

June 8, 2020

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1735-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

RE: Comment on the FY2021 IPPS Proposed Rule Designation

To Whom We May Address:

Thank you for allowing us the opportunity to submit comments on the FY 2021 IPPS proposed rule. The Association of Clinical Documentation Integrity Specialists (ACDIS) is grateful for the efforts of your organization to improve the nation's health, and for your willingness to review additional information during the public comment period before issuing your final rules. It's clear that great time and effort was invested in the proposed rule, and we appreciate and recognize this work of public service. ACDIS would also like to acknowledge the consideration you have given to the circumstances of the current COVID 19 pandemic and its impact on the nation's healthcare systems. We also wish to thank you for all of your work and support during this extraordinary time.

Last year, the FY 2020 IPPS Proposed Rule recommended a significant change in CC/MCC status for a large number of secondary diagnoses. The ICD-10-CM committee acknowledged the public comment submissions that cautioned against such a radical change and suspended the recommended changes until further study could be performed. In October 2019, the committee held a public listening session regarding determination of CC/MCC status for a secondary diagnosis. This year's proposed rule includes a list of "Guiding Principles" to determine diagnosis code severity. ACDIS welcomes this decision to change how CC/MCC status will be determine and we look forward to participating in the process of establishing this new protocol.

The FY 2021 IPPS Proposed Rule also includes new ICD-10-CM codes for Cytokine Release Syndrome (CRS) based on the current grading system established by the American Society for Transplantation and Cellular Therapy (ASTCT).<sup>1</sup> CRS has emerged as an established diagnosis in association with CAR-T cell therapy for various cancers, and we are now seeing this syndrome in patients who present with COVID 19.<sup>2</sup> ACDIS welcomes this addition, but we request further consideration of how the CRS codes are incorporated into the ICD -10-CM system.

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<sup>1</sup> Lee, David W. et al, "ASTCT Consensus Grading For Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells". *Biology Of Blood and Marrow Transplantation*, vol. 25, no. 4, 2019, pp. 625-638.

<sup>2</sup> Mehta, Puja, et al. "Covid 19: Consider Cytokine Storm Syndromes and Immunosuppression". *The Lancet*, vol. 395, no. 10229, 2020, pp 1033-1034

Grades	Toxicity
Grade 1	Mild reaction, infusion interruption not indicated, intervention not indicated
Grade 2	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics, IV fluids), prophylactic medications indicated for <= 24 hrs
Grade 3	Prolonged (e.g., not rapidly responsive to symptomatic medication or brief interruption of infusion), recurrence of symptoms following initial improvement, hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
Grade 4	Life-threatening consequences, pressor or ventilatory support indicated
Grade 5	Death

Based on the toxicity descriptions found in the ASTCT CRS Grading<sup>1</sup> system, grades 3, 4 and 5 are assigned to unstable patients requiring hospitalization to arrest further deterioration. Assignment of ICD-10-CM codes D89.833, D89.834 and D89.835 would indicate that the provider is treating a complicated patient with major comorbid conditions that require high resource use.

ICD-10-CM	Description	CC	MDC	MS-DRG
D89.831	Cytokine Release Syndrome, grade 1	N	16 25	814, 815, 816 977
D89.832	Cytokine Release Syndrome, grade 2	N	16 25	814, 815, 816 977
D89.833	Cytokine Release Syndrome, grade 3	N	16 25	814, 815, 816 977
D89.834	Cytokine Release Syndrome, grade 4	N	16 25	814, 815, 816 977
D89.835	Cytokine Release Syndrome, grade 5	N	16 25	814, 815, 816 977
D89.839	Cytokine Release Syndrome, grade unspecified	N	16 25	814, 815, 816 977

We are concerned that CRS grades 3, 4, and 5 have not been assigned a diagnosis severity (CC/MCC) designation.

We believe that the low data volumes in MedPAR for Medicare patients undergoing CAR-T cell therapy complicated by CRS will create a barrier for determining CC/MCC status for CRS as a secondary diagnosis. The FY 2021 IPPS Proposed Rule indicates that the analysis performed to

create a MS-DRG for CAR-T cell found only 94 Medicare patients that had received CAR-T cell therapy in a non-clinical trial setting.<sup>3</sup> Given that the median age of the CAR-T cell patient is 56-58 years old, we anticipate that MedPAR will continue to demonstrate low patient volumes for Medicare patients receiving CAR-T cell therapy in the coming years.

We would like to suggest that diagnosis severity assignment for the various grades of CRS be used as a test case for the newly proposed guiding principles. The guiding principles as described in the IPPS Proposed Rules for FY 2021 do not indicate that a required threshold for number of occurring cases for Medicare patients be attained before an analysis of diagnosis severity assignment occurs. Based on the ASTCT CRS grading system, grades 3, 4 and 5 meet diagnosis severity criteria for 7 of the 9 proposed guiding principles.

1. Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility: **CRS Grades 4 and 5.**
2. Denotes organ system instability or failure: **CRS Grades 3, 4 and 5.**
3. Involves a chronic illness with susceptibility to exacerbations or abrupt decline
4. Serves as a marker for advanced disease states across multiple different comorbid conditions
5. Reflects systemic impact: **CRS Grades 3, 4 and 5**
6. Post-operative condition/complication impacting recovery: **CRS Grades 3, 4 and 5**
7. Typically requires higher level of care: **CRS Grades 3, 4 and 5**
8. Impedes patient cooperation and/or management: **CRS Grades 3, 4 and 5**
9. Recent (last 10 years) change in best practice, or in practicing guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use: **CRS Grades 3, 4 and 5.**

ACDIS is also requesting that the CRS coding logic be expanded to include the COVID-19 patient population (MDC 4 with MS-DRG 205 and 206). Based on current academic literature, CRS is a common occurrence and a focus of treatment in patients presenting with advanced COVID-19. The appearance of CRS in the COVID-19 patient population also indicates that the new CRS codes meet the 4<sup>th</sup> guiding principle of a “marker for advanced disease states across multiple different comorbid conditions”.

Thank you for the opportunity to comment on the proposed FY 2021 IPPS rules. We look forward to your review of our comments, and to our future participation in the rule-making process. We greatly appreciate your time and consideration.

Sincerely,

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Director, ACDIS  
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<sup>3</sup> Centers for Medicare and Medicaid Services (2020). *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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals*. Retrieved from <https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10122.pdf>

Signed on behalf of the members of the ACDIS Regulatory Committee and the ACDIS membership

**About ACDIS:**

ACDIS is a professional association representing more than 6,500 clinical documentation Integrity (CDI) professionals nationwide. Their backgrounds include registered nurses (RN), health information management (HIM) professionals, case managers, quality improvement personnel, and physicians. CDI professionals work to ensure complete and accurate documentation in the medical record, which is integral to accurate assignment of ICD-10-CM diagnosis and ICD-10-PCS procedure codes and the Medicare Severity diagnosis-related groups (MS-DRG) discussed in this proposed rule.