



American Society for
Transplantation and Cellular Therapy

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

May 2, 2024

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-4207-NC; Request for Information – Medicare Advantage Data

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comments regarding the Medicare Advantage (MA) Data Request for Information (RFI). In the document, CMS notes that they are interested in comments on all aspects of data related to the MA program—both data elements currently collected and those that are not. ASTCT’s comments are focused primarily on how claims data and prior authorization data could be more comprehensively collected, shared, and utilized.

The ASTCT is a professional membership association of more than 3,700 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society’s clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell-based gene therapies for genetic immune system and blood disorders.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT’s Director of Government Relations, at amaloney@astct.org.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Cutler".

Corey Cutler, MD, MPH
President, ASTCT



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Request: Study the potential inclusion of MA claims in rate-setting and release the findings

The ASTCT requests CMS examine and publish how including MA claims data would impact the Inpatient Prospective Payment System (IPPS) rate-setting for certain MS-DRGs, particularly for MS-DRGs that are focused on high-intensity procedure-driven hospitalizations, like those mapped to pre-MDC MS-DRGs 014/016/017 and 018 for hematopoietic stem cell transplant (SCT) and chimeric antigen receptor t-cell therapy (CAR-T), respectively.

Based on recent CMS data more Medicare beneficiaries (50%+) are now enrolled in MA plans rather than traditional Part A and Part B, also known as Fee-for-Service (FFS) Medicare.¹ The Congressional Budget Office has predicted that the percentage of beneficiaries enrolled in MA plans will grow to more than 61% by 2032.² This is a dramatically different beneficiary enrollment landscape than when CMS overhauled the DRG system with the development of Medicare-severity DRGs in 2007, when the MA enrollment rate was just under 20%.²

MA enrollment varies significantly across the United States, with substantially higher enrollment on the coasts, the populous Southern states (e.g., Texas, Tennessee, Georgia, and Florida) and the upper Midwest (Michigan, Minnesota and Wisconsin).² This variation means that the FFS claims that Medicare utilizes for rate-setting are not only decreasing in total number (representing less than half of beneficiaries) but also becoming cumulatively less representative of the national population's distribution, along with the hospitals that serve that population. Additionally, the states where MA enrollment is the highest (and therefore where FFS enrollees are fewest) are also the states where there are likely to be the most academic medical centers and specialized hospitals, which are historically the fastest adopters of new therapies for rare and complex diseases.

As the percent of beneficiaries enrolled in FFS decreases, the number of FFS claims used for the rate-setting process will also decrease and become less representative for predicting resource utilization. **In the FY 2022 MedPAR data utilized for FY 2024 Inpatient Prospective Payment System (IPPS) rate-setting, there were at least 390 MA CAR-T claims that were not included in rate-setting—an amount that would have increased the total volume by 50%. Similarly, there were more than 1,600 MA SCT claims that were not included in rate-setting, which would have increased the collective total volume by 36%.³** Given the geographical disparities in MA enrollment, FFS claims from a limited number of centers in certain geographic areas of the country will drive an increasing proportion of the rate-setting data, even though they may further skew the IPPS resource calculations. Furthermore, as CMS

¹ Fuglesten Biniek J, Freed M, Damico A, Neuman T, *Half of All Eligible Medicare Beneficiaries are Now Enrolled in Private Medicare Advantage Plans*, Palo Alto (CA): KFF, May 1, 2023: <https://www.kff.org/policy-watch/half-of-all-eligible-medicare-beneficiaries-are-now-enrolled-in-private-medicare-advantage-plans/>.

² Freed M, Fuglesten Biniek J, Damico A, Neuman T, *Medicare Advantage in 2022: Enrollment Update and Key Trends*, Palo Alto (CA): KFF, August 25, 2022: <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/>.

³ CMS MEdPAR [Hospital National Limited Data Set](#), FY 2022



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has acknowledged, most MA plans utilize IPPS MS-DRG base payments as the basis for payment to hospitals for MA beneficiaries, and hospitals must accept FFS rates for MA enrollees seeking care out of their plan's network. For the reasons stated above, the use of a set of claims that is no longer nationally representative to establish payment for treating both FFS and MA beneficiaries is not logical.

Hospitals that bill an MA plan for an inpatient stay must also submit a copy of that claim to their local Medicare Administrative Contractor (MAC) for informational purposes, known as a "shadow claim." **The ASTCT recommends that CMS model the inclusion of MA shadow claims on relative weights and share the findings with stakeholders for feedback in a future rulemaking cycle.** A higher volume of claims will make the analyses CMS conducts on claims more statistically robust and ensure that both FFS payments and IPPS benchmarks used by MA plans are more representative of the full range of patients treated and the care provided to them by IPPS hospitals. Additionally, a higher volume of claims could help CMS as they further explore appropriate mechanisms to address therapies that represent low volumes of claims data as previously discussed in the [48854 FR IPPS 2023 FR](#).

The ASTCT asks that CMS conduct or commission a pilot study from a reputable firm that examines the effect of including MA shadow claims with FFS claims on IPPS rate-setting for the Pre-MDC MS-DRGs. Additionally, CMS should release all claims data used in the study, including data for both MA and FFS encounters, for independent stakeholder analysis.

The ASTCT further requests that CMS mirror this type of study for OPSS rate-setting as well. **However, given CMS does not currently receive OPSS claims from hospitals or MA plans, we request CMS begin the contractual and procedural changes necessary to require MA plans to begin sharing this data with CMS – with the subsequent goal of studying the potential impact on rate-setting and sharing all the data with stakeholders for analysis and research.**

Request: Require MA plans to release data on metrics for prior authorization for cell and gene therapies

The ASTCT was disappointed CMS excluded drugs from the Interoperability and Prior Authorization Final Rule (CMS-0057-F). By failing to address prior authorization for drugs, CMS has unfortunately failed to address one of the biggest culprits of delay to timely care. However, we still believe CMS' intent for this rule is to minimize burden and increase patient access to timely care. Thus, we request, at a minimum, that MA plans be required to release data on metrics for prior authorization for cellular and gene therapy products (i.e. those products listed on the Food and Drug Administration's Approved Cellular and Gene Therapy Products⁴), like the reporting requirements finalized in CMS-0057-F.

⁴ US FDA. Approved Cellular and Gene Therapy Products. Online: <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>



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As noted in this letter’s preamble, the ASTCT membership provides specialized biologics, like CAR-T and hematopoietic stem cell-based gene therapies, to patients with genetic immune system and blood disorders. CAR-T, for example, is recognized as a novel therapy for patients who have little to no other treatment options. Our members have recently raised examples of long and uncoordinated prior authorization processes for CAR-T which result in confusion, additional work by all parties, and ultimately delayed care for the patient.

CMS previously stated that publicly reporting metrics about prior authorization would allow payers to assess their internal performance, understand trends and determine where improvements may be necessary, as well as serve as a tool for patients to evaluate a payer’s performance when selecting a plan. This is especially needed for cell and gene therapies. By excluding cell and gene therapies from the finalized rule altogether, CMS has ignored the patients most in need of timely access to life-saving care.

The ASTCT requests that CMS require MA plans, at a minimum, to separately release data on metrics for prior authorization for cell and gene therapy products based on the presence of a product-specific HCPCS and/or ICD-10-PCS code, like the reporting requirements finalized for payers in CMS-0057-F. Specifically, the ASTCT requests CMS require MA plans to track and publish the following for cell and gene therapies, separately from the aggregate reporting metrics already required:

- The percentage of standard prior authorization requests that were approved, denied, or approved after appeal;
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved;
- The percentage of expedited prior authorization requests that were approved, denied, or approved after appeal; and
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, both for standard and expedited prior authorizations.

The ASTCT sincerely appreciates CMS’ review of our comments and would be pleased to engage with CMS on any technical questions it may have.