

POSITION PAPER

I. April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS) [CR11216]

II. Committee Representatives

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III. Introduction

On March 15, 2019, CMS released the April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS). *Transmittal 4225*, among other subjects, addressed the billing of CMS' product HCPCS Q-codes for Chimeric Antigen Receptor T-cell (CAR-T) therapy: Q2041 and Q2042. CMS restated its position from the FY 2019 OPPS final rule that the CAR-T Category III CPT® codes 0537T, 0538T, and 0539T were assigned to status indicator "B" (not separately payable). It also laid out three coding scenarios, two of which instruct hospitals to report these codes on outpatient claims as non-covered charges. For one scenario, where the CAR-T administration occurs in the inpatient setting, CMS instructs providers to use a revenue code different from the one the National Uniform Billing Committee (NUBC) unanimously approved in August 2018 for use starting April 1, 2019, for CAR-T product/drug reporting. These instructions, among others, have raised questions about CMS' adherence to HIPAA transaction code set requirements which all payers and all providers must abide by. *Transmittal 4225* was a topic on the agenda at the April 9, 2019, NUBC meeting where the committee expressed its grave concern to CMS about the issuance of instructions that run counter to the NUBC's authority.

The NAHRI Professional Advocacy Committee wants to address this topic because of its importance to the revenue cycle process, provider billing operations, and overall data integrity—not to mention questions that beneficiaries could raise about what non-covered charges mean and the possible need for an advance beneficiary notice. The current CMS instructions would require separate, manual, parallel processes to be designed, implemented, and managed by hospitals. Moreover, hospitals would undergo this significant effort solely to adhere to unusual and unnecessarily complex instructions from one payer who is not abiding by the rules set by the NUBC, a legally recognized standards-setting organization under HIPAA. CMS' instructions are raising many questions as they appear to conflict with NUBC instructions about appropriate coding and submission of claims. While CMS appears to have heard some of the concerns, it likely needs to hear from even more providers. The NUBC has the authority to govern how claims are coded and submitted for adjudication, regardless of

The National Association of Healthcare Revenue Integrity (NAHRI) Professional Advocacy Committee is responsible for the research and development of position papers that can help further the revenue integrity profession and bring awareness to matters impacting revenue integrity practices.

Committee members include:

- Lawrence A. Allen, MBA, CPC, CEMA
- Zarina Khabibulina, MD, CCS, CCM, CDIP
- William L. Malm, RN, ND, CMAS, CRCR
- Terri Rinker, MT (ASCP), MHA
- Donna Schneider, RN, MBA, CPHQ, CPC-P, CHC, CPCO, CHPC
- John D. Settlemyer, MBA, MHA, CPC
- Debra Seyfried, MBA, CMPE, CPC-I, CPC
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payer. This puts providers in a bind, as they may need to bill Medicare for CAR-T services in one manner while billing other payers in another manner. It is clear that Medicare's instructions are counterintuitive and should either be revised or rescinded.

IV. Narrative

The AMA approved four Category III CPT codes describing CAR-T services: 0537T, 0538T, 0539T, as well as 0540T (administration of CAR-T therapy). The first three codes describe the cell collection and cell processing procedures for CAR-T. In the FY 2019 OPPS final rule, Medicare assigned these three codes as status indicator "B": codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x). Yet, confusingly, CMS also stated in the rule that "it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for HCPCS codes reported for services in which no separate payment is made under the OPPS."

CMS, in the billing scenarios provided in the April transmittal, stated that these codes may be reported on outpatient claims as "non-covered" charges. This has caused concern, and was a topic of discussion at the NUBC meeting on April 9. There, the committee stressed that these services are covered hospital outpatient services ordered by physicians and provided to patients as incident-to services; they are simply not something hospitals or patients would consider non-covered. Collection and processing services associated with an autologous stem cell transplant might be thought of as analogous services. Moreover, these services are mentioned as part of the overall therapy that is being considered for national coverage, with evidence development by CMS, in the recent proposed decision memorandum that CMS released for CAR-T.

Furthermore, the inpatient billing scenario outlined in this transmittal provides instructions that would require providers to deviate from their typical coding practices. It instructs that providers may hold on to outpatient charges provided in real time to a patient described by these Category III CPT codes if the infusion of the CAR-T product subsequently occurs in the inpatient setting. Providers may then report the CAR T-cell collection and preparation services as described by CPT codes 0537T, 0538T, and 0539T on the inpatient claim (type of bill 11X) using revenue code 0891 (special processed drugs – FDA (Food and Drug Administration) approved cell therapy – charges for modified cell therapy).

There are several problematic issues with CMS' instructions:

- Holding outpatient charges to place on an inpatient bill
- The language of "may be," which means that various staff will report them differently, or not report them at all, and in turn CMS will receive inconsistent information
- The instruction to report these patient care services—likely provided out of a lab department—with revenue code 0891, which is a new pharmacy revenue code for cell and gene therapy products
- Reporting Part B services on Part A claims

Sharing your concerns about the burden the transmittal instructions impose will help keep this issue and the NUBC's message at the forefront."

- Reporting outpatient services that occur far more than three days prior on an inpatient claim—likely highly problematic for claims processing and date-of-service reporting
- The misrepresentation of cell collection and preparation services—they are provider services, not “steps in the manufacturing process”

The NUBC raised these concerns with CMS, which had representatives present at the April 9 meeting.

V. Actions

The NAHRI Professional Advocacy Committee wants to make sure that the NUBC is supported by the provider community and that CMS continues to hear loud and clear from providers that these instructions are confusing, run contrary to typical practice, impose undue administrative burden, and put providers in a difficult position.

It is important that providers submit comments to CMS on this issue now as the agency deliberates what to do with its guidance. We believe this may be an inflection point with CMS hearing from providers, the NUBC, and provider associations that their instructions need revision. Comments from providers about the burden the transmittal instructions impose will help ensure that the needed revisions occur immediately, while keeping the issue and the NUBC’s message at the forefront.

CMS must understand the provider perspective and the importance of adhering to HIPAA transaction set requirements. Even short comments sent via email and addressed to individuals at CMS with NUBC staff copied can make a difference. There is no deadline, but comments that are received now will keep the issue fresh for both entities and hopefully encourage CMS to issue its revisions relatively soon.

Send your comments to:

- Carol Blackford at Carol.Blackford@cms.hhs.gov
- Ing Jye Cheng at IngJye.Cheng@cms.hhs.gov
- Esther B. Markowitz at Esther.Markowitz@cms.hhs.gov
- David Rice at David.Rice1@cms.hhs.gov
- Tiffany T. Swygery at Tiffany.Swygert@cms.hhs.gov
- Donald Thompson at Donald.Thompson@cms.hhs.gov

Copy the NUBC staff on your messages to CMS:

- Suzanne Lestina at slestina@aha.org
- Todd Omundson at tomundson@aha.org

“CMS must understand the provider perspective and the importance of adhering to HIPAA transaction set requirements.”

VI. Resources

MLN Matters. (2019). April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS). Retrieved from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11216.pdf>.

NUBC. (2019). NUBC Meeting, April 9–10, 2019. Retrieved from www.nubc.org/aboutus/PDFS/April2019TentSchedule.pdf.