Hospital B**
- Markup 400%

*Prepared by Nimitt Consulting Inc.*
Two Hospital Example

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, in our example, is 0.25 for both hospitals
- Because of the difference in total charges between Hospital A and B, CMS calculates a VERY different cost for each hospital

<table>
<thead>
<tr>
<th>Hospital A</th>
<th>Hospital B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>$689,450</td>
<td>$1,906,000</td>
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<td>$172,363</td>
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<td>$1,678,000</td>
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<tr>
<td>$228,000</td>
<td>$419,500</td>
</tr>
</tbody>
</table>

Prepared by Nimitt Consulting Inc.
HOSPITAL A & B PAYMENT COMPARISON

With and without NTAP

Hospital-specific adjustments and charging practices matter

- Graphs show that appropriate charging is the key to getting outlier payment and NTAP
- Adjustments such as IME and DSH must be computed by each hospital; they can have a significant impact as can an adjusted outlier payment
- The higher the base MS-DRG payment, the higher the impact of the adjusters

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ASSESS YOUR FACILITY

Are you more like Hospital A or B?

What is your CAR-T dollar charge?

- Check the CDM for your CAR-T product charge(s)

- Determine if updates are needed: review your drug pricing methodology

- Share CMS’ quotes about charging practices and review Sections 2203 and 2202.4 of the Provider Reimbursement Manual, Part 1, Chapter 22

Compute your financial impact

- Ask finance to estimate what your institution’s FY 2022 payment for CAR-T will look like

- Provide your average total charge for your CAR-T cases

- Provide your operating CCR, geographic adjustment factor, wage index, IME, and DSH to get to an accurate payment estimate for your organization

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Have hospital charging practices changed given CMS’ language 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)
FY 2023 IPPS proposals impacting MS-DRG 018 and cell therapies
A few highlights

- Rule released April 18th, just ahead of Tandem!
- 1,786 pages long; comments due **June 17, 2022**
- CMS proposes and/or seeks comments on the following:
  - Use of National Drug Codes (NDCs) rather than specific ICD-10-PCS codes to identify NTAP drugs/biologics
  - To make manufacturer submitted new technology add-on payment (NTAP) applications publicly available
  - Use of a new electronic portal to take MS-DRG classification requests starting FY 2024
  - A blended average of all FY 2021 cases and non-COVID cases to create relative weights for FY 2023
  - Whether NTAP should be granted to new therapies; including two cell therapies and two HSCT specific therapies
  - To permanently limit wage-index & relative weight decreases each year
  - Mechanisms to address rare diseases and conditions represented by low volumes in Medicare's claims data
  - Social determinants of health through an RFI
  - Much more, including the usual topics of wage-index, disproportionate share, quality, interoperability etc.
FY 2023 PROPOSED RULE

MS-DRG 018

- CMS proposes to continue excluding clinical trial claims and claims with pharmacy charges < $373,000 from rate-setting
- Payment adjuster proposed to increase to 0.20 for cases without product cost
- CMS proposes to continue NTAP for two products
- No new products added to MS-DRG 018; two products being reviewed for NTAP
- Base payment rate proposed to increase
- Fixed loss outlier threshold increases

### MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies

<table>
<thead>
<tr>
<th></th>
<th>NATIONAL UNADJUSTED PPS PAYMENT a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cases with Full Product Cost</strong></td>
<td>$248,807</td>
</tr>
<tr>
<td><strong>Cases Without Full Product Cost b</strong></td>
<td>~$49,761</td>
</tr>
</tbody>
</table>

### Payment

- **Fixed Loss Outlier Threshold**
  - **MS-DRG**
    - $248,807
  - **NTAP**
    - $272,675*
  - **"Donut Hole"**
    - $43,214

* Amount shown is 65% of the list price of a CAR-T product with NTAP, which CMS proposed to continue for FY 2023

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FY 2023 PROPOSED RULE

MS-DRG 018 relative weight change

• Relative weights depend on many factors

• FY 2021 claims data used to develop FY 2023 relative weights include COVID-19 related cases
  • CMS believes these cases may impact the weight distribution across MS-DRGs
  • CMS proposes to use a blended average of all cases and non-COVID cases to develop the relative weights for FY 2023

*CMS provides an alternate relative weight set using its usual methodology

Current FY 2022 MS-DRG 018 relative weight = 37.4501

FY 2023 R.W. = 36.6104  
FY 2023 Alt R.W.* = 36.3298

Provider charging practices do not appear to have significantly improved given the relative weight is proposed to drop for FY 2023

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What does the future hold?

The relative weight is impacted by a number of factors including the following:

- **Provider charging** practices
- **Volume** and **types of cases** from providers
- **New products** getting assigned to MS-DRG 018
- CMS’ **unprecedented rate-setting** methodology for MS-DRG 018

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

FY 2020 claims data used to simulate the impact on the R.W. if CMS removed one or both parts of its current rate-setting methodology for MS-DRG 018.

- R.W. = 20.51  (if both criteria removed)
- R.W. = 28.91  (if the $373K criteria is removed)
- R.W. = 37.4501 (MS-DRG 018 relative weight)

*Prepared by Nimitt Consulting Inc.*
“We received additional feedback and suggestions including recommendations for Town Hall meetings/listening sessions to discuss...these issues; exploration of what was described as a different set and kind of MS-DRGs that would reward providers for controlling patient care costs, without consideration of product costs outside of their control; and evaluation and creation of multiple MS-DRGs for cell and gene therapy cases: one to cover patient care costs, the other to cover product costs across therapeutic product categories.

We appreciate this additional feedback and will continue to consider these issues and suggestions in connection with future rulemaking. We also intend to continue engaging with stakeholders by sharing updates from our analysis of claims data as we examine and explore potential refinements for these therapies under the IPPS.”
Outpatient Prospective Payment System (OPPS) reimbursement for CAR-T services and products and physician reimbursement
OUTPATIENT SERVICES

Outpatient CAR-T services represented by CPT codes

Just because codes exist does not mean payers have to recognize them for payment (e.g., Medicare only recognizes payment for the administration code).
OUTPATIENT PAYMENT

The services

CMS remains firm in its rationale that: “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>Relative Weight</th>
<th>Payment Rate</th>
<th>Relative Weight</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>
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<td></td>
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<td>0540T</td>
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<td>3.8685</td>
<td>$325.64</td>
<td>$14.89</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

Cell collection and cell processing services can be billed in multiple ways, since they are assigned status indicator “B”; discussed further in the coding and billing section.

Prepared by Nimitt Consulting Inc.
**The products**

- Provider charging practices do NOT impact outpatient reimbursement since payment is based on the average sales price (ASP) + 6%
- New CAR-T products with pass-through payment status, including for 340B providers, are paid ASP + 6%
- When pass-through expires, payment to 340B hospitals made at ASP - 22.5%^  

<table>
<thead>
<tr>
<th>Current Codes</th>
<th>Final January 2022</th>
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<tbody>
<tr>
<td><strong>HCPCS Code</strong></td>
<td><strong>Short Descriptor</strong></td>
</tr>
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<td>Lisocabtagene car pos t</td>
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</tr>
<tr>
<td>C9399</td>
<td>Ciltacabtagene autoleucel</td>
</tr>
</tbody>
</table>

**Note:** For Medicare, when new products are approved that do not yet have an assigned HCPCS code, hospitals report C9399 (unclassified drugs or biologicals) to Medicare and the National Drug Code (NDC) and payment is made based on 95% of AWP as a carrier priced item. Additionally, the patient co-payment is capped at the inpatient deductible amount, which is approximately $1,408 for CY 2021.

^ This does not apply to PPS-exempt hospitals, such as specific cancer and children’s hospitals

Prepared by Nimitt Consulting Inc.
### Addendum B – Relative Value Units and Related Information Used in CY 2022 Final Rule

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Status</th>
<th>Description</th>
<th>Work RVUs°</th>
<th>Non-Facility PE RVUs°</th>
<th>Facility PE RVUs°</th>
<th>Mal-Practice RVUs°</th>
<th>Total Non-Facility RVUs°</th>
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<tbody>
<tr>
<td>0537T</td>
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<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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</tr>
</tbody>
</table>

- CMS assigns status “B” to the cell collection and cell processing codes
  - “B” = service bundled into some other service presumably provided on same day
  - Services with status “B” are denied when billed, but the entire claim is not. It is considered a best practice to still report these codes, to let CMS and AMA/CPT know the frequency of the service

- CMS assigns status “C” to the CAR-T administration CPT code
  - “C” = payment determined by the carrier and that is your local MAC
  - The physician must submit a letter to MAC and provide information describing the service and the resource intensity involved in order to receive appropriate payment
CAR-T coding and billing review
• Last year, the ASTCT published a CAR-T therapy coding and billing guide

• This guide was released by ASTCT's GR committee to provide a comprehensive review of accurate and complete coding and billing for CAR-T therapy and its related ancillary services for hospitals, regardless of the CAR-T product used

• The guide addresses FDA-approved commercial products, as well as products administered as part of a clinical trial or expanded access program, and aims to clarify the major billing differences and considerations between government and private payers

• The guide can be downloaded here: ASTCT CAR-T Therapy Coding and Billing Guide

• The ASTCT also publishes coding options grids for CAR-T as a resource to get an at-a-glance view of coding options for CAR-T and related services and diagnoses, which can be downloaded here:
  • CAR-T Therapy Collection and Cell Processing Coding Options
  • CAR-T Therapy Administration Coding Options
  • CAR-T Therapy Product Coding Options
  • CAR-T Therapy Complications Coding Options
CODING AND BILLING

FY 2022 CAR-T updates

**ICD-10-PCS**
- As of October 1, 2021, all FDA-approved CAR-T products with product-specific ICD-10-PCS codes are in the XW0 table
- Codes previously in the XW2 Table have been deleted and replaced with XW0 codes
- Two new product-specific codes created in the XW0 table and non-product specific autologous and allogeneic CAR-T codes exist in XW0

**ICD-10-CM**
- Complications of IEC therapy T-codes and ICANS diagnosis codes became effective October 1, 2021
- T80.82XA to be coded first, then the diagnosis code of either CRS or ICANS; CRS cases group to MS-DRGs 814-816 and ICANS to MS-DRGs 023, 024, and 091 - 093
- New diagnosis codes created for personal history of CAR-T therapy, cellular therapy, and gene therapy

**Billing and Other Key Items to Review**
- Are claims being submitted for the professional service of CAR-T administration? Is a letter sent to the MAC seeking payment?
- No changes to revenue, value code, or condition code reporting but check internal practices
- Do you bill EAP and clinical trial claims correctly? Do you audit?
- Review cost reporting instructions for line 78 once released by CMS
- Are you reporting modifier –KX to indicate REMS certification?

See the Appendix for detailed information on these topics
Billling

Modifier KX

- Medicare released a transmittal in January 2022 to the Medicare Administrative Contractors (MACs) related to the CAR-T NCD
- It explains that CAR-T is covered only when administered at a REMS-certified healthcare facility
- In order to signal to the MAC that CAR-T has been administered at a REMS-certified facility, modifier –KX must be appended to the CAR-T administration CPT code of 0540T
  - Applies to institutional and professional claims
  - For institutional claims, once a provider has been identified as an FDA REMS-approved facility, they are added to a special CMS edit that allows their claims to automatically process whether the modifier is added or not
  - For professional claims, modifier –KX must be reported every time

CMS Manual System

<table>
<thead>
<tr>
<th>Department of Health &amp; Human Services (DHHS)</th>
<th>Centers for Medicare &amp; Medicaid Services (CMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pub 100-20 One-Time Notification</td>
<td>Date: January 12, 2022</td>
</tr>
<tr>
<td>Transmittal 11179</td>
<td>Change Request 12480</td>
</tr>
</tbody>
</table>

NOTE: Specific to NCD 110.24, CAR-T, CMS is providing further clarifying information regarding coverage/claims processing: CMS does not prohibit Part B payment for reasonable and necessary CAR-T services, so long as the therapies are furnished in Risk Evaluation and Mitigation Strategies (REMS)-approved facilities and the claims include the appropriate coding. For instance, the physician/NPP would provide the CAR-T service at a Part A facility, Inpatient (IP) or Outpatient (OP) setting, and would bill Part B for the administration only (0540T).

The term “associated clinics” was formulated for CAR-T because many oncologists provide infusion services in specialized infusion centers that may be adjacent to oncology offices or may be set up separately as OP infusion centers. Basically, any place that is not located within a hospital but is properly equipped as an infusion center would be considered an “associated clinic” for the purpose of the REMS.

The -KX modifier can only be used on Part A OP and Part B claims but not Part A IP claims. However, once a provider has been identified as an FDA REM-approved facility, they are added to a special edit that allows all claims IP and OP to automatically process as an FDA REM-approved facility, whether the -KX modifier is present or not. This is a clarification that Part A claims will process. The -KX modifier is still required on Part B claims. See CR 12177 for the initial implementing instructions.
CAR-T DENIALS

Providers starting to see denials

- Are you seeing claim denials that you’ve not seen before?
- Is it for an existing product administration or a new product?
- Have you checked with your MAC on whether your facility is on a REMS certified list?
- Are you administering in a free-standing physician practice?
- Has your MAC implemented any edits that do not seem consistent with the NCD or a CMS transmittal?
- Other reasons...
CAR-T Provider Checklist

☑️ How do you set CAR-T product charge(s)? Do 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?
Looking Ahead
ALL ABOARD!

The MS-DRG 018 gold rush

• MS-DRG 018: Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies
  • Pre-MDC DRG – the presence of mapped ICD-10-PCS codes automatically points to MS-DRG 018
  • Unprecedented CMS decision to create two payment levels for a single MS-DRG
  • Highest-paying MS-DRG in IPPS history

• Currently contains:
  • Autologous CAR-T products, specific and “generic”/clinical trial product codes
  • Allogeneic CAR-T products – generic/clinical trial product codes
  • Lifileucel Immunotherapy – clinical trial tumor infiltrating lymphocyte product

• As of right now, limited to “CAR-T and Other Immunotherapies”
  • How broadly will “Other Immunotherapies” be interpreted?
  • Will it be modified to include non-immunotherapy/non-cancer high-cost cell and gene therapies?

How will MS-DRG 018 evolve?

• Like other payers, CMS is looking at the intersection of a robust pipeline and a constrained budget
• If you were CMS:
  • Would you keep MS-DRG 018 narrowly focused or drive all novel cell and gene therapies into it?
  • Would you keep the unprecedented reimbursement and rate-setting methodology?
  • Would you be okay with a lot of clinical heterogeneity?
  • Will there be enough volume for future splits?
  • What message would you send to industry about drug prices by how you handle MS-DRG 018?
**NEW INDICATIONS COMING FASTER**

**Current CAR-T product landscape**

<table>
<thead>
<tr>
<th>CAR-T Product</th>
<th>Indication</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>tisagenlecleucel</td>
<td>Peds* B-ALL</td>
<td>8/30/2017</td>
</tr>
<tr>
<td>tisagenlecleucel</td>
<td>3L DLBCL</td>
<td>5/1/2018</td>
</tr>
<tr>
<td>lisocabtagene maraleucel</td>
<td>3L DLBCL</td>
<td>2/5/2021</td>
</tr>
<tr>
<td>idecabtagene vicleucel</td>
<td>MM</td>
<td>3/27/2021</td>
</tr>
<tr>
<td>ciltacabtagene autoleucel</td>
<td>MM</td>
<td>2/28/2022</td>
</tr>
<tr>
<td>axicabtagene ciloleucel</td>
<td>MCL</td>
<td>7/24/2020</td>
</tr>
<tr>
<td>brexucabtagene autoleucel</td>
<td>FL</td>
<td>3/5/2021</td>
</tr>
<tr>
<td>brexucabtagene autoleucel</td>
<td>B-ALL</td>
<td>10/21/2021</td>
</tr>
<tr>
<td>axicabtagene ciloleucel</td>
<td>2L DLBCL</td>
<td>4/1/2022</td>
</tr>
</tbody>
</table>

*Indications are Adult unless specified as Peds
- B-ALL: B-cell acute lymphoblastic leukemia
- DLBCL: Diffuse large B-cell lymphoma
- FL: Follicular lymphoma
- LBCL: Large B-cell lymphoma
- MCL: Mantle cell lymphoma
- MM: Multiple Myeloma

NEW INDICATIONS COMING FASTER

*Prepared by Nimitt Consulting Inc.*

42
Medicare’s CAR-T NCD: coverage to label

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

Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

B. The use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered. Autologous treatment for cancer with T-cells expressing at least one CAR is non-covered when the requirements in Section A are not met.

C. This policy continues coverage for routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1.

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.
NCDs and significant cost determination

- Medicare Advantage plans make binding bids in advance of an upcoming calendar year
  - Bids are based on actuarial models and Medicare coverage requirements
- When new NCDs are finalized, the cost of the covered therapy is evaluated against the significant cost determination criterion
  - Based on “the average cost of furnishing a single service”
  - Set at $100,000 for 1999 with annual per capita growth percentage adjustments
- If a newly covered service is deemed covered and is also above the significant cost determination threshold:
  - Payment for that service or therapy is the responsibility of FFS Medicare until MA plans can incorporate those costs into their prospective bids
  - After 1-2 years (depending on timing), MA plans then resume financial responsibility for the costs going forward
  - MA plans are responsible for diagnostic services and “most follow-up services” surrounding the service or therapy even during the time period when it is covered by FFS


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FUTURE COVERAGE DECISIONS

Significant cost process incentivizes NCA requests

• 26M beneficiaries (42%) are in MA plans
  • 51% expected by 2030
• Potential outcomes of an NCA for MA Plans:
  • Service is non-covered = No MA responsibility
  • Service is covered and meets significant cost threshold = No MA responsibility for 1-2 years
  • Service is covered but does not meet significant cost threshold = MA pays

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

References: KFF.org 2021 Medicare Advantage enrollment; CMS CAR-T NCA Requestor Letter

Re: Formal Request for National Coverage Determination for Chimeric Antigen Receptor T-Cell Therapies

Dear Ms. Syrek Jensen:

The FDA recently approved the initial chimeric antigen receptor (CAR) –T cell therapies. UnitedHealthcare (UHC) submits the request below for a National Coverage Determination for these therapies to clarify the circumstances under which the therapies will be covered and to create consistent patient access to the therapies across the country and financial sustainability in the Medicare Advantage program with regard to these therapies.

As UHC anticipates emerging clinical advances, including these CAR-T therapies, UHC has several concerns that while promising clinically, CAR-T therapies could create significant financial risks for CMS, both Original Medicare FFS and Medicare Advantage plans. As CMS is aware, Medicare Advantage plans cover services as they are covered under Original Medicare, including Part B drugs. For that reason, we believe there is an industry-wide need for a National Coverage Determination (NCD) to ensure a level playing field across Medicare Advantage plans, so that providers and members are better equipped to make treatment decisions. Absent a National Coverage Determination, providers and beneficiaries could get inconsistent treatment decisions and inconsistent MAC decisions, leading to inconsistent coverage determinations, depending on a beneficiary’s location. Accordingly, United urges CMS to act expeditiously to issue the NCD discussed below.¹

References: KFF.org 2021 Medicare Advantage enrollment; CMS CAR-T NCA Requestor Letter

Prepared by Nimitt Consulting Inc.
What does the existing CAR-T NCD mean?

“[A]utologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR)”

• Any autologous CAR-T for any cancer falls under the NCD

Not included in the CAR-T NCD – but not non-covered:

• Allogeneic CAR-T for cancer
• Autologous and/or allogeneic CAR-T for non-cancer indications
• Non-T cell CAR products for any indication (CAR NK, CAR-M)
• Non-CAR cell therapies (TIL, iPSC, NK)

Will we see: 1) more NCAs, 2) modifications to this NCD, or 3) nothing further?

Reference: CMS National Coverage Determination 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy
The next twists: significant cost analyses...

- **Scenario 1**: The current CAR-T NCD is adjusted to include allogeneic products for cancer.
- **Scenario 2**: The current CAR-T NCD is adjusted to include non-cancer indications.
- **Scenario 3**: A new NCD creates coverage for TILs for cancer.

NCD 110.24 covers all autologous CAR-T products for cancer.

FFS paid for CAR-T while MA plans adjusted their bids to include treatment of cancer with autologous CAR-T.

Going forward, annual MA bid adjustments should include predicted costs for auto CAR-T for all cancers.

How will the significant cost decision play out in the following scenarios?
Discussion and Thank you!

Questions?
ICD-10-PCS

FY 2022 brings streamlined coding

As of October 1, 2021, all FDA-approved CAR-T products with product-specific ICD-10-PCS codes are in the XW0 table

- Codes previously in the XW2 Table have been deleted and replaced with XW0 codes
- Two new product-specific codes created in the XW0 table
- Non-product specific autologous and allogeneic CAR-T codes also exist in XW0

### TABLE 6B - NEW PROCEDURE CODES

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Description</th>
<th>O.R.</th>
<th>MDC</th>
<th>MS-DRG</th>
</tr>
</thead>
<tbody>
<tr>
<td>XW033C3</td>
<td>Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3</td>
<td>N**</td>
<td>018</td>
<td></td>
</tr>
<tr>
<td>XW043C3</td>
<td>Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3</td>
<td>N**</td>
<td>018</td>
<td></td>
</tr>
<tr>
<td>XW23346</td>
<td>Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6</td>
<td>N**</td>
<td>018</td>
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<tr>
<td>XW23376</td>
<td>Transfusion of Lisocabtagene Maraleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6</td>
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<td>018</td>
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<tr>
<td>XW24346</td>
<td>Transfusion of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6</td>
<td>N**</td>
<td>018</td>
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<tr>
<td>XW24376</td>
<td>Transfusion of Lisocabtagene Maraleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6</td>
<td>N**</td>
<td>018</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 6D - INVALID PROCEDURE CODES

**New for FY 2022**


Prepared by Nimitt Consulting Inc.
ICD-10-CM

FY 2022 diagnosis coding

1. Diagnosis codes related to CAR-T (Complications T-codes and ICANS) became effective October 1, 2021
   • New T-code T80.82XA for complications of IEC therapy to be coded first, then the grade of either CRS or ICANS
   • CRS cases, coded with the new T-code, group to MS-DRGs 814, 815, and 816 (same as before, just utilizing the new T-code)
   • ICANS cases map to MS-DRGs 023, 024, 091, 092, 093

2. New diagnosis codes exist for personal history of CAR-T therapy, cellular therapy, and gene therapy

![New Complications Code for Complications of CAR-T](image)

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
<th>MS-DRG Assignment</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>T80.82XA</td>
<td>Complication of immune effector cellular therapy, initial encounter</td>
<td>814, 815, 816</td>
<td>N</td>
</tr>
<tr>
<td>T80.82XD</td>
<td>Complication of immune effector cellular therapy, subsequent encounter</td>
<td>814, 815, 816</td>
<td>N</td>
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<tr>
<td>T80.82XS</td>
<td>Complication of immune effector cellular therapy, sequela</td>
<td>814, 815, 816</td>
<td>N</td>
</tr>
</tbody>
</table>

### CRS Codes

- D89.831 Cytokine release syndrome, grade 1
- D89.832 Cytokine release syndrome, grade 2
- D89.833 Cytokine release syndrome, grade 3
- D89.834 Cytokine release syndrome, grade 4
- D89.835 Cytokine release syndrome, grade 5
- D89.839 Cytokine release syndrome, grade unspecified

### ICANS Codes

- G92.00 Immune effector cell-associated neurotoxicity syndrome, grade unspecified
- G92.01 Immune effector cell-associated neurotoxicity syndrome, grade 1
- G92.02 Immune effector cell-associated neurotoxicity syndrome, grade 2
- G92.03 Immune effector cell-associated neurotoxicity syndrome, grade 3
- G92.04 Immune effector cell-associated neurotoxicity syndrome, grade 4
- G92.05 Immune effector cell-associated neurotoxicity syndrome, grade 5

Reference: FY 2022 IPPS Final Rule CMS Coding Table 6A – New Diagnosis Codes
OTHER CLAIM CODES

CAR-T revenue and value codes

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

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

Revenue Codes Required as of 2019

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

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

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

These are part of the transaction code set released by the National Uniform Billing Committee (NUBC). Revenue codes must be used by ALL providers and payers but value codes are payer-specific. Value codes allow product costs to be sent to payers on claims.
BILLING

CMS provides options for reporting services with status B

Cell collection and cell processing services can be billed in multiple ways, since they are assigned status indicator “B”

- “B” = no payment so go find a better code

1. **Report them separately**, accept the rejection because this allows the provider to report each individual service at the time rendered and allows CMS to collect data

2. **Build the dollars** for cell collection and cell processing into the charge for the CAR-T product (report product code and not the CPT service codes)

3. **Drop outpatient charges** for cell collection and cell processing **but hold them** and report them on the inpatient administration claim

*Best practice: Report all codes and charges separately at the time they occur*
Expanded access and FDA approved CAR-T with different trial product

CMS has two payment rates for MS-DRG 018; the full payment when a product cost is incurred and a reduced payment when it’s not

- Transmittal R10360CP explains how expanded access cases must be reported for providers to accurately be paid the lower MS-DRG amount
- It also explains how cases should be reported when something other than a CAR-T is under trial, so the full MS-DRG payment can be made.
- In both situations, the burden is on providers to report additional information on their claim to receive correct payment

More on expanded access

Condition codes are also defined by the NUBC to report specific information about the overall claim. Certain condition codes are commonly used, while others are payer-specific.

- Transmittal 10470 released two new condition codes:
  - Condition code 90: relevant to CAR-T is used to report a service provided as part of an Expanded Access Approval (EA)
    - Informational only for now which means it does not impact payment but should still be reported
  - CMS expects providers to report accurately in order to be paid accurately when a CAR-T product cost is not incurred (explained in the reimbursement section)