ASTCT Review of Key Proposed Changes in FY2021 IPPS for CAR-T and Allogeneic HCT

Tuesday, May 19, 2020
11:00 AM – 12:00 PM CST
Today’s Webinar

• We will have a Q&A portion at the end of the webinar, so please submit any questions during this webinar in the Zoom panel at the bottom of your screen.

• The slides and recording of this presentation will be distributed after the webinar.

If you have any questions, please email info@astct.org
ASTCT Webinar

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Today’s Topics

Some Highlights from the FY 2021 IPPS Proposed Rule

FY 2021 CAR-T Proposed Reimbursement

FY 2021 Allogeneic Stem Cell Transplant Reimbursement

Summary, Next Steps, and Staying Engaged
Some Highlights from the FY 2021 Medicare Inpatient Prospective Payment System Proposed Rule
Timeline/Calendar

• Rule released May 11th, 2020
• Text and tables at: https://www.cms.gov/index.php/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-home-page
• Comments due July 10th
• Due to the public health emergency, CMS has waived the 60-day effective notice date of the final rule which means the final rule can be released as late as September 1st
• Providers to implement changes starting October 1, 2020
Highlights of Key Proposals for FY 2021

- Specific proposals for CAR-T and allogeneic stem cell transplant
  - Details in the next two sections
- Financial update to the national standardized amount, with statutory adjustments
- Wage-index and disproportionate share changes
- Update to outlier threshold with increase of about $4,000 to $30,006 consistent with 5.1% of total IPPS payments
- Annual code changes (additions and deletions) and MS-DRG assignment changes
  - Including new Cytokine Release Syndrome codes!

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>ICD-10-CM</th>
<th>Change</th>
<th>ICD-10-PCS</th>
<th>Change</th>
</tr>
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<tbody>
<tr>
<td>FY 2016</td>
<td>ICD-10-CM</td>
<td>69,823</td>
<td>ICD-10-PCS</td>
<td>71,974</td>
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<td>FY 2017</td>
<td>ICD-10-CM</td>
<td>71,486</td>
<td>+1,663</td>
<td>ICD-10-PCS</td>
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<tr>
<td>FY 2018</td>
<td>ICD-10-CM</td>
<td>71,704</td>
<td>+218</td>
<td>ICD-10-PCS</td>
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<tr>
<td>FY 2019</td>
<td>ICD-10-CM</td>
<td>71,932</td>
<td>+228</td>
<td>ICD-10-PCS</td>
</tr>
<tr>
<td>FY 2020</td>
<td>ICD-10-CM</td>
<td>72,184</td>
<td>+252</td>
<td>ICD-10-PCS</td>
</tr>
<tr>
<td>FY 2021 (Proposed)</td>
<td>ICD-10-CM</td>
<td>72,616</td>
<td>+432</td>
<td>ICD-10-PCS</td>
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</tbody>
</table>
Highlights of Key Proposals for FY 2021 (Cont.)

• New Technology Add-On Payment (NTAP)
  • Per usual, CMS proposes to continue NTAP for some products and proceeds to discontinue others (see Appendix A)
  • Some new approvals based on FDA breakthrough pathway for devices and antibacterial/antifungal and infectious disease products
  • New requests applied under typical pathways, including two CAR-T products under review

• Future Rate-Setting toward Market-based MS-DRG Pricing

• Charity and Bad Debt – proposing new regulations [Share with your finance teams!]
FY 2021 CAR-T Reimbursement Proposal
Backstory

Context for Understanding the Proposal
FY 2020: Time is Running Out For NTAP

MS-DRG 016 National Unadjusted PPS Payment of $43,127*

NTAP Payment (up to 65%); the maximum for CAR-T = $242,450

Outlier Payment Varies (and after the fixed loss threshold of $26,473 is accounted for)

Total PPS Case Payment**

Recall: both NTAP and outlier are dependent on total billed charges for the case and the hospital’s overall operating cost to charge ratio (CCR).

* Payment amount before hospital-specific adjustments such as wage index, medical education and disproportionate share are applied

* PPS-exempt hospitals have a different payment mechanism
A Different Approach is Required for FY 2021 Rate-Setting Due to Limitations in the FY 2019 Claims Data

<table>
<thead>
<tr>
<th>Small Overall Case Volume</th>
<th>High Percentage of Clinical Trial Cases (reported with Z00.6 ICD-10-CM Code)</th>
<th>High Variability in Pharmacy Charges</th>
<th>No Visibility of CAR-T Product Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Approximately 360 PPS cases annually in the inpatient setting even though several thousand per year had been expected</td>
<td>• Related to the robust pipeline, product cost, reimbursement challenges, etc.</td>
<td>• Inaccurate/sub-optimal hospital charges being reported</td>
<td>• Rolled up into general pharmacy charges with no HCPCS or NDC codes on inpatient claims</td>
</tr>
<tr>
<td></td>
<td>• Highest proportion of trial to non-trial cases compared to any other MS-DRG</td>
<td>• Clinical trial cases not reported with the Z00.6 diagnosis code</td>
<td>• Revenue code 0891 went into effect 4/1/2019</td>
</tr>
</tbody>
</table>
Thinking through the Creation of a New CAR-T MS-DRG

What is CMS’ frame of mind?

1. Maintain clinical and resource homogeneity
2. Avoiding systematic overpayment and underpayment
3. Do not deviation from usual rate-setting unless necessary
4. Address charge compression: what’s that?
5. Ensure beneficiary access to innovative therapies while not driving up spending

With respect to CAR-T, CMS has raised questions/concerns about what it was seeing in the data.
FY 2021 Rate-Setting Options on a Continuum

Business as usual: either keeping CAR-T in MS-DRG 016 or creating a new autologous T-cell immunotherapy MS-DRG

Simple programming changes where certain cases are removed or treated differently

Address mark-up issues, high pharmacy charge variability and/or charge compression

Create a new structure and series of cell therapy MS-DRGs where patient care is separate from the product

In the FY 2019 IPPS final rule CMS said, we are considering approaches and authorities to encourage value-based care and lower drug prices
**FY 2021 Simulated National Payment Rates on a Continuum for Discussion with CMS on December 15, 2019**

**CMS Normal Rate-Setting**
- Business as usual

**CMS Making Minor Methodological Changes***
- Use only certain cases and/or treat them “differently”

**PROVIDER PERSPECTIVE**

- **MS-DRG 016 Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy cases** ($46,948)
- **NEW MS-DRG Payment for T-cell Immunotherapy** where the FY 2021 payment rate is created using FY 2019 cases with no clinical trial Z00.6 diagnosis code: $183,006
- **NEW MS-DRG Payment for T-cell Immunotherapy** where the FY 2021 payment rate is created using all FY 2019 CAR-T cases ($130,750)

**Option 1:** **NEW MS-DRG Payment for T-cell Immunotherapy** where the FY 2021 payment rate is created using FY 2019 cases with no clinical trial Z00.6 diagnosis code: $183,006

**Option 2:** **NEW MS-DRG Payment** where the FY 2021 payment rate is created using FY 2019 cases with no clinical trial Z00.6 diagnosis code AND with pharmacy charges > $373,000: $229,224

**Option 3:** **NEW MS-DRG Payment** where the FY 2021 payment rate is created using FY 2019 cases with no clinical trial Z00.6 diagnosis code AND with pharmacy charges > $746,000: $246,152

*Note: Dollars are unadjusted for wage index, IME, & DSH and based on first two quarters of FY 2019 SAF data

*Any option under minor methodological changes would require CMS to address how to pay clinical trials in FY 2021*
CMS’ FY 2021 CAR-T Reimbursement Proposal

- Discontinue NTAP as planned for Kymriah and Yescarta on 9/30/2020
- **Create New MS-DRG 018: Chimeric Antigen Receptor (CAR) T-cell Immunotherapy**
  - Compute the relative weight for this new MS-DRG differently
    - Exclude “clinical trial” cases, **which CMS defines as:**
      - (1) cases with the clinical trials diagnosis code (Z00.6) or
      - (2) cases with standardized drug charges < $373,000
    - Proposed relative weight of 37.1412
  - CAR-T claims with the Z00.6 diagnosis code to be paid at a reduced rate
    - The reduction percentage in the proposed rule is 0.15, but will change with final rule data

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**CMS’ proposal mostly aligns with what ASTCT requested, but it does not address how to treat cases with no commercial CAR-T product cost despite ASTCT having raised this with CMS**
“We agree with the requestors it is appropriate to consider the development of a new MS-DRG using the data that is now available.... We distinguished between clinical trial and non-clinical trial cases in this analysis because we agree with the requestors who indicated that given the high cost of the CAR T-cell product, it is appropriate to distinguish cases where the CAR T-cell product was provided without cost as part of a clinical trial so that the analysis appropriately reflects the resources required to provide CAR T-cell therapy outside of a clinical trial... While we generally prefer not to create a new MS-DRG unless it would include a substantial number of cases, our clinical advisors believe that the vast discrepancy in resource consumption as reflected in the claims data analysis and the clinical differences warrant the creation of a new MS-DRG.”

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description</th>
<th>Number of Cases</th>
<th>Average Length of Stay</th>
<th>Average Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>016</td>
<td>ICD-10-PCS codes XW033C3 or XW043C3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All cases</td>
<td>2,212</td>
<td>18.2</td>
<td>$55,001</td>
</tr>
<tr>
<td></td>
<td>All cases</td>
<td>262</td>
<td>16.3</td>
<td>$127,408</td>
</tr>
<tr>
<td></td>
<td>Non-clinical trial cases</td>
<td>94</td>
<td>17.2</td>
<td>$274,952</td>
</tr>
<tr>
<td></td>
<td>Clinical trial cases</td>
<td>168</td>
<td>15.8</td>
<td>$44,853</td>
</tr>
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</table>
Time for Some Math: What’s the Payment?

PPS hospital specific adjusted MS-DRG case payment reflective of the hospital specific wage index, indirect medical education, and disproportionate share, will impact the total case payment. PPS-exempt hospitals have a different payment methodology.

NEW MS-DRG 018
Unadjusted PPS Payment* of About $240,000

NTAP Payment (up to 65%); the maximum for CAR-T = $242,450

Outlier Payment Varies (and after the fixed loss threshold of $30,006 is accounted for)

Total Case Payment*
Comparing Current Reimbursement to Proposed Changes: Two Hospital Case Example

### Hospital and Patient Characteristics

Both hospitals A and B:
- Are certified to provide CAR-T
- Pay the manufacturer $373,000
- Have a wage-index of 1.0 and no other adjustments
- Overall operating cost-to-charge ratio of 0.25
- Have exact same patient care charges

The only difference between Hospital A and B is the CAR-T product charge billed on the claim.

Hospital B’s charges is reflective of its operating CCR of .25 [Hospital A’s is not].

<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><strong>110%</strong></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><strong>0891</strong></td>
<td><strong>Cell therapy drug</strong></td>
</tr>
<tr>
<td>0001</td>
<td>Total Charges</td>
</tr>
</tbody>
</table>
Win, Lose, or Draw?

- NTAP to be discontinued
- New MS-DRG
- Usual rate-setting would have resulted in a much lower MS-DRG payment
- CMS kept all adjustments in place
- The FY 2021 relative weight would have been higher if ALL hospitals would have reported accurately
Initial Reactions and Some Questions

**Reactions/Questions**
- “This is an unprecedented rate-setting change…really a sea-change”
- “How can this be a win if my hospital loses on most of our CAR-T cases?”
- “Wow, this is much better than our hospital had expected”
- “If all hospitals had charged correctly, how high could MS-DRG 018 have been?”
- “How does this impact how we set our CAR-T product charge?”

**Questions Related to CMS’ Payment Proposal**
- What more can CMS do, or is this it?
- Shouldn’t CMS use the Z-code and the $373,000 threshold to create the relative weight and to adjust the relative weight?
- Doesn’t CMS risk overpayments and/or underpayments if it only uses Z00.6 to flag cases for adjusted payment? What about the “no CAR-T cost” cases?

**Long Term Fit?**
- How well will new products integrate into the new rate-setting structure?
- How long will CMS use the $373,000 drug threshold when calculating the relative weight?
- Will much of this be moot if/when CMS implements some form of market-based updated to the IPPS payment system?
The Z00.6 Over/Under Payment Conundrum

Use of Z00.6

UNDERPAYMENT: When Z00.6 is reported for a non-CART trial where another drug is being investigated, the hospital will be underpaid for its commercial CAR-T case.

OVERPAYMENT: If Z00.6 is not reported because of a coding error or for expanded access program use, the hospital will be overpaid.

Options to Mitigate These Issues

- ASTCT provided CMS with options on differentiating CAR-T cases with and without product charges that went beyond the use of Z00.6 but none were proposed
- Require providers to report actual product acquisition cost using Value Code 90 (it was 86)
- Require National Drug Codes (NDC)
- Use the presence/absence of a token charge in revenue code 0891 with or without Z00.6 to gauge whether the provider incurred a cost for the commercial CAR-T product
- Combination of the above and/or other data quality checks to ensure accurate payment
Assess Impact on Your Facility

What is Your CAR-T Dollar Charge?

• Find your CAR-T product charge on your institutional chargemaster
• Review and determine if it needs updating. What is your typical drug pricing methodology?
• Review Section 2203 and 2202.4 of the Provider Reimbursement Manual, Part 1, Chapter 22

Compute Your Financial Impact

• Ask finance to estimate what FY 2021 payment for CAR-T will look like for your institution
• Provide your average total charge for your CAR-T cases
• Provide your operating CCR, geographic adjustment factor, wage index, IME, DSH
Other CAR-T Related Proposals for FY 2021

• CMS reviewed NTAP requests for two new CAR-T Products (pages 485 – 536)
• For FY 2021 NTAP, CMS will evaluate the cost criterion for CAR-T therapy technologies using the proposed threshold for the new CAR-T MS-DRG
  • New cost threshold of $1,237,393
• New Cytokine Release Syndrome (CRS) diagnosis codes effective Oct 1, 2020
  • Codes already approved
  • Currently reviewing CMS’ proposed MS-DRG assignment
  • CMS believes these codes cannot be reported as a principal diagnosis – we’re investigating
CAR-T Comments for Your Comment Letters

- Creation of new MS-DRG 018 and the relative weight methodology

- Is CMS trying to pay a reduced amount only for clinical trial cases defined by Z00.6 or for CAR-T cases with no CAR-T product cost?

- Discontinuation of NTAP for current CAR-T products

- NTAP applications for new CAR-T products (KTE-X19; Liso-cel)

- Monitor the decision on ICD-10-PCS codes for the two new products (if CMS grants new codes, they would be product-specific (existing infusion codes are not product-specific))

- MS-DRG Assignment of ICD-10-CM CRS codes and designation as “unacceptable principal diagnosis”
FY 2021 Allogeneic Stem Cell Transplant Reimbursement Proposal to Enact Section 108
Payment Trend and FY 2021 Proposed Payment Rates
Stem Cell Transplant MS-DRGs
Refresher: Allogeneic HCT Reimbursement

Past: Donor Cost Reimbursement in Allogeneic Transplant MS-DRG 014 was Grossly Inadequate

- CMS’ rate-setting system undervalued allogeneic donor search and cell acquisition costs
- Change Needed!
- Advocacy started to get the Patient Access to Cellular Transplant (PACT) Act into legislation

Coming Soon! Cost-based Reimbursement for Donor Costs!

- PACT Act language included in the Further Consolidations Appropriations Act (FCAA) of 2020 as Section 108
- Became law on Dec. 20, 2019
- Directs CMS to develop a separate cost-based reimbursement methodology to pay for donor search and cell acquisition costs
- This is as good as it gets! 🙌
Steps to Cost-based Reimbursement

Effective date:
Cost reporting periods beginning on or after October 1, 2020

No change to the definition of donor search and cell acquisition

Each hospital will need to develop a standard average charge across all allogenic HCTs.

Hospitals will have to maintain an itemized statement that identifies services furnished, the charges, person receiving the service, and the recipient’s health care insurance number.

Interim payments will be made as a pass-through using the standard charge reported on claims.

Cost reporting changes and new instructions forthcoming through separate rulemaking.

Implementation budget neutral
Other Notable Updates

• Allogeneic Transplant MS-DRG 014 will not split for CC/MCC and without CC/MCC
  • This is due to CMS’ analysis of the case volumes, which were insufficient to meet CMS’ criteria for a split

• The title/label of MS-DRG 016 is proposed to revert to “Autologous Bone Marrow Transplant with CC/MCC”, due to the new proposed MS-DRG 018 for CAR-T cases

• No changes were proposed to MS-DRG 017 for “Autologous Bone Marrow Transplant w/o CC/MCC”

• No wholesale proposed changes to codes that qualify for CC/MCC, but CMS announces guiding principles for a future overhaul
Allogeneic Stem Cell Transplant Comments for Your Comment Letters

Thank you for much needed, long-awaited payment relief

Thank you for using the current definition of donor search & cell acquisition cost

Thank you for acknowledging more cost reporting instructions are needed to capture all related and unrelated donor costs accurately in report line 77

One key question for now…Why is CMS proposing that providers report a “single standard charge” across related/unrelated donors, across all cell types, and all payers?

This is likely to be problematic and needs to be reviewed further
Getting Over the Finish Line…

Submit comments on proposed changes for FY2021 including where additional guidance and/or technical clarifications are needed for CAR-T and HCT

https://www.regulations.gov/comment?D=CMS-2020-0052-0001

Begin thinking about CMS’ market-based data collection and future rate-setting proposal

Specifics for your organization to reference are coming soon!
Questions?

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ASTCT Membership

BECOME A MEMBER TO:

• CONNECT WITH THE ASTCT COMMUNITY
  • Network and learn at annual meetings and events, actively engage with committees, and join special interest groups.

• IMPROVE PRACTICE AND PATIENT OUTCOMES
  • Solicit expert counsel from your peers on challenging cases.

• ENHANCE YOUR SKILLS AND GROW YOUR PRACTICE
  • Find jobs and identify training opportunities and find highly qualified job candidates for your center or organization.

• EDUCATE AND SUPPORT
  • Advance your skills and expertise in the field through access to *BBMT: Transplantation and Cellular Therapy*, the field’s number one journal, as well as online access to journal articles as far back as 1998.

• ADVOCATE
  • Support the adoption of government policies and regulations helpful to advancing quality patient care.

MEMBERSHIP TYPES:

• MEMBER
  • Individuals with an M.D. or a Ph.D. and demonstrated expertise in clinical transplantation or cellular therapy.

• ASSOCIATE MEMBER
  • Individuals with an M.D. or a Ph.D. who otherwise do not meet the criteria for full membership.

• AFFILIATE MEMBER
  • Allied non-M.D. or non-Ph.D. professionals who are integral members of the BMT team or who have an interest in clinical transplantation or cellular therapy.

• IN-TRAINING MEMBER
  • Open to fellows in training in a BMT or hematology/oncology program or one of the following: NP, PA, Pharm.D., Ph.D., RN.

• INTERNATIONAL JOINT MEMBER
  • ASTCT offers joint memberships with other BMT societies around the world. If you are a member of one of these societies, please contact that organization for details.

• INSTITUTIONAL AFFILIATE MEMBER
  • Institutional Affiliate Membership provides Affiliate Members (non-MD) within an institution to purchase membership as a group, offering a single invoice for multiple members.
Thank you for attending!

General email: info@astct.org

www.astct.org

Twitter: @ASTCT
Appendix A

NTAP Applications and Approvals for FY 2021
## FY 2021 NTAP Applications and Approvals

<table>
<thead>
<tr>
<th>Technology</th>
<th>Newness Start Date</th>
<th>Propose to Continue or Discontinue NTAP for FY 2021</th>
<th>Previous Final Rule Citations</th>
<th>Proposed Maximum NTAP Amount for FY 2021</th>
<th>Coding Used to Identify Cases Eligible for NTAP</th>
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</thead>
<tbody>
<tr>
<td>KYMRIAH® and YESCARTA®</td>
<td>November 22, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41283 through 41299) and (84 FR 42185 through 42187)</td>
<td>None</td>
<td>XW033C3 or XW043C3</td>
</tr>
<tr>
<td>VYXEOS™</td>
<td>August 3, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41299 through 41305) and (84 FR 42187 through 42188)</td>
<td>None</td>
<td>XW033B3 or XW043B3</td>
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<tr>
<td>VABOMERE™</td>
<td>August 29, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41305 through 41311) and (84 FR 42188 through 42189)</td>
<td>None</td>
<td>XW033N5 or XW043N5 or National Drug Codes (NDC) 65293–0009–01 or 70842–0120–01</td>
</tr>
<tr>
<td>remedi® System</td>
<td>October 6, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41311 through 41320) and (84 FR 42189 through 42190)</td>
<td>None</td>
<td>0H660DZ and 0SH03M4M in combination with 0SH33M5 or 0SH34M3Z</td>
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<tr>
<td>ZEMDRI™</td>
<td>June 25, 2018</td>
<td>Continue</td>
<td>(83 FR 41326 through 41334) and (84 FR 42190 through 42191)</td>
<td>$4,083.75</td>
<td>XW033G4 or XW043G4</td>
</tr>
<tr>
<td>GLAPREZA™</td>
<td>December 21, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41334 through 41342) and (84 FR 42191)</td>
<td>None</td>
<td>XW033H4 or XW043H4</td>
</tr>
<tr>
<td>Sentinel® Cerebral Protection System</td>
<td>June 1, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41342 through 41348) and (84 FR 42191 through 42192)</td>
<td>None</td>
<td>X2A5312</td>
</tr>
<tr>
<td>AQUABEAM System</td>
<td>December 21, 2017</td>
<td>Discontinue</td>
<td>(83 FR 41348 through 41355) and (84 FR 42192 through 42193)</td>
<td>None</td>
<td>XV508A4</td>
</tr>
<tr>
<td>AndexXa™</td>
<td>May 3, 2018</td>
<td>Continue</td>
<td>(83 FR 41355 through 41362) and (84 FR 42193 through 42194)</td>
<td>$18,281.25</td>
<td>XW03372 or XW04372</td>
</tr>
<tr>
<td>AZEDRA®</td>
<td>July 30, 2018</td>
<td>Continue</td>
<td>(84 FR 42194 through 42201)</td>
<td>$98,150</td>
<td>XW033S5 and XW043S5</td>
</tr>
<tr>
<td>CABLI™IV®</td>
<td>February 6, 2019</td>
<td>Continue</td>
<td>(84 FR 42201 through 42208)</td>
<td>$33,215</td>
<td>XW013W5, XW033W5 and XW043W5</td>
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<td>ELZONRIS™</td>
<td>December 21, 2018</td>
<td>Continue</td>
<td>(84 FR 42231 through 42237)</td>
<td>$125,448.05</td>
<td>XW033Q5 and XW043Q5</td>
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<td>Balversa™</td>
<td>April 12, 2019</td>
<td>Continue</td>
<td>(84 FR 42237 through 42242)</td>
<td>$3,563.23</td>
<td>XW0DXL5</td>
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<td>ERLEADA™</td>
<td>February 14, 2019</td>
<td>Discontinue</td>
<td>(84 FR 42242 through 42247)</td>
<td>None</td>
<td>XW0DX5</td>
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<tr>
<td>SPRAVATO™</td>
<td>March 5, 2019</td>
<td>Continue</td>
<td>(84 FR 42247 through 42256)</td>
<td>$1,014.79</td>
<td>XW097M5</td>
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<tr>
<td>XOSPATA™</td>
<td>November 28, 2018</td>
<td>Continue</td>
<td>(84 FR 42256 through 42260)</td>
<td>$7,312.50</td>
<td>XW0DXV5</td>
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<td>JAKAFY™</td>
<td>May 24, 2019</td>
<td>Continue</td>
<td>(84 FR 42265 through 42273)</td>
<td>$3,977.06</td>
<td>XW00XT5</td>
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<tr>
<td>T2Bacteria® Panel</td>
<td>May 24, 2018</td>
<td>Continue</td>
<td>(84 FR 42278 through 42288)</td>
<td>$97.50</td>
<td>XXE5XM5</td>
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</table>