ASBMT Town Hall

August 29, 2018

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Today’s Topics

Coverage
- HCT: Lymphoma and Autoimmune Diseases
- CAR-TNCA and MEDCAC
- Blue Distinction Centers for Cellular Immunotherapy

Payment System Updates
- Anticipated Changes: NUBC & ICD-10
- MPFS Proposed Rule for CY2019
- OPPS Proposed Rule for CY 2020
- CAR-TCPTCodes
- IPPS Final Rule for FY 2019
Coverage
HCT Coverage Expansion Efforts

Lymphoma

• Need for clear coverage status of HCT for lymphoma in Medicare beneficiary population; general HCT and post-CAR-T
• Efforts by NMDP underway through conversations with regional MACs
• CGS (Ohio and Kentucky) will have expanded coverage soon. Palmetto and Noridian efforts being scheduled.

Autoimmune

• New ASBMT position statement on sclerodema
• Data on HCT for other autoimmune diseases growing
• Planned outreach to national payers
Reminder: CMS opened a National Coverage Analysis in May 2018

- Proposed decision will be available in February 2019; Final decision in May 2019

Potential final decision options

- National Coverage Determination = national policy for coverage
- Coverage with Evidence Development = prospective study format; requires submission and approval of specific study protocol, data submission to resolve study questions
- Dismissal of NCA (unlikely)

How to follow this issue:
- www.CMS.gov - enter “chimeric” in the main search box at top of page.
CAR-T: MEDCAC Meeting (8/22)

Focus on Patient Reported Outcomes (PROs)

- Format: invited speakers, presenters who submitted materials in advance and public speakers; panel discussion and Q&A; voting on final questions
- Panel included individuals from clinical, research and advocacy backgrounds

Voted on a series of pre-set questions

- PROMIS tool rated most valid and generalizable to the Medicare population
- Fixed-time frequency over 24-month period

Final impact on NCA process unknown until February 2019.

- First time CMS has discussed PROs in this setting
- Could be integrated into a final NCD or CED
- Could simply continue as matter of interest to CMS
- May be seen in potential future payment models

ASBMT-affiliated presenters:

Merav Bar, FHCRC/SCCA
Heather Jim, Moffitt
Kathryn Flynn, MCW/CIBMTR
Gunjan Shah, MSKCC
Surbhi Sidana, Mayo MN

CIBMTR organizing next steps for collaborative effort on CAR-TPROs
Blue Distinction Centers: CAR-T

Key Notes:
- FACT IEC accreditation required; FACT is preparing for more survey requests
- Shared decision-making model; patient experience survey
- Reporting to CIBMTR required; other quality measures directly to BCBSA
- Model likely to be reflected in other national payer systems
- Potential advantages—may result in faster authorization times and/or additional patient benefits, such as travel and lodging
Payment System Updates
FYI: Potential Code Changes Under Consideration

**National Uniform Billing Committee**
- August 7-8, 2018
- Robust discussion about adding new revenue codes to allow for more detailed reporting of cell and gene therapy services and products
- Implementation sometime in 2019; more detail to come when the final minutes are posted

**ICD-10 Coordination & Maintenance Committee**
- September 11, 2018
- Relevant code requests – T-cell depleted HCT; CAR-T complications (CRS)(potential)
Medicare Physician Fee Schedule
Proposed Rule
Key Proposed Changes for CY 2019

E/M Documentation and Payment Proposals

• Select your documentation method (i.e., 1995/1997 guidelines, medical decision-making, or time)
• One payment rate for low level and one rate for levels 2-5 + add-on codes to supplement collapsing of payment rates

Additional Documentation Burden Reduction Proposals

• Eliminate requirement for practitioners to document the medical necessity of a home vs. office/outpatient visit
• Allow practitioners to document only what has changed since last visit rather than re-documenting information
• Allow practitioners to review/verify info entered by ancillary staff or beneficiary, rather than re-entering it in the record

Additional Payment Proposals

• Multiple Procedure Payment Reduction (MPPR) extended to E/M visits and procedures by physicians in the same group – the “pay-for” for the add-on codes
• Provide payment for two E/M visits billed by a physician of the same specialty for unrelated problems
• New codes proposed for two non-face to face services called “communication based technology services”
• Interprofessional consultations via phone or internet in service of the patient

CMS Seeking Comments on all Proposals; Special interest in:

• Implementation start date: 2019 vs. 2020
• Will the proposals reduce clinician burden?
• How will the proposals impact program integrity and/or create unintended consequences?
Proposed Office Visit Payment Change Details

- Proposed documentation changes accompanied by proposed payment changes for E/M visit codes (99201-99215)
  - “Streamline” & simplify
  - One rate for level one
  - One rate for E/M visit levels 2-5 for new patients and one for established patients
- Applicable to physician and NPP in all settings (i.e., facility and non-facility places of service)
- Two add-on codes proposed to supplement these changes
  - Specialty care services code GCG0X with an approximate payment of $9 to be billed in addition to the E/M visit code to describe visit complexity inherent to E/M services associated with various specialties
  - Primary care services code GPC1X with an approximate payment of $5 to be billed in addition to the E/M visit code for established patients when the visit includes primary care services

### TABLE 19: Preliminary Comparison of Payment Rates for Office Visits New Patients

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>CY 2018 Non-facility Payment Rate</th>
<th>CY 2018 Non-facility Payment Rate under the proposed Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>99201</td>
<td>$45</td>
<td>$44</td>
</tr>
<tr>
<td>99202</td>
<td>$76</td>
<td></td>
</tr>
<tr>
<td>99203</td>
<td>$110</td>
<td>$135</td>
</tr>
<tr>
<td>99204</td>
<td>$167</td>
<td></td>
</tr>
<tr>
<td>99205</td>
<td>$211</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 20: Preliminary Comparison of Payment Rates for Office Visits Established Patients

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Current Non-facility Payment Rate</th>
<th>Proposed Non-facility Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>$22</td>
<td>$24</td>
</tr>
<tr>
<td>99212</td>
<td>$45</td>
<td>$45</td>
</tr>
<tr>
<td>99213</td>
<td>$74</td>
<td>$93</td>
</tr>
<tr>
<td>99214</td>
<td>$109</td>
<td>$109</td>
</tr>
<tr>
<td>99215</td>
<td>$148</td>
<td>$148</td>
</tr>
</tbody>
</table>
What We Are Hearing...

- **The major documentation and payment proposals are not likely to be finalized for CY 2019**
  - Burden reduction not likely since clinicians would still have to follow CPT for other payers
  - Time to implementation too short with many open questions about implementation and program integrity

- Some of CMS’ other documentation proposals to reduce burden are likely to be supported and if implemented should serve to reduce burden

- CMS should revisit its Telehealth rule instead of making piecemeal changes such as issuing new codes for “communication based technology services”

- Too many open questions that CMS would have to address through sub-regulatory guidance which it will not have sufficient time to do so for CY 2019

- Late release of the rule means CMS has a compressed window to review and address comments before release of the final rule which means much of what has been proposed will likely be postponed

- Thousands have already submitted their comments against the proposal...
**MPFS Summary and Action Items**

- ASBMT has been participating in a number of multi-specialty efforts
  - E/M Coalition (led by American Geriatrics Society), others by ACP and AMA
  - Group letters to the Hill and CMS sharing concerns
  - Extensive analysis and conference calls underway; waiting for final letters to mirror in our comments.

- CMS predicts 1% total impact change to Hematology/Oncology
  - AMA assessment looks closer to -16%; HCT not feasible to separately analyze

- The proposed changes have sparked a joint CPT/RUC working group to reassess the E/M code series in its entirety. More information will be shared as it develops.

**For comment submission:**

- Share impact to your program and facility – reduction in ability to fund positions, etc.
- Respond to CMS’ key questions about whether its proposals will reduce burden and increase access
  - Initial feedback from providers: No
- ASBMT will share formal comment as soon as possible before September 10 deadline.
Medicare Outpatient Payment Proposed Rule
## HCT Related OPPS Proposed Payments for CY2019

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>APC</th>
<th>Payment Rate</th>
<th>Single Frequency</th>
<th>Total Frequency</th>
<th>Median Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>38205</td>
<td>PBSC, Allo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38206</td>
<td>PBSC, Auto</td>
<td>5242</td>
<td>$1,222.97</td>
<td>290</td>
<td>4364</td>
<td>$1,479.47</td>
</tr>
<tr>
<td>38207</td>
<td>Cryopreservation</td>
<td>5241</td>
<td>$383.39</td>
<td>123</td>
<td>3994</td>
<td>$928.76</td>
</tr>
<tr>
<td>38208</td>
<td>Thaw, w/o wash</td>
<td>5241</td>
<td>$383.39</td>
<td>22</td>
<td>496</td>
<td>$217.93</td>
</tr>
<tr>
<td>38209</td>
<td>Thaw, with wash</td>
<td>5241</td>
<td>$383.39</td>
<td>2</td>
<td>12</td>
<td>$6,089.49</td>
</tr>
<tr>
<td>38210</td>
<td>T cell depletion, Allo</td>
<td>5241</td>
<td>$383.39</td>
<td>6</td>
<td>47</td>
<td>$176.40</td>
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<tr>
<td>38211</td>
<td>T cell depletion, Auto</td>
<td>5241</td>
<td>$383.39</td>
<td>1</td>
<td>3</td>
<td>$689.58</td>
</tr>
<tr>
<td>38212</td>
<td>Red cell removal</td>
<td>5241</td>
<td>$383.39</td>
<td>0</td>
<td>45</td>
<td>$0.00</td>
</tr>
<tr>
<td>38213</td>
<td>cell removal, 1+ apheresis</td>
<td>5241</td>
<td>$383.39</td>
<td>0</td>
<td>5</td>
<td>$0.00</td>
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<tr>
<td>38214</td>
<td>Plasma depletion</td>
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<td>$383.39</td>
<td>35</td>
<td>1727</td>
<td>$1,015.27</td>
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<tr>
<td>38215</td>
<td>MNC concentration</td>
<td>5241</td>
<td>$383.39</td>
<td>13</td>
<td>282</td>
<td>$722.80</td>
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<tr>
<td>38220</td>
<td>Bone marrow aspiration</td>
<td>5072</td>
<td>$1,370.32</td>
<td>5276</td>
<td>5352</td>
<td>$1,930.07</td>
</tr>
<tr>
<td>38221</td>
<td>Bone marrow biopsy</td>
<td>5072</td>
<td>$1,370.32</td>
<td>56676</td>
<td>57284</td>
<td>$1,937.86</td>
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<tr>
<td>38230</td>
<td>Marrow harvest, allo</td>
<td>5242</td>
<td>$1,222.97</td>
<td>11</td>
<td>23</td>
<td>$2,590.39</td>
</tr>
<tr>
<td>38232</td>
<td>Marrow harvest, auto</td>
<td>5243</td>
<td>$3,912.23</td>
<td>7</td>
<td>74</td>
<td>$5,449.53</td>
</tr>
<tr>
<td>38240</td>
<td>HCT, Allo</td>
<td>5244</td>
<td>$25,645.86</td>
<td>36</td>
<td>36</td>
<td>$29,789.10</td>
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<tr>
<td>38241</td>
<td>HCT, Auto</td>
<td>5242</td>
<td>$1,222.97</td>
<td>14</td>
<td>379</td>
<td>$844.06</td>
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<tr>
<td>38242</td>
<td>DLI, Allo</td>
<td>5242</td>
<td>$1,222.97</td>
<td>22</td>
<td>141</td>
<td>$1,573.30</td>
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<tr>
<td>38243</td>
<td>Boost, Allo</td>
<td>5242</td>
<td>$1,222.97</td>
<td>0</td>
<td>5</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

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**Action Items:** Submit comments on the OPPS rule by Sept 24, 2018

1) Request CMS study the creation of an Autologous HCTC-APC

2) Request technical updates:
   a. Assign revenue code 0815 to its list of packaged revenue codes for proper calculation of C-APC 38240
   b. Provide detailed instructions for new Cost Center 77
CAR-T Product Outpatient Payment

From Addendum B of the OPPS Proposed Rule

- Separate payment available for CAR-T product based on the average sales price (ASP) plus 6% IF CAR-T infused in the outpatient setting
- Q codes as defined still include “leukapheresis and other dose preparation procedures”

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Payment Rate</th>
<th>Minimum Unadjusted Copayment</th>
<th>Actual Copayment (Inpatient Deductible Maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2040</td>
<td>Tisagenlecleucel car-pos t</td>
<td>$500,838.643</td>
<td>$100,167.73</td>
<td>$1,340.00</td>
</tr>
<tr>
<td>Q2041</td>
<td>Axicabtagene ciloleucel car+</td>
<td>$395,380.000</td>
<td>$79,076.00</td>
<td>$1,340.00</td>
</tr>
</tbody>
</table>
New CPT Codes for CAR-T Services

Codes for CAR-T services requested and approved at the May 2018 CPT meeting.

- Submitted in conjunction with ASH, ASCO and CAP
- Category III codes: “temporary set of codes for emerging technologies, services and procedures”
- Codes released July 1st for January 1st, 2019 implementation
- New CAR-T header in the CPT Book: “Cellular and Gene Therapy”

- **0537T**: Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
  - preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
- **0538T**: Receipt and preparation of CAR-T cells for administration
- **0540T**: CAR-T cell administration, autologous

No discussion in the outpatient rule, but Addendum B does not have APC payment rates proposed

- Status indicator “B” = an alternate code recognized by OPPS when submitted on Part B bills (12x and 13x) may be available.
- Comment indicator “NP” = CMS is accepting comments

The ASBMT presented on this to CMS’ Hospital Advisory Panel on August 20th

- Panel recommended CMS align with ASBMT’s suggested status indicators and APC assignments until more data is gathered.

Action Items: Critical to Submit Comments on the OPPS Rule to Medicare by Sept 24, 2018

1) Remove patient care services from the CAR-T Q-codes, making the code description just for the drug itself

2) Provide payment for new Category III CAR-T CPT codes as recommended by the HOP Panel and the ASBMT

Note: If CMS does not make the change requested providers may have to continue using the unlisted code 38999 and/or seek guidance from CMS on what to report. Timeline for final decision = November 2018
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.

- The MACs met in late July to discuss coding, reimbursement, and coverage issues; appear to understand the need to add these codes to their policies.

- We anticipate sending a letter of request to the MACs with code co-sponsors in September; on-going monitoring of policies post-request.

- Manufacturers: Partnership on this effort would be very much appreciated.
Reminders About Reporting CAR-T Services

- There are no perfectly suitable codes for reporting the various services associated with CAR-T available for use in 2018.

- In the absence of perfectly suitable codes, the ASBMT follows the guidance from the introductory section of the CPT manual which states:
  
  - "Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the approximate unlisted procedure or service code."

- This may be in contrast to other guidance so hospitals and clinicians must decide what codes to report to reflect their CAR-T services

- Reporting unlisted codes create unique challenges, but can be done to report the services provided and to receive payment.
**Key Question: Can Physicians Get Paid for the CAR-T Services They are Providing?**

**Answer:** Yes!

**How?**
- By reporting unlisted codes in **2018**
- By reporting new Category III CAR-t CPT codes in **CY 2019**

**Follow-Up**
- MDs need to send a letter to their MACs describing what service was provided and similarities to transplant services.
- The table provides crosswalks for **CY 2018 and CY 2019**

<table>
<thead>
<tr>
<th>Current CY 2018 Reporting and RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS Codes</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>38999</td>
</tr>
<tr>
<td>38999</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>January 1, 2019 Reporting and Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS Codes</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>0537T</td>
</tr>
<tr>
<td>0540T</td>
</tr>
</tbody>
</table>
Additional Questions

- When will RVUs be assigned to the new CAR-T CPT codes?
  - Answer: RVUs will not formally be evaluated or assigned until the Category III codes are converted to Category I (likely 3-7 years from now).

- Neither 38999 or the new CAR-T CPT codes have RVUs assigned to them. As a hospital-based physician, how can I get credit for the work I am doing for CAR-T? Would it be better for me to report an E/M visit code?
  - Answer Part 1: Provide your billing and finance team the table provided here so they can cross-walk your use of the unlisted code to an appropriate RVU to track your work effort until actual RVUs are assigned in a few years.
  - Answer Part 2: Reporting an E/M visit code would be inappropriate since CPT instructs coding to the highest level of specificity and not selecting approximate codes; for CY 2018 this means reporting the unlisted code and for 2019 it means using the new CART-T CPT codes.
Medicare Inpatient Payment Final Rule
CMS Inpatient Final Rule: Effective 10/1/2018

HCT

- Did not develop pass-through mechanism for donor acquisition costs
- Did not provide instructions for new HCT cost center 77, as requested
- Fixed diagnosis code issues for Multiple Myeloma in the code editor

CAR-T

- “…given the relative newness of CAR T-cell therapy… we believe it would be premature to adopt changes to our existing payment mechanisms, either under the IPPS or for IPPS-excluded cancer hospitals, specifically for CAR T-cell therapy…”
- Finalized assignment to MS-DRG 016, with modified name: Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy
- Assigned NTAP status to Kymriah and Yescarta (maximum payment of $186,500)
- Did NOT finalize CCR of 1.0 or pass-through; Did NOT provide fix for Exempt facilities

Additional Resource: NMDP/BTM IPPS Summary
https://t.co/ZjHDlbxNM4
Shifting CAR-T payment issues to OPPS rule

- In the IPPS Final Rule CAR-T Payment section, CMS included the following (p.123):
  - “Building on President Trump’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment in the CY 2019 OPPS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries’ out of pocket spending.”

Request for comment in OPPS rule:

- Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model
- CAP program is a long-standing discussion between CMS and industry
- Extensive set of questions (p. 171) on types of drugs and providers to include, vendor specifications, value-based payment parameters, beneficiary cost-sharing and regulatory barriers.

CAR-T should not be subject to CAP models

- Currently low volume, autologous, manufactured on-demand, cannot be shipped to a CAP vendor
- Comments to CMS will reflect that the program does not/should not apply to these therapies
## FY2019 Inpatient Payment Rates for HCT

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>FY2019 Base Rate (w/o center adjustments)</th>
<th># of Cases in MedPar File (non-exempt) FY2017</th>
<th>Geometric Mean Charge in MedPar File (non-exempt) FY2017</th>
<th>Geometric Mean LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>014 - Allogenic HCT</td>
<td>$71,700</td>
<td>952</td>
<td>$259,692</td>
<td>27.1</td>
</tr>
<tr>
<td>016 - Autologous HCT with CC/MCC or CAR-T</td>
<td>$39,000</td>
<td>2,095</td>
<td>$150,467</td>
<td>17.1</td>
</tr>
<tr>
<td>017 - Autologous HCT w/o CC/MCC</td>
<td>$26,000</td>
<td>135</td>
<td>$102,814</td>
<td>7.9</td>
</tr>
</tbody>
</table>
Inpatient cases group to MS-DRG 016 based on the presence of the CAR-T ICD-10-PCS codes (XW033C3 and XW043C3) on the claim; NTAP also dependent on presence of CAR-T PCS codes.

In addition to the MS-DRG payment, total covered charges are evaluated on each IPPS case for possible additional NTAP and outlier payment, both of which are dependent on the hospital’s billed charges and the hospital’s overall operating cost to charge ratio (CCR) from the Medicare cost report.

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Weight</th>
<th>Base Payment Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS-DRG 016 Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy</td>
<td>6.5394</td>
<td>$39,236</td>
</tr>
</tbody>
</table>

* This is the national unadjusted rate for PPS hospitals; PPS-exempt hospitals have a different payment mechanism.
Components of Medicare Payment Calculations

Variable information feeds into fixed information: the variables are used in fixed formulas to get to the final hospital case payment.

Variable Information:
- Individual patient care charges
- Overall CCR
- Hospital specific adjustments
  - Wage Index
  - Indirect Medical Education (IME) adjustment
  - Disproportionate Share (DSH)

Fixed Information:
- MS-DRG Assignment
- New Technology Add-On Payment (NTAP) Payment Possibility
- Outlier Payment Possibility

Final Hospital Case Payment
NTAP and Outlier Both Available for FY2019

Comparison of FY2018 and FY2019 Payment Mechanisms

FY 2019
- MS-DRG 016, $39,951
- NTAP up to $186,500
- "Donut Hole" Fixed Loss Outlier $25,769
- Variable Outlier Payment

FY 2018
- Various MS-DRGs ~$6K-$16K
- "Donut Hole: Fixed Loss Outlier $26,713
- Variable Outlier Payment

Legend:
- MS-DRGs
- NTAP
- "Donut Hole" Fixed Loss Outlier Threshold
- Variable Outlier Payment
Sample Claims from Two Different PPS Hospitals

- Hospital A and B provide CAR-T therapy and each acquire the product for $373,000
- Hospital A uses a 10% mark-up; Hospital B uses a higher mark-up reflective of its operating CCR

<table>
<thead>
<tr>
<th>Hospital A Example Inpatient Hospital Claim</th>
<th>Hospital B Example Inpatient Hospital Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Markup</strong></td>
<td>110%</td>
</tr>
<tr>
<td>FL 42 Revenue Code</td>
<td>FL 43 Description</td>
</tr>
<tr>
<td>0121</td>
<td>Room &amp; Board</td>
</tr>
<tr>
<td>0250</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>0270</td>
<td>Supplies</td>
</tr>
<tr>
<td>0300</td>
<td>Laboratory</td>
</tr>
<tr>
<td>All other dept. charges (radiology, etc.)</td>
<td>All other</td>
</tr>
<tr>
<td>0636*</td>
<td>Detailed drugs</td>
</tr>
<tr>
<td>0001</td>
<td>Total Charges</td>
</tr>
</tbody>
</table>

Note: Hospital A uses a 10% markup (rather than its overall hospital cost-to-charge ratio of 0.25) to mark-up the $373,000 CAR-T product cost to $410,300.

Note: Hospital B does use its overall hospital cost-to-charge ratio of 0.25 (i.e., mark-up 400%) to mark-up the $373,000 CAR-T product cost to $1,492,000.

* In the claims examples shown, the CAR-T product charge is split out from all other pharmacy charges for illustrative purposes to demonstrate how detail line item reporting of CAR-T product HCPCS codes can occur. This would require explicit instructions from CMS.
Hospital A and B have different total charges reflective of their different patients and their internal charging practices.

CMS takes these total billed charges and reduces them to a “calculated cost” using the hospital’s overall CCR which happens to be .25 for both Hospital A and B.

Given the difference in total charges, CMS “calculated costs” are different and this information is used in determining the final inpatient payment amounts.
Calculated Cost Impacts Final Payment

- Previously calculated costs
  - Hospital A = $159,575
  - Hospital B = $430,000

- Hospital payment impacted by:
  - Actual case/type of patient
  - Total covered charges reported
  - Wage-index, IME and/or DSH
  - Hospital’s overall operating CCR

- Hospital payment consists of:
  - MS-DRG payment
  - NTAP payment
  - Outlier payment

Note: Despite payment differentials, neither hospital in the example recovers the cost of the product.
## IPPS Next Steps

### Society/Coalitions
- Continue to advocate with CMS
- Ask Hill staff to push CMS on the issue
- Legislative briefings and education
- Evaluate need for new MS-DRG request (due November 1)

### Your Facility/Program
- Change will be driven from hospitals connecting with Hill offices
- **Submit comments through the OPPS rule**
- Let ASBMT/ASH know the impact of the final rule on patient treatment patterns and financial decision-making

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Calendar note: CMS staff will begin working on the FY 2020 rule from November - February for an April 2019 release; they need input, data and Congressional pressure prior starting now!
Questions?
Appendix
FY 2019 Medicare CAR-T Case Payment Example for Two PPS-Hospitals with a Wage-Index of 1.0 and Different Mark-Ups

- Hospital specific adjustments
- Wage-index of 1.0 for both hospitals
- Neither hospital has an adjustment for IME or DSH
- Each hospital uses different mark-ups

<table>
<thead>
<tr>
<th>Hospital A</th>
<th>CAR-T Product Mark-Up = 110%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example MS-DRG 016 Base Payment 2019 Final</td>
<td>$39,951</td>
</tr>
<tr>
<td>FY2019 Final Fixed Loss Outlier Amount</td>
<td>$25,769</td>
</tr>
<tr>
<td>Total Charges from Inpatient Claim</td>
<td>$638,300</td>
</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$159,575</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital B</th>
<th>CAR-T Product Mark-Up = 400%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example MS-DRG 016 Base Payment 2019 Final</td>
<td>$39,951</td>
</tr>
<tr>
<td>FY2019 Proposed Fixed Loss Outlier Amount</td>
<td>$25,769</td>
</tr>
<tr>
<td>Total Charges from Inpatient Claim</td>
<td>$1,720,000</td>
</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$430,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital A</th>
<th>Inpatient NTAP Calculation Based on a CAR-T Mark-Up of 110%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example MS-DRG 016 Base Payment 2019 Final</td>
<td>$39,951</td>
</tr>
<tr>
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<td>$638,300</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$159,575</td>
</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calc Cost Less MS-DRG Payment</td>
<td>$119,624</td>
</tr>
<tr>
<td>Estimated NTAP Cap (1/2 of $373,000 of product cost)</td>
<td>$186,500</td>
</tr>
<tr>
<td>Estimated NTAP Payment (based on 50% of excess cost or NTAP cap)</td>
<td>$59,812</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital B</th>
<th>Inpatient NTAP Calculation Based on a CAR-T Mark-up of 400%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example MS-DRG 016 Base Payment 2019 Final</td>
<td>$39,951</td>
</tr>
<tr>
<td>Total Charges from inpatient claim</td>
<td>$1,720,000</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$430,000</td>
</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calc Cost Less MS-DRG Payment</td>
<td>$380,849</td>
</tr>
<tr>
<td>Estimated NTAP Cap (1/2 of $373,000 of product cost)</td>
<td>$186,500</td>
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<table>
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<tr>
<th>Hospital A</th>
<th>Inpatient NTAP + Outlier Calculation Based on Mark-Up of 110%</th>
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</thead>
<tbody>
<tr>
<td>Example MS-DRG 016 Base Payment 2019 Final</td>
<td>$39,951</td>
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<tr>
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</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$159,575</td>
</tr>
<tr>
<td>Outlier w/NTAP Threshold (MS-DRG Pmt + NTAP + Fixed Loss Threshold)</td>
<td>$125,532</td>
</tr>
<tr>
<td>Step 1: Outlier Calc: (Calculated Hospital Cost - Outlier Threshold)</td>
<td>$34,043</td>
</tr>
<tr>
<td>Step 2: If value of step one is negative, then no outlier payment; if the value is positive, provider receives 80% of step 1 amount</td>
<td>$27,234</td>
</tr>
<tr>
<td>Total payment (MS-DRG Payment + NTAP + Outlier)</td>
<td>$126,997</td>
</tr>
</tbody>
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<th>Inpatient NTAP + Outlier Calculation Based on a Mark-Up of 400%</th>
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<tr>
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</tr>
<tr>
<td>Example Hospital Operating CCR</td>
<td>0.25</td>
</tr>
<tr>
<td>Calculated Hospital Cost (Charges * CCR)</td>
<td>$430,000</td>
</tr>
<tr>
<td>Outlier w/NTAP Threshold (MS-DRG Pmt + NTAP + Fixed Loss Threshold)</td>
<td>$252,220</td>
</tr>
<tr>
<td>Step 1: Outlier Calc: (Calculated Hospital Cost - Outlier Threshold)</td>
<td>$57,788</td>
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<tr>
<td>Step 2: If value of step one is negative, then no outlier payment; if the value is positive, provider receives 80% of step 1 amount</td>
<td>$368,675</td>
</tr>
<tr>
<td>Total payment (MS-DRG Payment + NTAP + Outlier)</td>
<td>$126,997</td>
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</table>