



AMERICAN SOCIETY OF HEMATOLOGY

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June 24, 2019

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1716-P; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma:

The American Society of Hematology is pleased to offer comments on the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions affecting our members.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH looks forward to working closely with the agency to refine and implement these proposals and offers comments on issues of particular importance to our members as follows:

1. CAR-T Reimbursement Recommendation for FY 2020 IPPS
2. Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-on Payments
 - a. KYMRIA[®] (Tisagenlecleucel) and YESCARTA[®] (Axicabtagene Ciloleucel)
3. CAR-T Reimbursement Recommendations for FY 2021 and Beyond
4. CAR-T Reimbursement for PPS-exempt centers

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5. Proposed Adoption of electronic Clinical Quality Measure, Use of Opioids – Concurrent Prescribing
6. Sanofi NTAP Application for Cablivi

CAR-T Reimbursement Recommendation for FY 2020 IPPS

CMS requested comments on payment alternatives for chimeric antigen receptor T-cell (CAR-T) therapy. ASH's members are at the forefront of this therapy, conducting research and providing this potentially curative treatment to patients with lymphoma and leukemia. Patients receiving CAR-T therapy are the sickest of the sick and have typically exhausted all other treatments, including chemotherapy, radiation, or stem cell transplant. This therapy represents a potentially life-saving option to patients whose care needs are currently unmet by existing therapeutics and who would otherwise receive high-cost, ineffective treatments.

The Society has been actively engaged on this issue, working closely with CMS, and other stakeholder groups, to share our thoughts and concerns. ASH's main priority is protecting and improving appropriate patient access to this potentially curative therapy. As of September 30, 2018, there have only been 348 CAR-T Medicare cases, and of that, at Prospective Payment System (PPS) hospitals, only 108 were non-clinical trial cases (Appendix A). ASH believes that one reason for this low case count is due to the poor reimbursement under Medicare and is pleased to provide recommendations to help address this matter.

With CAR-T being the first of the cell and gene therapies to be approved, ASH has urged CMS to develop an innovative payment solution to accommodate this new wave of treatment options. The Society appreciates the agency's willingness to consider payment alternatives that may be outside of its normal reimbursement methodology. ASH's proposal for reimbursement of CAR-T therapy for FY 2020, the same as that submitted by the American Society for Transplantation and Cellular Therapy (ASTCT), is outlined below and in Appendix B.

- Increase the amount of the maximum add-on payment amount for new technologies to 80 percent of the lesser of the costs of the new medical service or technology or the amount by which the costs of the case exceed the standard DRG payment for all products awarded a new technology add-on payment (NTAP), and
- Implement a cost-to-charge (CCR) ratio of 1.0 to calculate both the NTAP and the outlier, only to be applied to the two currently U.S. Food and Drug Administration (FDA)-approved CAR-T products. This can be accomplished using the National Uniform Billing Committee (NUBC) code revisions that were effective on April 1, 2019 on inpatient claims.

In order to operationalize ASH's proposed use of the CCR of 1.0, CMS would specifically:

- Compute the "Patient Care Cost" Only: Subtract the line item drug charge reported in new revenue code 0891 - Special Processed Drugs – FDA Approved Cell Therapy¹ - from the total inpatient charges on the CAR-T claim. Multiply the result by the hospital's overall CCR to get the calculated patient care cost.
- Derive the new "Total Case" Cost: Add the calculated patient care cost to the CAR-T drug cost that results in the newly calculated cost. CMS can use the average sales price (ASP) of \$373,000 or require hospitals to report value code 86 on their inpatient claims. NUBC approved value code 86 for use, beginning April 1, 2019. Value code 86 represents the actual cell/gene therapy invoice/acquisition cost and is for use with revenue category 089x.¹ ASH, ASTCT, and the American Hospital Association (AHA) have all requested previously that CMS mandate reporting of value code 86.

¹ <http://www.nubc.org/subscribersonly/PDFs/Cell%20Therapy%20Changes%20August%202018.pdf>

- Use the newly calculated cost as the starting point in the NTAP and outlier calculations.

Increasing the NTAP amount and operationalizing the CCR of 1.0 in this way - recognizing the CAR-T product acquisition cost, not the marked-up charge - provides numerous benefits to the institutions providing CAR-T, the patients in need of this therapy, as well as to CMS.

For institutions, it will eliminate the need for mark-up of the CAR-T product, ensuring that all institutions, regardless of their mark-up practices, are eligible to receive the full NTAP. The data available, included in Appendix C, shows that while many institutions are appropriately marking up the cost of the CAR-T product in order to access the full NTAP, there are also many institutions not appropriately marking up the charge, and therefore, not receiving the full NTAP that is available.

Additionally, if CMS accepts ASH's suggestion of increasing the NTAP to 80 percent, the agency would cover \$298,400 of the \$373,000 product cost for all institutions. Institutions will still not be made whole on the acquisition cost, but this will help alleviate more of the financial burden faced when providing potentially curative therapies, such as CAR-T. ASH appreciates that CMS's proposal increases the NTAP cap to 65 percent for all eligible products; however, the Society, does not believe this proposal goes far enough to improve patient access to CAR-T and other new technologies. Even with the proposed increase to the NTAP amount for CAR-T, institutions will still be covering a significant portion of the product cost.

ASH first made the request to increase the NTAP cap to 80 percent in discussions with the agency earlier this year and believes this suggestion is a logical outgrowth of CMS' proposal. This increase will be meaningful for centers delivering CAR-T as well as other NTAP-eligible products and services. Furthermore, AHA performed an analysis that showed that only 33 percent of NTAP dollars have been paid out since the NTAP was first implemented in 2001.² CMS has saved a significant sum on these payments that may offset the additional increase ASH is recommending.

ASH has heard anecdotally that institutions have been reluctant to make the investments necessary to run a CAR-T program knowing that under the best-case scenario, they will not be able to recuperate half of the product's cost for Medicare patients. To reiterate, as of September 30, 2018, there have only been 348 CAR-T Medicare cases, and of that, at PPS hospitals, only 108 were non-clinical trial cases (Appendix A). An increase in the NTAP amount and using the CCR of 1.0 (to ensure that all institutions receive this full NTAP payment) should increase access to CAR-T therapy for patients because more institutions will be willing and financially able to provide it.

For CMS, this proposal will mitigate the agency's concerns about making significant changes to its payment systems and about overpaying centers for this therapy. This method is the least disruptive to current CMS formulas and applies the same change to both the NTAP and the outlier methodologies. Furthermore, using a CCR of 1.0 to base the NTAP and outlier payments on actual product acquisition cost will protect the outlier pool from being distorted by preventing these payments from being made on the basis of extraordinary mark-up.

Additionally, mandating use of value code 86 would protect CMS from making an NTAP payment for clinical trials or other situations where the hospital did not incur cost because the amount reported in the value code line would be zero. Requiring use of value code 86 would account for situations when a patient receives an outpatient CAR-T infusion and the hospital gets a 340B discount, but then subsequently admits the patient and bills the claim as an inpatient stay. More importantly, value code 86 would allow for accurate data to be collected for future rate setting and for this reason, the Society urges CMS to mandate reporting of the value code. The

² <https://www.aha.org/system/files/2018-06/180625-ipps-proposed-rule-fy2019.pdf>

agency could add an edit between value code 86 and the CAR-T ICD-10-PCS procedure codes to give providers an opportunity to resubmit the claim when the value code is left incomplete.

Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-on Payments

KYMRLAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

ASH supports CMS continuing the NTAP for KYMRLAH® and YESCARTA® for all of FY 2020. ASH is currently analyzing Medicare claims data for CAR-T therapy. It is evident from our review that more data is needed before it would be appropriate to make further decisions toward rate-setting and/or developing alternative payment proposals. Expanding the NTAP for all of FY 2020 and requiring institutions to report value code 86 on inpatient claims, as outlined above, will help to allow continued data collection to inform future payment decisions.

CAR-T Reimbursement Recommendations for FY 2021 and Beyond

ASH supports CMS' proposal to continue to assign CAR-T cases to MS-DRG 016 in FY 2020. ASH cannot recommend the creation of a new MS-DRG at this time based on existing data, which includes a small number of CAR-T cases with inconsistent charges. ASH appreciates that the agency is considering different approaches for future rate setting for CAR-T and urges CMS to consider the suggestions below as the agency thinks about a CAR-T specific MS-DRG for FY 2021 and beyond.

First, as previously stated, ASH recommends that CMS require institutions to report value code 86 on their inpatient claims. CMS acknowledges, and ASH agrees, that to-date there is a wide variation in CAR-T claims data. For data collected between October 1, 2017 and September 30, 2018, total charges for claims used for rate setting range from \$5,913 to \$2,429,675 (Appendix D). Using claims with this much variation for rate setting will lead to an inaccurate and inappropriate MS-DRG relative weight; overtime, additional and more accurate data will allow for more precise rate setting. NUBC approved value code 86, which represents the actual cell/gene therapy invoice/acquisition cost, for use beginning April 1, 2019. Requiring this code to be reported beginning October 1, 2019, will provide CMS with data on the CAR-T product acquisition costs for the agency to use for rate setting beginning in FY 2022.

Second, when engaging in rate setting for CAR-T, ASH recommends CMS create a MS-DRG specific to patient care costs and a separate payment to cover the product cost. Both can employ the averaging process that is the foundation of PPS payment. ASH proposes that CMS base this separate payment on the same portion of the average sales price (ASP) as is finalized for the NTAP (i.e. 50 percent, 65 percent, or 80 percent) until the agency has accurate data on the product cost. Separating patient care costs from the product cost would allow CMS to apply adjustments as usual on patient care costs.

Third, ASH strongly urges the agency to exclude clinical trial cases when developing a new MS-DRG for CAR-T. Again, using data collected between October 1, 2017 and September 30, 2018, when looking at PPS hospitals, the average pharmacy charges for clinical trial cases as compared to non-clinical trial cases, are \$101,041 versus \$623,726, respectively (Appendix A). This discrepancy is due to the fact that the product charge is not included in clinical trial cases. Creating a MS-DRG for CAR-T without excluding clinical trial cases will result in woefully inadequate payment to institutions. Clinical trial claims are not truly representative of the average cost of a case and ultimately, ASH believes CMS should exclude these claims from the calculated rate for MS-DRG 016 in FY 2020 as well.

CAR-T Reimbursement for PPS-exempt centers

CMS requested comments on how to improve the process for reimbursement for PPS-exempt centers under the Tax Equity and Fiscal Responsibility Act (TEFRA) in light of the current environment, especially

considering issues such as CAR-T. ASH has focused its IPPS rule comments on policies applicable to PPS institutions, but recognizes that PPS-exempt centers that operate under TEFRA are responsible for half of the CAR-T cases. As such, the Society supports the request by the Alliance of Dedicated Cancer Centers for CMS to implement a prompt and automatic payment adjustment for cancer hospitals providing CAR-T therapy in recognition that it is a reasonable cost directly related to patient care under TEFRA.

Proposed Adoption of Two Opioid-Related eCQMs

ASH is concerned about the proposed electronic Clinical Quality Measure (eCQM), Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e), and requests that CMS exclude individuals with an active diagnosis of sickle cell disease (SCD) in this measure. Under the Hospital Inpatient Quality Reporting (IQR) Program, hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year. The Safe Use of Opioids – Concurrent Prescribing eCQM focuses on concurrent prescriptions of opioids and benzodiazepines at discharge, an area of high-risk prescribing, but would also include patients on both long acting and short acting opioids. The goal of the measure is to reduce preventable mortality and costs of adverse events associated with prescription opioid use and could contribute to efforts to combat the current opioid epidemic.

The Society, however, believes this measure could unintentionally negatively impact individuals with SCD, many of whom are on long acting and short acting opioids. Recurrent severe acute painful crises and chronic daily pain are the most common complications of SCD. Severe acute painful crises often require treatment in the hospital emergency department. Chronic pain from a variety of causes including avascular necrosis (death of bone tissues due to a lack of blood supply), leg ulcers, and other neuropathic pain, is also prevalent. Opioids may be the only option to provide relief and allow patients to function.

ASH is concerned that the proposed eCQM could potentially mean that SCD patients who need their medications prescribed at discharge are less likely to get them if the provider and/or institution does not want to be penalized by CMS for “inappropriate prescribing.” ASH recognizes and appreciates that the agency proposes an exclusion for patients with an active diagnosis of cancer and urges CMS to also exclude individuals with an active diagnosis of sickle cell disease.

The Federal government has recently recognized the unique needs of individuals with sickle cell disease through the following:

- The [Centers for Disease Control and Prevention](#) (CDC) clarified that its *Guideline for Prescribing Opioids for Chronic Pain* is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management. The CDC specifically noted the challenges of managing the painful complications for sickle cell disease and highlighted the importance of clinical practice guidelines addressing use of opioids as part of pain control in patients with sickle cell disease, including the National Institutes of Health *National Heart, Lung, and Blood Institute’s Evidence Based Management of Sickle Cell Disease Expert Panel Report for guidance for management of sickle cell disease*, to guide treatment and reimbursement decisions.
- The [Centers for Medicare and Medicaid Services](#) in the CY 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, recommended for beneficiaries with SCD be excluded from the opioid safety edits. This is reiterated in CMS’s [Opioid Prescription in Medicare Beneficiaries: Prescription Opioid Policies and Implications for Beneficiaries with Sickle Cell Disease](#).
- The Health and Human Services Pain Management Best Practices Inter-Agency Task Force highlighted the CDC’s clarification, outlined above, in its [final report](#), released May 2019.

Additionally, ASH has outlined its position regarding this important matter in its [Statement on Opioid Use in Patients with Hematologic Diseases and Disorders](#).

Sanofi NTAP Application for CABLIVI

ASH supports the Sanofi Company's NTAP application for Cablivi (caplacizumab-yhdp) for FY 2020. ASH subject matter experts were consulted and agree that using Cablivi for treatment of patients with acquired thrombotic thrombocytopenic purpura (aTTP) has the potential to save the lives of those individuals who do not respond to current conventional treatment, plasma exchange, corticosteroids, and rituximab. Cablivi differs from the treatments currently available for aTTP because it immediately prevents platelets from binding to the abnormally large von Willebrand factor molecules, a key abnormality of TTP. Without bound platelets, the thrombosis is prevented. Cablivi blocks the tissue injury, but corticosteroids, rituximab, and plasma exchange, are still needed to affect the cause of the disease.

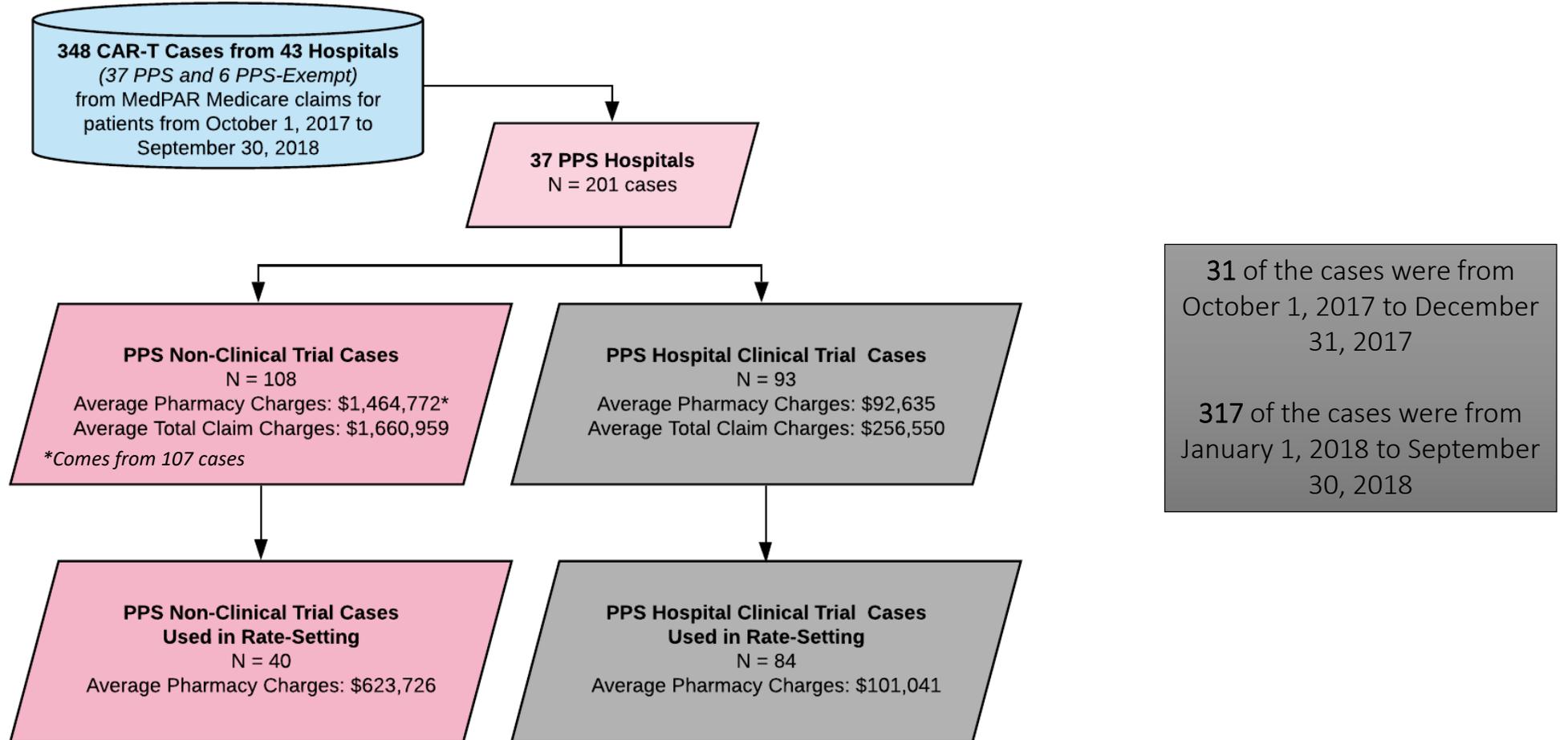
Thank you for the opportunity to provide comments on the proposed rule for the Hospital Inpatient Prospective Payment Systems for 2020. We welcome the opportunity to discuss these comments with you and your team at any time. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

A handwritten signature in black ink, appearing to read "Roy L. Silverstein". The signature is fluid and cursive, with a large initial "R" and "S".

Roy L. Silverstein, MD
President

Breakdown of Case Volume



Appendix B

ASTCT and ASH Working Draft Document of CAR-T Reimbursement Options for FY 2020

		Options for FY 2020					
	FY 2019	CMS' proposal of changing NTAP cap from 50% to 65%	CMS' proposal of changing NTAP cap from 50% to 80%	COMBO Proposal: CMS' proposal of changing the NTAP cap from 50% to 65% AND adds in the use of actual product acquisition cost as a way to effectuate the "CCR of 1.0" concept in the NTAP and outlier formula	COMBO PROPOSAL: Starts with CMS' proposal of changing the NTAP cap (we model 80%) AND adds in the use of actual product acquisition cost as a way to effectuate the "CCR of 1.0" concept in the NTAP and outlier formula	FY 2020 - CMS Request for Comments on Uniform NTAP at 65% for CAR-T Only	FY 2020 - Improvement Upon CMS' Request for Comments on Uniform NTAP for CAR-T Only from 65% to 80%
Options ¹	Current	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
MS-DRG ²	016	016	016	016	016	016	016
NTAP	Current methodology	Update to the percentage cap used in the current formula	Larger update to the percentage cap used in the current formula	Update to the percentage cap used in the current formula & then exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back \$373,000 for CAR-T product cost (or using data in the value code field) and then apply the usual formula	Larger update to the percentage cap used in the current formula & then exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back \$373,000 for CAR-T product cost (or using data in the value code field) and then apply the usual formula	Change formula to 65% of NTAP as uniform payment	Change formula to 80% of NTAP as uniform payment
Outlier	Current methodology	Current methodology		Exclude the CAR-T product charge from total charges, reduce remaining charges to cost, then add back \$373,000 for CAR-T product (or using data in the value code field) plus MS-DRG payment plus outlier threshold cost and apply the usual formula		Current methodology	
Financial Impact Based on Hospital A w/ 10% Mark up	(\$303,003)	(\$300,216)	(\$297,503)	(\$50,607)	(\$39,417)	(\$145,057)	(\$89,107)
Financial Impact Based on Hospital B w/ 400% Mark up	(\$61,325)	(\$50,607)	(\$39,417)	(\$50,607)	(\$39,417)	(\$50,607)	(\$39,417)
Notes:							
(1) Each option is based on the sample claims provided							
(2) MS-DRG payment based on the assumption that both hospitals have a wage index of 1.0 and no adjustments for IME or DSH in order to isolate issues of charge compression.							
(3) Financial impact to individual hospitals will vary based on hospital's charging practices, hospital's own operating cost-to-charge ratio, wage index, IME and/or DSH adjustments, amount of outlier received (we used a simple formula and did not compute capital and operating separately), and most importantly actual patient care costs (i.e., patients with complications requiring additional drugs, therapies, intensive care, etc. will be more costly than our simple example) of the case.							

Name	Total # of CAR-T Cases	CAR-T CLAIMS USED IN RATE-SETTING		CAR-T CLAIMS NOT USED IN RATE-SETTING	
		Not Clinical Trial	Clinical Trial	Not Clinical Trial	Clinical Trial
MASSACHUSETTS GENERAL HOSPITAL	25	\$1,675,013	\$23,110	\$1,609,480	\$8,361
RONALD REAGAN U C L A MEDICAL CENTER	*	\$1,641,085		\$1,547,962	\$1,256
FROEDTERT MEMORIAL LUTHERAN HOSPITAL	*	\$1,423,914	\$28,146	\$1,972,535	
NEW YORK-PRESBYTERIAN HOSPITAL	*	\$1,334,905		\$887,624	
BARNES JEWISH HOSPITAL	*	\$1,330,024		\$685,714	
STANFORD HEALTH CARE	15	\$1,078,560	\$535,780	\$1,102,317	
VANDERBILT UNIVERSITY MEDICAL CENTER	*	\$1,054,290	\$9,525		\$5,853
STRONG MEMORIAL HOSPITAL	*	\$797,296		\$787,371	
HOSPITAL OF UNIV OF PENNSYLVANIA	*	\$543,850	\$13,149		
CLEVELAND CLINIC	*	\$460,472	\$109,038		
BRIGHAM AND WOMEN'S HOSPITAL	27	\$422,227	\$3,744	\$1,419,116	\$19,862
UNIVERSITY OF MARYLAND MEDICAL CENTER	*	\$383,789	\$21,665	\$387,689	
UCSF MEDICAL CENTER	*	\$155,777	\$34,983		
THE UNIVERSITY OF CHICAGO MEDICAL CENTER	22	\$29,818	\$47,369	\$2,111,318	
UPMC PRESBYTERIAN SHADYSIDE	14	\$22,755	\$59,589	\$6,082,928	
UNIVERSITY OF WASHINGTON MEDICAL CTR	*	\$19,491			
MAYO CLINIC HOSPITAL ROCHESTER	*	\$18,172			
UNIVERSITY OF COLORADO HOSPITAL AUTHORIT	*	\$13,255	\$20,643		
EMORY UNIVERSITY HOSPITAL	*	\$8,484	\$5,183	\$32,041	
UNIVERSITY OF ALABAMA HOSPITAL	*	\$7,372	\$36,524		
BETH ISRAEL DEACONESS MEDICAL CENTER	*	\$3,729	\$7,831		
BANNER GATEWAY MEDICAL CENTER	*			\$1,268,376	
UC SAN DIEGO HEALTH HILLCREST - HILLCRES	*		\$8,478		
PRESBYTERIAN ST LUKES MEDICAL CENTER	*		\$11,205		
NORTHSIDE HOSPITAL	*		\$8,242		
NORTHWESTERN MEMORIAL HOSPITAL	*		\$39,144		\$47,212
UNIVERSITY OF LOUISVILLE HOSPITAL	*		\$284,098		
UNIVERSITY OF MICHIGAN HEALTH SYSTEM	*			\$2,289,023	
THE NEBRASKA MEDICAL CENTER	11		\$17,743	\$2,031,448	\$20,065
HACKENSACK UNIVERSITY MEDICAL CENTER	*		\$5,323		
MOUNT SINAI HOSPITAL	*		\$21,615		
MONTEFIORE MEDICAL CENTER	*			\$2,633,405	
UNIVERSITY OF NORTH CAROLINA HOSPITAL	*		\$7,212		
BAYLOR UNIVERSITY MEDICAL CENTER	*		\$706		
UT SOUTHWESTERN UNIVERSITY HOSPITAL	*			\$49,369	
UNIVERSITY OF UTAH HOSPITALS AND CLINICS	*		\$33,637		
SEATTLE CHILDREN'S HOSPITAL	*			\$115,016	

PPS Hospital Pharmacy Charges

“*” = Numbers with counts of less than 11, or counts that could lead to a calculation of less than 11; all further breakdowns of the total number by clinical trial and non-clinical trial for volume would have met this criteria; therefore those breakdowns have not been shown

Pharmacy Charge Breakdown for Claims Used in FY 2020 Rate-Setting

124 claims used in rate-setting from PPS hospitals

Variable	Label	N	N Miss	Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum	Mean	Std Dev
cc_drugs	Pharmacy	124	0	286.0000000	7982.00	19473.50	164340.50	1721193.00	269649.05	490810.64
cost_drugs		124	0	32.2597452	1088.60	2361.17	16376.31	233609.38	32277.92	59570.15
TOTAL_CHARGES		124	0	5913.00	81245.50	150386.50	491862.50	2429675.00	455130.19	604968.79
total_cost_standardized		124	0	1073.30	16739.00	29329.20	70047.43	317317.08	65247.56	77435.90

flag_clinical_trial=0. Not clinical trial

Variable	Label	N	N Miss	Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum	Mean	Std Dev
cc_drugs	Total Charge Amount	40	0	734.0000000	12019.00	385549.00	1315653.50	1721193.00	623726.28	652753.08
cost_drugs		40	0	82.7924928	1593.07	59155.82	173608.34	233609.38	79672.07	82359.66
TOTAL_CHARGES		40	0	17449.00	109782.50	467773.00	1454186.50	2429675.00	835453.90	797232.56
total_cost_standardized		40	0	3676.73	20122.04	76012.09	222607.78	317317.08	118921.69	107114.77

flag_clinical_trial=1. Clinical trial

Variable	Label	N	N Miss	Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum	Mean	Std Dev
cc_drugs	Total Charge Amount	84	0	286.0000000	7518.00	15015.00	57802.50	1124430.00	101040.85	259978.64
cost_drugs		84	0	32.2597452	953.9835592	2039.34	5936.04	92554.46	9709.28	21760.90
TOTAL_CHARGES		84	0	5913.00	76802.50	131693.00	264669.50	1522500.00	274023.67	375255.92
total_cost_standardized		84	0	1073.30	16253.36	24739.34	49707.01	172173.10	39688.45	38018.19