ASTCT Webinar - June 12, 2019

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American Society for Transplantation and Cellular Therapy
Today’s Topics

- News, Advocacy, and Hill Updates
- Coverage
- FY 2020 IPPS Proposed Rule
- Latest from CMS on CAR-T Billing Guidance
- Next Steps and Looking Ahead
News, Advocacy, and Hill Updates

- ASTCT Hill Day
- ASTCT meetings with CMS
- Centers pushing Congress for CAR-T solutions

Important Dates
- FY 2020 IPPS Comments Due June 24
- TBD: Final NCD decision delayed
  - "CMS will not be issuing a final National Coverage Determination on CAR T-cell therapy for cancer today, but a decision is forthcoming." –May 17, 2019

- Advocacy Efforts
  - PACT Act (H.R. 2498/S. 1268)
  - ASTCT Letters of Support
  - Reps. Brian Higgins and Tom Reed’s CAR-T Reimbursement Letter

- ASTCT Appropriations Request
Additional News

Other ongoing activities:

- Congressional Hearings
  - E&C Surprise Billing
  - WM Universal Health Coverage
- Senate HELP Lowering Healthcare Costs
- Senate Special Committee on Aging Investigating Drug Prices

Recently introduced legislation

- PCORI reauthorization
CMS/Medicare NCA for CAR-T: Process Flow

- **NCA announced 5/16/2018**
- **Comment period - 30 days**
  - ASBMT comments submitted 6/18

- **Draft decision memo issued 2/15/2019**
  - Individual stakeholder meetings
  - MEDCAC Mtg on PROs 8/22/2018

- **Comment period - 30 days**

- **Final Decision NOT YET RELEASED**

- **Final Decision effective until new NCA process**

Administrator Verma’s Comments on NCD

“"It’s not only new technology for the entire medical community, cancer care, but it’s also new ground for the agency. So we want to make sure that we’re doing this appropriately, dotting our i’s and crossing our t’s. It’s just taking a little bit more time because it’s not a routine type of decision," Verma said.

CMS delayed the CAR-T coverage policy on May 17 without explanation.

Verma said she has been spending time on, and is concerned about, ways to pay for increasingly expensive drugs, including CAR-T. Former FDA Commissioner Scott Gottlieb has been outspoken about Medicare policies that he says discourage the development of drugs administered in hospitals, even though that’s the area of personalized medicine that holds the most promise.

Verma said she plans to reach out to researchers and other experts to discuss how to pay for new, expensive drugs.

“I think we need to have a serious discussion about how we are going to pay for these treatments. These drugs that are coming out are one time, they’re curative treatments and so these are very different than what we’ve dealt with in the past and I think the payment systems that we have in place are really not set up to deal with that,” Verma said.

She added she is especially worried about the effects of expensive drugs on state Medicaid programs.

“I haven’t found the silver bullet, but I am looking for it," she said.
HIGHLIGHTS FROM THE FY 2020 MEDICARE INPATIENT PROSPECTIVE PAYMENT SYSTEM PROPOSED RULE
Highlights of Key Proposals for FY 2020 IPPS

- Financial update to the national standardized amount less various reductions
- Wage-index and disproportionate share changes
- Coding changes
  - Changes to administration table/transfusion codes (impacts code options available for stem cell transplant)
  - T-cell depleted ICD-10-PCS stem cell transplant procedure code for FY 2020
  - Changes in MS-DRG CC/MCC assignment for a lot of codes (neoplasms hit hard but others as well)
- New Technology Add-On Payment (NTAP) requests and changes
- CAR-T payment - we’ll discuss this one in detail
Complete View of the National Standardized Amounts Proposed After All Adjustments Factored In*

<table>
<thead>
<tr>
<th>FFY 2020 Proposed Rule</th>
<th>Hospital Submitted Quality Data and is a Meaningful EHR User</th>
<th>Hospital Submitted Quality Data and is NOT a Meaningful EHR User</th>
<th>Hospital Did NOT Submit Quality Data and is a Meaningful EHR User</th>
<th>Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User</th>
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<td>3.2</td>
<td>3.2</td>
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</table>

Applicable Percentage Increase Applied to the Standardized Amount after all adjustments are applied: 3.2000 0.8000 2.4000 0.0000

* Additional aggregate dollars available to hospitals from the disproportionate share (DSH) policy
MS-DRG Changes, ICD-10 Update, and Relative Weight Updates

- Grouper version 37 proposed for FFY 2020, with approximately 762 MS-DRGs

- FFY 2020 MS-DRG relative weights computed from:
  - Claims from FFY 2018 MedPAR file with discharges through September 2018
  - Cost report data from the December 31, 2018 quarterly update of the FY 2017 HCRIS

- Codes additions, deletions, and/or MS-DRG assignment changes impact relative weights

- For FFY 2020, CMS proposes an outlier threshold of $26,994 so that outlier payments are maintained at 5.1% of total IPPS payments with an adjustment for outlier reconciliation
### Summary of Major Coding Changes

<table>
<thead>
<tr>
<th>Tables (Tab)</th>
<th>MS-DRG Issue</th>
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<tr>
<td>6A-F</td>
<td>Transfusion procedures</td>
<td>List of transfusion procedures with body system/region values &quot;5&quot; Peripheral Artery and &quot;6&quot; Central Artery</td>
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<td>6P.1b</td>
<td>Dilation of a carotid artery</td>
<td>List of ICD-10-PCS procedure codes describing dilation of a carotid artery with an intraluminal device being removed from MS-DRGs 037, 038, and 039</td>
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<tr>
<td>6P.1c</td>
<td>Proposed severity level changes</td>
<td>Full list of ICD-10-CM diagnosis codes with proposed severity level changes</td>
</tr>
<tr>
<td>6P.1d</td>
<td>Proposed severity level changes</td>
<td>List of ICD-10-CM diagnosis codes describing pressure ulcers with proposed severity level changes</td>
</tr>
<tr>
<td>6P.1e</td>
<td>Proposed severity level changes</td>
<td>List of ICD-10-CM diagnosis codes describing obstetrical complications with requested changes to severity levels</td>
</tr>
</tbody>
</table>

* CMS proposes significant deletions to the lists of codes that are major complications and comorbidities (MCCs) and complications and comorbidities (CCs). For example, all secondary cancers are being removed from the list of CCs and pressure ulcers are being removed from the list of MCCs.

**Deletion of a bunch of codes we are used to in the stem cell transplant administration table**

**NEW T-cell depleted stem cell transplant code for FY 2020**
FY 2020 Payment Rate Changes for Stem Cell Transplant MS-DRGs

HCT Inpatient MS-DRG Payment Rate Trend

- 2010: $36,920
- 2011: $33,228
- 2012: $35,548
- 2013: $35,184
- 2014: $34,974
- 2015: $34,520
- 2016: $36,469
- 2017: $36,407
- 2018: $38,817
- 2019: $39,951
- Proposed 2020: $42,493

- 2010: $24,340
- 2011: $24,848
- 2012: $24,443
- 2013: $25,823
- 2014: $24,272
- 2015: $27,288
- 2016: $26,765
- 2017: $27,257
- Proposed 2020: $27,940

(Marked trends for Allo - MDRG 014, Auto w/ CC/MCC - MDRG 016, and Auto - MDRG 017)
New Technology Add-On Changes

- CMS proposes to increase the marginal cost factor and the cap from 50% to 65% for new technology add-on payments (NTAP)

- CMS proposes to continue NTAP for 10 of 13 technologies
  - Chimeric antigen receptor t-cell therapy (CAR-T) to continue as one of the NTAPs with continued assignment to MS-DRG 016

- CMS reviews 17 applications for NTAP designation

- CMS proposes to recognize FDA breakthrough/expedited device approvals as meeting the new and substantial clinical improvement criteria associated with NTAP but does not propose this for drugs

- CMS requests comments on other ways to recognize substantial clinical improvement of new technologies for CMS to approve for NTAP
SPOTLIGHT ON MEDICARE CAR-T REIMBURSEMENT PROPOSALS FOR FY 2020
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 016 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>
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</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 (maximum of $186,500) and the outlier payment mechanism.

* PPS-exempt hospitals have a different payment mechanism.
FY 2020 IPPS Proposed Rule Overview for CAR-T

(1) CAR-T cases to remain in MS-DRG 016
(2) Increase the NTAP cap from 50% to 65% for all NTAPs (for CAR-T = cap of $242,450)
(3) Continue the NTAP for another year
(4) For the PPS-Exempt Centers CMS asked for input/comment on the TEFRA adjustment process

The Proposals

(1) Making a uniform add-on payment that equals the proposed maximum add-on payment of $242,450 by eliminating the use of the CCR in calculating the NTAP for Kymriah and Yescarta
(2) Using a higher percentage than the proposed 65% to calculate the maximum NTAP amount
(3) Using a CCR of 1.0 for the NTAP, outlier, and the PPS-Exempt Centers
(4) What is the best way to create a new MS-DRG for CAR-T? Lots of questions being asked…

Seeking Comment

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

The Tea Leaves

06.15.2019
## Two Hospital Case Example to Evaluate Payment Options for FY 2020

### Hospital and Patient Characteristics

Both hospitals A and B:

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

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

### Hospital A Example Inpatient Hospital Claim

<table>
<thead>
<tr>
<th>Description</th>
<th>Units</th>
<th>Total Charges</th>
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<tr>
<td>Room &amp; Board</td>
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<td>Pharmacy</td>
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<td>Supplies</td>
<td>20</td>
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<td>Laboratory</td>
<td>520</td>
<td>$32,000</td>
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<td>All other</td>
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<td>$75,000</td>
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<tr>
<td><strong>CAR-T Drug</strong>*</td>
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<td><strong>$410,300</strong></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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</table>

### Hospital B Example Inpatient Hospital Claim

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<td>All other</td>
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<tr>
<td><strong>CAR-T Drug</strong>*</td>
<td>1</td>
<td><strong>$1,492,000</strong></td>
</tr>
<tr>
<td><strong>Total Charges</strong></td>
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<td><strong>$1,720,000</strong></td>
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</table>

*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.*
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”

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

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

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

CMS’ Proposal for FY 2020 is to Change the 50% NTAP Cap to 65%
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.

\[
\text{Calculated Cost} \quad \text{MS-DRG Payment Amount} \quad \text{NTAP Payment Amount} + \text{Fixed Outlier Threshold of}$25,769 \quad \times 0.8 = \text{Outlier Payment}
\]
Review of Financial Impact Today

- Hospital charges and drug mark-up practices impact financial impact
- With wage-index, IME, and DSH adjustments applied the impact may not be as great as shown here
- CMS appears to understand this as evidenced by statements made in the proposed rule and hence proposes a change and seeks comments on several options for FY 2020
Breakdown of Case Volume MedPAR FY 2018

348 CAR-T Cases from 43 Hospitals
(37 PPS and 6 PPS-Exempt) from MedPAR Medicare claims for patients from October 1, 2017 to September 30, 2018

37 PPS Hospitals
N = 201 cases

PPS Non-Clinical Trial Cases
*Comes from 107 cases
Average Pharmacy Charges: $1,464,772*
Average Total Claim Charges: $1,660,959

PPS Hospital Clinical Trial Cases
N = 93
Average Pharmacy Charges: $92,635
Average Total Claim Charges: $256,550

31 of the cases were from October 1, 2017 to December 31, 2017

317 of the cases were from January 1, 2018 to September 30, 2018

PPS Non-Clinical Trial Cases Used in Rate-Setting
N = 40
Average Pharmacy Charges: $623,726

PPS Hospital Clinical Trial Cases Used in Rate-Setting
N = 84
Average Pharmacy Charges: $101,041
Array of PPS Hospital Pharmacy Charges Only...Yes Some Look Very Odd

<table>
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<tr>
<th>Name</th>
<th>Total # of CAR-T Cases</th>
<th>Not Clinical Trial</th>
<th>Clinical Trial</th>
<th>Not Clinical Trial</th>
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<td>$115,016</td>
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</table>

“*” = Numbers with counts of less than 11, or counts that could lead to a calculation of less than 11; all further breakdowns of the total number by clinical trial and non-clinical trial for volume would have met this criteria; therefore those breakdowns have not been shown.
Continuum of Options For Consideration For FY 2020

Status Quo
- MS-DRG 016
- Usual NTAP
- Usual Outlier
- Usual Process for PPS-Exempt including impact of recent MAC letter

CMS’ Proposal to Change NTAP Cap to 65% for PPS Hospitals
- MS-DRG 016
- Change NTAP cap from 50 to 65% in current formula
- Usual outlier

Uniform NTAP for PPS Hospitals
- MS-DRG 016
- NTAP paid to all PPS hospitals irrespective of the product billed charge
- Usual outlier

CMS’ Proposal for PPS Hospitals to Change NTAP Cap +CCR 1.0
- MS-DRG 016
- Change NTAP cap to a higher amount (i.e. 80%)
- Change NTAP and outlier calcs so actual product cost is used instead of billed charges reduced to cost method

PPS Exempt
- CMS requests comments on how to address payment issues in terms of their payment system (i.e., TEFRA)

Our Modeling has focused on these 3 options for PPS Hospitals
Comparing CMS’ Proposed Option of Changing the NTAP Cap or Possibly Moving towards a Uniform Add-On Payment
CMS’ Proposal Doesn’t Go Far Enough So ASTCT Proposes a Different Solution

1) Increase NTAP cap to 80 percent for all NTAPs

2) Apply a CCR of 1.0 to calculate the NTAP and the outlier for CAR-T

**CCR of 1.0 = Full** recognition of actual CAR-T product acquisition cost, not the CAR-T billed charge in CMS’ NTAP and outlier formulas

• This was definition used by ASTCT when originally proposed in 2017.
<table>
<thead>
<tr>
<th>Options</th>
<th>FY 2019</th>
<th>Current</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
<th>Option 5</th>
<th>Option 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS-DRG</td>
<td>016</td>
<td>016</td>
<td>016</td>
<td>016</td>
<td>016</td>
<td>016</td>
<td>016</td>
<td>016</td>
</tr>
<tr>
<td>NTAP</td>
<td>Current methodology</td>
<td>Update to the percentage cap used in the current formula</td>
<td>Update to the percentage cap used in the current formula</td>
<td>Update to the percentage cap used in the current formula</td>
<td>Larger update to the percentage cap used in the current formula &amp; then exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back $373,000 for CAR-T product cost and then apply the usual formula</td>
<td>Change formula to 65% of NTAP as uniform payment</td>
<td>Change formula to 80% of NTAP as uniform payment</td>
<td></td>
</tr>
<tr>
<td>Outlier</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
<td>Current methodology</td>
</tr>
<tr>
<td>Financial Impact Based on Hospital A w/ 10% Mark up</td>
<td>($303,003)</td>
<td>($300,216)</td>
<td>($297,503)</td>
<td>($50,607)</td>
<td>($39,417)</td>
<td>($145,057)</td>
<td>($89,107)</td>
<td></td>
</tr>
<tr>
<td>Financial Impact Based on Hospital B w/ 400% Mark up</td>
<td>($61,325)</td>
<td>($50,607)</td>
<td>($39,417)</td>
<td>($50,607)</td>
<td>($39,417)</td>
<td>($50,607)</td>
<td>($39,417)</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
1. Each option is based on the sample claims provided.
2. MS-DRG payment based on the assumption that both hospitals have a wage index of 1.0 and no adjustments for IME or DSH in order to isolate issues of charge compression.
3. High variability in financial impact across hospitals depending on actual wage index and whether adjustments for medical education and/or DSH are applicable.

Note: There are other variations we have worked up that can be shared if necessary including changing how the outlier is calculated in the situation of a uniform NTAP in order to protect the overall outlier pool from high CAR-T marked up charges.
What Does Using a CCR of 1.0 Really Mean?

Step 1: Compute “Patient Care Cost” ONLY

\[
\text{Total Inpatient Charges on CAR-T Claim} - \text{Line item drug charge reported in new revenue code 0891}} \times \text{Hospital’s Overall Cost-to-Charge Ratio (CCR)} = \text{Calculated Patient Care Cost}
\]

Step 2: Derive NEW Total Case Cost

\[
\text{Calculated Patient Care Cost} + \text{CAR-T Drug Cost} = \text{NEWLY CALCULATED COST}
\]

Step 3: Use NEWLY Calculated Case Cost as the Starting Point in the NTAP and Outlier Calculations

It does NOT mean multiplying the line item pharmacy charge by a CCR of 1.0 as CMS states in the proposed rule!
A Closer Look at Option 4

**NTAP:**
- Increase to 80%, rather than 65% as proposed, is needed to make a meaningful difference in reimbursement
- CMS hasn’t historically paid out full NTAP so this is reasonable

**CCR of 1.0:**
- Solution unique to CAR-T since revenue code 0891 allows specific isolation of the CAR-T product charge
- All hospitals treated equally regardless of charging practices
- CMS has options on how to operationalize this and does not require significant changes in CMS formulas
- Fair and adequate NTAP reimbursement that recognizes cost of new technology
- Prevents overpayment of outlier from extraordinary markup

This of this as a “combo” approach of what CMS proposed and what CMS asked for comment on for doing something “special” for CAR-T
Future Rate Setting...Looking Towards 2021 and Beyond

- Comments will address many of the issues CMS raised in the proposal regarding future rate setting

- Existing data show why CMS must **not** engage in typical rate setting

- ASTCT has stressed the need to collect accurate data since 2017. NUBC coding changes (effective April 1) will help improve data, but not soon enough for FY 2021 rate setting

- CMS must work with ASTCT to better educate hospitals about coding and billing requirements for CAR-T
We Have to Act...What Can You Do?

Submit comments to CMS for making changes for FY 2020

Discuss the need for different rate-setting for FY 2021...rate-setting as usual will not generate appropriate payment even if CMS creates a new CAR-T MS-DRG

Given what the claims data to date look like, providers should review their claims now and if there are errors, correct and resubmit
Review and Verify Accuracy of CAR-T Claims

- All CAR-T claims should be reviewed for:
  - Presence of CAR-T product charge when hospital incurred the acquisition cost
  - Correct dollar value of the CAR-T product charge based on the hospital’s mark-up policy
  - If hospital did not incur the cost of the CAR-T cells due to clinical trial or off-label, both manufacturers have National Clinical Trials to collect data regarding these cases that must be reported on claims
  - Correct ICD-10-PCS code for the CAR-T administration
  - All other charges for reasonableness and accuracy

- Who can review CAR-T claims?
  - Revenue Integrity and/or nurse audit staff are qualified to review itemized statements and UB-04 claims for each CAR-T case
  - Provide a list of account numbers for each CAR-T case to one of these staff designated to conduct the review
  - Begin with the earliest case and work to the most current case
  - Submit adjustment claims, i.e., claim corrections, whenever errors are found
Correct, Revise, Adjust Your Claims!

- **Why correct claims?**
  - If the CAR-T product charge was not on the original claim for any reason, it is likely no NTAP payment was made. Adjusting the claim with the correct CAR-T product charge should result in some additional case payment for the NTAP and possibly outlier payment as well.
  - Ensure the CAR-T product charge amount accurately reflects your mark-up policy which should be based on your hospital’s CCR.
  - If the CAR-T product expense was not incurred due to the case being a clinical trial case, ensure value code D4 and NCT# is correctly reported on the claim.

- **Adjusting CAR-T Claims:**
  - Patient Financial Services (PFS) or the Revenue Cycle Staff are capable of submitting adjusted claims.
  - Adjustment claims (i.e., TOB 0117 or 0137) can be submitted one year from the date of discharge/service for any reason.
  - Automated reopenings (i.e., TOB 011Q or 013Q) can be submitted one year from the date of the initial remittance advice (i.e., the initial determination) for any reason.

[See SE1426 and Chapter 34 of the Medicare Claims Processing Manual, Section 10]
Finally….The Latest from CMS on CAR-T Billing
National Uniform Billing Committee (NUBC) Approved New Revenue Codes and a New Value Code for April 1, 2019 Implementation

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

<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>
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<tr>
<td>2</td>
<td>Specialized Biologic Processing and Storage - Prior to Transport</td>
<td>CELL/GENE TRANS PRIOR</td>
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<tr>
<td>3</td>
<td>Storage and Processing after Receipt of Cells from Manufacturer</td>
<td>CELL/GENE STOR PROC AFT</td>
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<tr>
<td>4</td>
<td>Infusion of Modified Cells</td>
<td>CELL/GENE INFUSION</td>
<td></td>
<td></td>
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<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.

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</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</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>

*NEW values for reporting cell acquisition cost*

Effective Dates:
UB-04: July 1, 2018, April 1, 2019

Form Locators 39-41
Page 14 of 19

NEW value code for reporting cell acquisition cost

http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf
"We are concerned that some of what’s written here may violate claims processing conventions and sets a dangerous precedent. Also asking hospitals to report what they would absolutely consider covered patient care services as non-covered charges on outpatient claims but allowing them to move to an inpatient claim even when it’s outside of the 3 day window is very strange."

- Excerpt from the NUBC April 9th meeting agenda on CAR-T billing methodology; full agenda and detailed questions can be found here: http://www.nubc.org/aboutus/PDFS/April2019TentSchedule.pdf

Do the words “may report” also allow providers the option to: “may not” report in the manner described?

How can the same services (i.e., cell collection and processing) be non-covered in one setting and covered in another? And does “non-covered” mean the services are not a benefit and an ABN can be given to patients?

Aren’t there concerns with comingling charges from different departments if cell collection and processing charges are reported on inpatient claims using the new pharmacy revenue code 891 and NOT the newly created revenue codes 0871, 0872, or 0873 which better represent where the expense associated with these services reside?

Comingling Part B and Part A services: How can outpatient charges for services provided to the patient weeks prior to an inpatient stay (clearly outside the 3 day window) be reported on an inpatient claim? Will claims even process or will dates have to be changed...which raises other questions...

What does this mean in terms of following NUBC claims rules and reporting of charges consistently to all payers?
The Latest...

- CMS listened to the NUBC and released new information in late May

- Review CMS’ new Special Edition Article SE1009

- The new information is better than the original March 15th transmittal, but not perfect
  - CMS eliminated the use of words “non-covered”
  - CMS allowing reporting of the new Category Three CPT codes
  - CMS trying to give flexibility in how providers can charge for cell collection and processing but this is where the guidance continues to raise questions...

ASTCT is in the process of updating its coding resource from April located here, so stay tuned: https://www.asbmt.org/practice-resources/coding-and-reimbursement/car-t-therapy
Thank You and Questions/ Discussion....