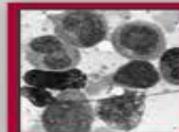


CAR-T NCA and CMS IPPS

ASBMT Town Hall
June 14, 2018
Stephanie Farnia – Sfarnia@asbmt.org



ASBMT™
American Society for Blood
and Marrow Transplantation

Goals and Logistics for Today

Provide high-level perspective from ASBMT

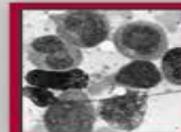
- Main perspectives and points to build out your comments

Content is intended for members/providers

- Have corporate council attendees joining us

Will receive a recording of the webinar afterwards

- Once file finalization is ready, sent via email



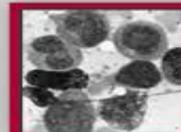
Agenda

Overview of the ASBMT CAR-T NCA comment letter

Planned IPPS response

- HCT comments
- CMS CAR-T proposals

Center comments needed!



NCA for CAR-T: CAG-00451N

Commented **against an NCD** due to potential for patient access barriers:

- CMS has very rarely pursued NCD/CED for FDA-approved drugs
- CAR-T has additional anti-cancer drug 'protection' by statute
- Treatment decisions should be left to the provider-patient relationship, incl. *site of care*
- Cell therapy community, FDA and manufacturers already structuring extensive post-market tracking and research
- The formal structure of an NCD and/or CED creates hard barriers that are difficult to modify
- No current reports of MACs denying CAR-T claims; better to work at local level at this point

Asked CMS to:

- Clarify full intent and scope of NCA process – i.e. on-label, off-label, all products, CED?
- Clarify that coverage should continue during the decision process
- Handle the MA plan financial concerns through a different vehicle



Comment Submission and Tracking

Comments due June 15 (Friday)

- **Note:** CMS will accept comments *from providers* after the comment period closes

Joint letter from ASBMT, CIBMTR and NMDP/BTM submitted on 6/13

- <http://asbmt.org/practice-resources/coding-and-reimbursement/car-t-therapy>

Team effort:

- Centers/members that provided input
- Consultant partners: Nimit Consulting, Connect 4 Strategies and Arnold & Porter

Key dates:

- MEDCAC meeting: August 22 (open to public; registration available soon)
- Proposed decision memo (and second comment period): February 2019
- Final decision: May 2019
- **CMS NCA Tracking Sheet:** <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=291>

IPPS: Transplant

No substantial change to base weights for MS-DRGs 014, 016 or 017

No proposal for donor acquisition payment

- Please reiterate the desire for that system of payment
- Reference HR4215 – PACT Act and share with your Gov Affairs team

Technical asks to CMS

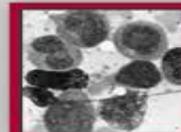
- Create an edit in the MCE to require the presence of revenue code 815 and one of the transplant ICD-10-PCS codes
- Use only correctly coded claims for MS-DRG 014 rate-setting (i.e. those with 815 and donor code)
- Add more detail in the final rule about cost report 77 and how hospitals need to capture their revenues and expenses
- Add revenue code 0815 to the cross-walk table
- Update the MCE to include all appropriate transplant procedure codes and diagnosis codes

ASBMT Objectives on CAR-T Payment

Goal: Structure that allows physicians to utilize what they feel is the best product for each patient, in the most appropriate care setting.

Therefore, seeking solutions that:

- Create a site-neutral, product-agnostic payment structure
- Remove provider responsibility for 'managing' product costs
- Minimize/remove financial losses for providing CAR-T
- Create flexibility for future products and combination therapies
- Minimally disrupt reimbursement for other cellular therapies/HCT



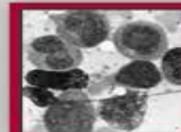
IPPS: CAR-T Proposals

Assignment of CAR-T cases to MS-DRG 016

Use of a cost-to-charge ratio (CCR) of 1.0 ★★

Potential for a new MS-DRG with "some portion of the ASP"

"Other alternative payment mechanisms"

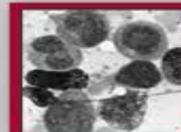


ASBMT Perspective on FY19 Proposals

We appreciate that CMS acknowledged stakeholder concerns

The proposals offered by CMS reflect ASBMT suggestions *and would improve current state to some degree in each of the scenarios*

There is still a profound change needed within the IPPS system as this new class of therapies come onto the market



Our Process

Built out a 'typical' claim with 'average' charges

- Average based on input from centers, estimates from trial experiences and early claims information
- Varying mark-ups utilized (i.e., 10% and 400%)

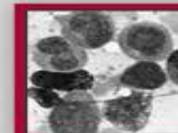
Modeled detailed scenarios (18-20) for PPS hospitals

Detailed out our assumptions/limitations:

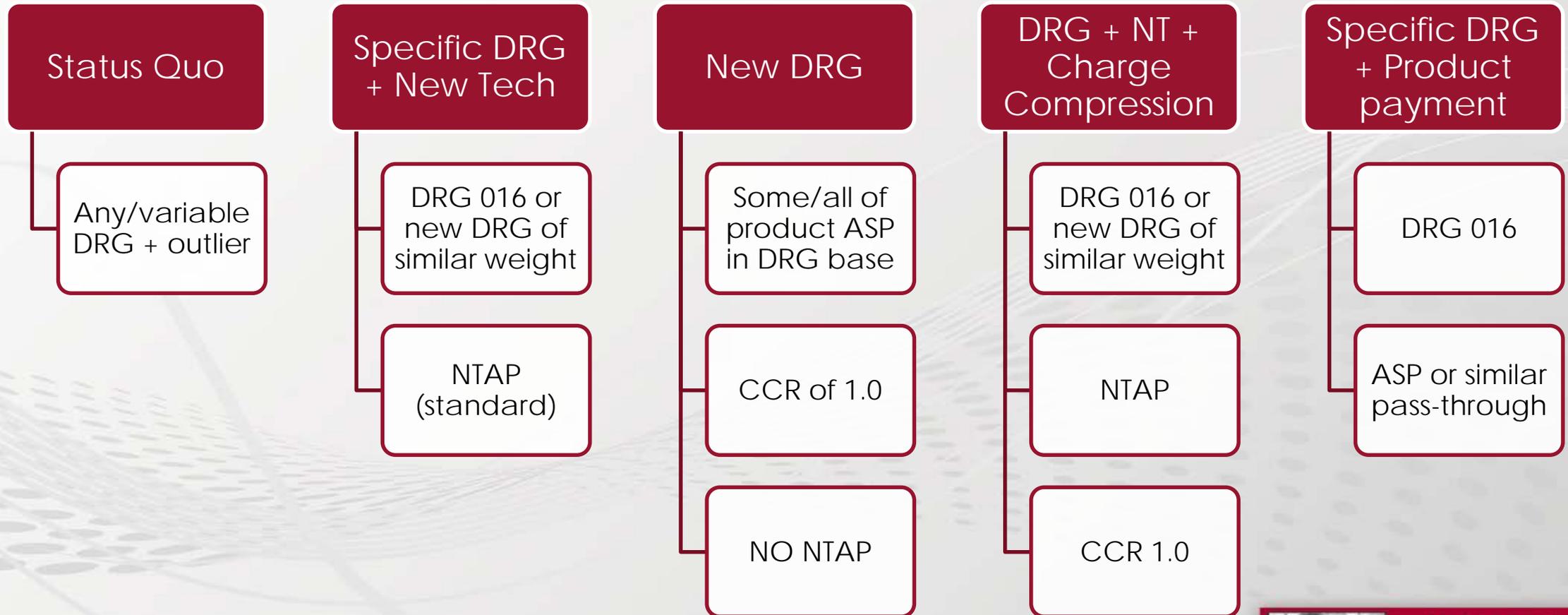
- Used national CCR of .25
- Budget neutrality would be required for new DRGs
- Centers paying full/close to full product cost

Eliminated unhelpful or very unlikely options

Recent review of potential wage index, DSH, IME adjustments

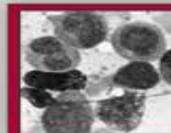


Main Options/Combinations



Outlier payment possibility in effect for all options

Review Spreadsheet



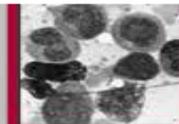
Decision-Marking Process: Extensive discussion and transparency

Centers and physicians

ASBMT leadership

Partner organizations: ASH, ASCO, ASGCT, AABB, BTM/NMDP, AACI, ACCC, SITC, CAP, NCCN, ADCC, LLS, LRF, others

Industry and Trade Groups



ASBMT Perspective/Decision on Comments

PPS Hospitals

- Asking that CMS operationalize their “CCR of 1.0” proposal through **add-on payment for full product cost**, using ASP, invoice or actual acquisition cost
 - For autologous, cell-based, gene-edited products with NTAP status?
- Specific placement in a pre-MDC MS-DRG
 - MS-DRG 016 may be acceptable in the short term

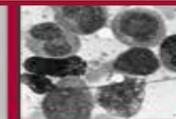
Exempt Cancer Centers

- Supporting the ADCC perspective on best solution for this group of 11 centers
- ADCC is requesting “CCR of 1.0” implemented through the standard cost report processes

Technical detail and implementation options for both facility types will be provided in respective letters.
Requests for changes to inpatient claims underway through NUBC.

Reality Check: Is this possible?

- Each stakeholder has their view of what CMS might do
 - Based on conversations had with CMS prior to proposed rule
 - Understanding of what “logical outgrowth” of CMS proposals
 - Based on previous experiences with CMS system – industry, providers, IPPS, OPPS
 - Based on views of the political environment
- Other payers are using this system
 - Medicaid plans: MA, WA, NY
 - Commercial payers
- It is legal and technically possible
 - CMS’s New Tech authority makes them able to consider this
 - Expected changes to the inpatient claim will make this easier



Will this make drug prices increase?

This is not a pro-pharma, 'supportive of price' recommendation

- Prices are already set based on assumption of ASP in OPSS setting

HHS Pricing Initiatives

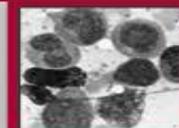
- This system would flex in real time vs delayed changes to the MS-DRG system

Next wave of products will bring inherent price pressure to the market

- Multiple products in one area (if clinically equivalent)
- Allo, Universal, off-the-shelf

Consider the opposite scenario

- I.e. - the lack of these mechanisms would cause prices to be adjusted in a downward manner, understanding provider pressures
- But – in FY2018: Vast majority in IPPS setting, No NTAP, No specific MS-DRG, No CCR of 1.0
- *There was no price adjustment because of these factors*



Bottom Line: Providers and Hospitals Need Relief and Change

Personalized products with little/no opportunity for discounts, bulk purchase, or sole sourcing

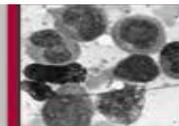
Little interchangeability of products based on disease/condition (MM, DLBCL, etc)

Centers providing one of these therapies likely providing several others – the averaging system does not work for this concentration of losses

Providers cannot create the desired 'efficiencies' within IPPS at the current prices

- The 'margin' on an admission without CRS does not make up for product losses

Providers are choosing to do the right thing for patients now, despite pressure to do otherwise – have taken substantial losses during the past year in the inpatient setting



Up Next: Meeting with CMS, Comment Submission

- Planned meeting with CMS on June 20
 - Will show CMS team our analysis, pro/cons with each and explain our final decision
- Potential for adjustments to our letter comments based on that conversation
- Plan to submit/post for member reference by June 22
 - Will be distributed via a member email by end of day 6/22
 - Will be posted to the main CAR-T page: <http://asbmt.org/practice-resources/coding-and-reimbursement/car-t-therapy>

Member Comments and Gov Affairs Teams

Member Comments:

- Comments from providers and hospitals **key**
- Organization level comments useful but personalization is best
- Share the discussions at your facilities – i.e. decision-making based on product cost, limited provision of CAR-T
- This will be a heavy lift for CMS – give them the political cover to help you

Government Affairs/Relations:

- Reports that the Hill is looking for input on this from hospitals/providers and has received little/no feedback
- PLEASE share both letters with your GA/GR teams to circulate to relevant offices
- Real opportunity for offices to help – a potential win for their key stakeholders

