June 21, 2019
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1716–P

The Association of Clinical Documentation Improvement Specialists (ACDIS) is pleased to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment system (IPPS) and proposed fiscal year (FY) 2020 rates, as published in the May 3, 2019 Federal Register (CMS-1716-P).

ACDIS is a professional association representing more than 6,500 clinical documentation improvement (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.

Their work also helps to ensure the accurate reporting of quality measures, medical necessity of inpatient admissions and procedures, hospital and physician profiles, and other publicly available data.

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.

There is much in the proposed rule that we consider to be positive. For example, we are supportive of the recognition of chronic and permanent atrial fibrillation as a CC. In the past, only persistent atrial fibrillation (I48.11 and I48.19) was recognized as a CC, while other forms of atrial fibrillation (such as permanent AF) were not recognized as such despite nearly identical treatment plans. Adding the code for chronic atrial fibrillation to the list of CCs is a more encompassing solution that captures all variants of persistent or permanent AF with similar treatments and implications for care.

In a similar vein we are supportive of the designation of isolated neutropenia (D70.9), phosphorus disorders (E83.39), cor pulmonale (I27.81), fecal impaction (K56.41), hypocalcemia (83.51) as CCs, recognizing the clinical implications of these conditions. The proposal to promote R78.81, "bacteremia," to MCC status shares a similar recognition of the increased needs for care in patients with this diagnosis; similarly, the role that antibiotic resistance plays in increasing the complexity of care is appreciated and noted in establishing codes Z16.21, Z16.24, and Z16.39 as CCs. We are supportive of these changes as well.

We also appreciate the desire to eliminate confusion within disease categories. Accordingly, we endorse the changes in the pressure ulcer codes (L02.415 to L89.95) from the current mix of non-CC and MCC status to a consistent CC status, recognizing the need for early intervention

and the intensity of services required for pressure ulcer care. The proposed CC status of Stage 1-2 pressure ulcers may also prompt more aggressive recognition, enhancing overall patient care.

We would also like to add our support for the recognition that feeding difficulties pose significant problems within pediatric care, and to thank you for the proposed designation of code R63.3, "Feeding Difficulties," as a CC.

We are also supportive of the drive to recognize social determinants of health and their consequences as significant drivers of patient care needs. We thank you for the addition of code Z59.0, "homelessness," as well as R62.7, "adult failure to thrive," to the list of designated CCs. We hope that more social determinants of health will be similarly recognized in the future.

CDI programs often work hand-in-hand with hospital quality departments to ensure that patients included in quality measures are appropriate for study. It is in our interest to ensure that quality measures are clinically relevant and pose no undue obstacles to appropriate physician documentation. Given the current concerns over opioid use, we support the addition of the opioid-related quality measures within the proposed rule. Similarly, as CDI programs are often involved in revenue cycle work, we are supportive of plans to adjust disparities between high and low wage index facilities as well as adjustments for uncompensated care as a way of keeping hospitals that serve those with greatest need as viable members of their communities.

ACDIS would like to comment on some of the proposed changes that we feel would have an unintentional detrimental impact on healthcare and the general public. One general concern references the extrapolation of the CMS Medicare database to other patient populations. For example, with the 700-plus codes for malignancies that are proposed for re-designation as "Non-CC's," it's quite understandable how Medicare claims data might indicate that these have no bearing resource use and patient care. Medicare data is by and large compiled from the elderly, who often have multiple medical conditions present that demand more intense care as drivers of claims and DRG assignment or may be receiving palliative care rather than aggressive therapy due to age and the presence of other medical problems. However, we are concerned that as history shows both Medicaid and private payers often take their cues from Medicare, a deletion of these codes to non-CC status may adversely impact those younger adult and pediatric patients with malignancies who do not have a multitude of other illnesses that would offset the malignancy in the calculations of resource allocations in older patients. Similarly, we suspect the data analysis of Medicare claims in patients with sickle cell disease, obstetric issues, and certain congenital and genetic conditions may be skewed because of the relatively small numbers of patients in the Medicare cohort with problems primarily seen in children and young adults. We urge CMS to reconsider all MCC/ CC changes within the proposed rule in light of what medical issues are common in different age groups and focus changes within the proposed rules to those problems not seen in the pediatric or young adult populations.

Acknowledging that the MedPAR database may not be an appropriate "source of truth" for pediatric or obstetrical patients puts us in opposition to some of the changes in the MCC/CC status of codes within the proposed FY 2020 rule. We are specifically concerned with the changes in the MCC/CC status of codes in relation to sickle-cell disease, hereditary hemolytic

anemias, congenital anomalies, and chromosomal aberrations. As clinicians, pediatricians recognize that each of these can be a dominant factor in caring for the child with complex problems. Because these patients may not survive into late adulthood (and therefore not be a factor within MedPAR) in no way compromises their needs for resource-intense medical care needs in their early years.

We would appreciate a statement by CMS that, given the limitations of the data set, these proposed changes only be considered appropriate for the Medicare population within CMS, as other populations are not appropriately represented in the data sample. We would ask that any further analysis of MCC/CC status for ICD-10 codes seen in younger age groups be performed using an appropriate database (i.e., Medicaid) and their associated cost reports.

An additional general concern is that clinical severity is often not consistently reflected in the MCC/CC designations. For example, the new rule proposes that moderate malnutrition (E44.0) be an MCC, while severe malnutrition (E43) is a CC despite terminology which clearly indicates an increased severity of needs. Similarly, as the code for an acute exacerbation of severe persistent asthma (J45.51) is not an MCC, it actually outweighs codes including the term "status asthmaticus" (J45.02, J45.22, J45.32, J45.42, J45.52). Clinically, status asthmaticus is a more severe condition. While the changes in the proposed rule might actually be beneficial to the hospital's bottom line, they are inconsistent with the clinical use of the relevant terms. We would encourage the rule to maintain the current status of E43 as an MCC, E44.0 as a CC, and J45.51 as a CC.

Finally, we have a question about the process by which these recommendations were clinically evaluated. We feel assured that the appropriate statistical calculations were made given the limitations of the data set (as discussed above). However, we would like to know more about the process by which the proposed rule was clinically assessed. Knowing more about the background, specialties, and process of selection of the clinical advisors reviewing the proposed rule would add transparency and credibility to the CMS effort.

Our detailed comments and rationale on the FY 2020 IPPS proposed rule are below.

Acute Posthemorrhagic Anemia

Position: ACDIS believes that CMS's analyses of Medicare expenditures for D62, Acute posthemorrhagic anemia, in most cases meets the level of a CC. Should CMS still remove D62 as a CC, they should also remove R71.0, Drop in hematocrit, as a CC.

Rationale: CMS's publication of its C1-C2-C3 methodology for D62, Acute Posthemorrhagic Anemia, is as follows:

ICD-10-CM Diagnosis Code	Code Description	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current Severity Designation	Proposed Severity Designation
D62	Acute posthemorrhagic anemia	330612	1.6949	551261	2.2724	587711	3.2134	CC	Non-CC

ACDIS notes that the value for C1 with D62 is 1.6949 which is closer to 2.0 as a CC than to 1.0 which would serve as a non-CC.

We note that the C2 value is above 2.0 and the C3 value is above 3.0, which demonstrates that D62 adds additional costs to these cases. Recognizing that C2 already have another CC and C3 already have another MCC, designating D62 as a CC will not have any impact on Medicare payments. Consequently, D62's impact on C1 should be the most prominent determinate of whether this diagnosis should be a CC or not. Given that it is closer to 2.0 than to 1.0, we believe that it should be a CC.

Should CMS opt to finalize its proposal to remove the CC status from D62, we believe that R71.0, Drop in hematocrit, should also be removed from the CC list. R71.0 is an ICD-10-CM Chapter 18 symptom code that should be integral to any acute posthemorrhagic or blood loss anemia. A drop in hematocrit can also occur with hemodilution in patients with most chronic anemias that do not serve as CCs. We believe that if R71.0 remains a CC and D62 is not a CC that there will be temptation for only document the symptom of a drop of hematocrit instead of the disease of acute posthemorrhagic anemia.

Recommendation: ACDIS recommends that CMS maintain D62, Acute posthemorrhagic anemia, as a CC. We also recommend that CMS remove R71.0, Drop in Hematocrit, as a CC.

Body mass index

Position: We would like to comment on the proposed designation change for ICD-10-CM codes Z68.41 (Body mass index 40.0-44.9 adult) and Z68.42 (Body mass index 45.0-49.9 adult) from "CC" to "non-CC" status. ACDIS appreciates and understands that the data analysis indicates that these two Z codes do not consistently demonstrate a CC type impact as a secondary diagnosis, but we respectfully disagree with these changes.

We believe that the actual clinical care of the patient with morbid obesity (defined by the Centers for Disease Control and Prevention as a BMI > 40) impacts resource use, health care costs, and needs for care that would not be reflected in the claims data that serves as the basis for the CMS analysis.

ICD 10 CM	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current subclass	Proposed subclass
Z68.41 (BMI 40.0-44.9, adult)	139,420	1.1139	209,300	2.0752	213,929	3.0814	CC	Non-CC
Z68.42 (BMI 45.0-49.9, adult)	60,408	1.1643	102,897	2.0789	109,928			

Rationale: It is our consideration that patients with a BMI > 40 have a significant impact on allocation of healthcare resources and should maintain their comorbidity status. Some of the difficulties with morbidly obese patients are readily apparent to clinicians. Patients who are morbidly obese have higher rates of additional conditions such as diabetes, hypertension, heart disease, and certain cancers. Such patients are also physically harder to manage, causing

difficulty for staff in lifting, turning, and ambulation. Their size may also hamper diagnostic efforts such as diagnostic radiologic studies or therapeutic procedures. The medical literature provides an extensive record of support for the premise that morbid obesity is linked to increased use of hospital resources and increased length of stay.

Patients with morbid obesity are also be linked to an increased incidence of work-related injuries. OSHA has recently noted the increase in musculoskeletal injuries reported by healthcare workers and found that they encounter unique risks because they "lift, reposition, and transfer patients who have limited mobility. Larger patients can pose particular challenges for safe handling[1]. Multiple states have enacted safe patient handling laws which require hospitals and other healthcare systems to acquire the necessary equipment to safely lift and move patients[2]. Hospitals are also investing capital providing imaging and OR suites that can accommodate the larger patient. Given that the CDC estimates that nearly 40% of Americans are morbidly obese[3], health care systems are absorbing significant impacts in injury, missed days of work, worker compensation claims, and purchase of capital equipment in caring for these patients. These are resources that cannot be codified in CMS claims data, but should be considered in determining the comorbidity status of codes Z68.41 and Z68.42.

Recommendation: We respectfully request that CMS review our comments and consider deferring the change in CC status for Z68.41 (BMI 40.0-44.9) and Z68.42 (BMI 45.0-49.9). We would also like to offer a compromise position: Promoting E88.81 Metabolic Syndrome from a non-CC to a CC. This would acknowledge the complicated morbidly obese patient and would be on par with other combination codes that CMS uses to define the public's health.

Cardiac Arrest

Position: We noted with extreme interest the changes in cardiac arrest codes I46.2, I46.8, and I46.9, relegating them from MCC to "non-CC" status. From a clinical perspective, it's difficult to envision a scenario in which cardiac arrest would not be considered a major complication of comorbid factor, and we strongly request that CMS defer this change.

Rationale: One might envision where database analysis might suggest that a cardiac arrest event might not be associated with changes in outcome measures. These patients are likely already subject to poor outcomes, and if resuscitation fails length of stay may actually fall. But this is a case where numbers belie the actual situation, and where the level of care provided to the patient in cardiac arrest—a swarming, time-critical, multidisciplinary level of intensity and resource utilization seen nowhere else within clinical care—may not be reflected in the MedPAR numbers. However, any clinician easily recognizes cardiac arrest for the crisis that it is, and there is no clinical logic in considering cardiac arrest as an insignificant or incidental.

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[1] https://www.osha.gov/dsg/hospitals/documents/1.2_Factbook_508.pdf

[2] https://journalofethics.ama-assn.org/article/safe-patient-handling-laws-and-programs-health-care-workers/2016-04

[3] https://www.cdc.gov/obesity/data/adult.html

This is a case where the numbers may say one thing, but clinical reality clearly says another.

Recommendation: We strongly request that CMS consider deferring the change to "non-MCC" status for cardiac arrest codes I46.2, I46., and I46.9.

Chronic Kidney Disease and End-Stage Renal Disease

Position: We are also concerned with the proposed designation change for ICD-10-CM codes N18.4 (Chronic Kidney Disease, Stage 4, aka "CKD 4"), N18.5 (Chronic Kidney Disease, Stage 5, aka "CKD 5"), and N18.6 (End-Stage Renal Disease, aka "ESRD"). We appreciate and understand that the process of data analysis that indicates that the former two codes do not consistently demonstrate a CC type impact as a secondary diagnosis. Clinically, this change makes sense as well. There is nothing one does with a patient in CKD 4 or 5 that is inherently different than a patient with CKD Stages 1-3. Medication doses are adjusted based on renal function, certain medications are avoided due to increased risks of renal injury, and changes in diagnostic imaging strategies may be required. But these considerations are no different than seen in any other patient, where these variables must be considered on a case-by-case basis. We are supportive of this change. In contrast, End-Stage Renal Disease (N18.6) is a significant cofounder in clinical care, and we request that CMS not change its current MCC status.

Rationale: The patient with ESRD by definition requires dialysis, an invasive procedure with significant risk. ESRD affects all facets of patient care, as these cases require heightened attention to fluid and electrolyte management, are at increased risk of infection, and are not responsive to less complex therapies for volume overload (i.e., diuretic use) other than dialysis. The process of dialysis itself increases the risk of complications of care, including electrolyte abnormalities; hypovolemia, syncope, and shock from increased fluid losses during the dialysis procedure, and problems with anticoagulation following heparin use.

The use of dialysis introduces significant impacts to patient care in terms of costs, risks, and time. Measures used for CMS assessment of MCC status such as length of stay do not accurately reflect the increased clinical needs of these patients, as the full scope of resources used in the care of these patients is not reflected in an analysis limited to the relationship between an ICD-10-CM code and outcome measures. Clinicians inherently recognize the complexity of these patients, and to designate ESRD as a CC seems fully inconsistent with decades of clinical insight.

Recommendation: We respectfully request that CMS consider deferring the change in MCC status for N18.6 (End-Stage Renal Disease).

Malnutrition

Position: ACDIS believes that CMS's analyses of Medicare expenditures for E42, Marasmus kwashiorkor, demonstrates that this code should remain an MCC, particularly since E40, Kwashiorkor, and E41, Marasmus, both remain MCCs. We believe that CMS's analyses of E43,

Unspecified severe protein-calorie malnutrition, and E44.0, Moderate protein-calorie malnutrition, in most cases meets the level of a CC. We strongly oppose CMS's proposal to make E44.0 an MCC, given that its C1-C2-C3 resource utilization metrics are lower than that of E43. Given the C1 metric for E43 and the volume of cases that this represents, we agree that E43 be a CC.

Rationale: CMS's C1-C2-C3 analyses of the various malnutrition code is as follows:

ICD-10-CM Diagnosis Code	Code Description	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current Severity Designation	Proposed Severity Designation
E40	Kwashiorkor	NA	NA	NA	NA	NA	NA	MCC	**MCC**
E41	Nutritional marasmus	NA	NA	NA	NA	NA	NA	MCC	**MCC**
E42	Marasmic kwashiorkor	2	3.2777	24	2.3066	32	3.523	MCC	**CC**
E43	Unspecified severe protein-calorie malnutrition	13297	2.1029	198321	2.584	345682	3.3797	MCC	**CC**
E44.0	Moderate protein-calorie malnutrition	13636	2.0567	119076	2.4914	183680	3.2746	CC	MCC

ACDIS notes that the C1 metric for E42 is 3.27 which serves as an MCC. While we note that the C2 metric for E42 is 2.3066, a value near that of a CC, the C3 metric for E42 is much higher than 3.0, suggesting that this diagnosis significantly adds to that of other MCCs. Given that E40, Kwashiorkor, and E41, Nutritional marasmus, both serve as MCCs and given that E42 has elements of both, we believe that this should stay as an MCC.

ACDIS notes that the all the C1, C2, and C3 metrics for E43.0, Unspecified severe protein-calorie malnutrition and E44.0, Moderate protein-calorie malnutrition, are at 2.0 for C1, meaning that this is at the level of a CC, and that the C2 and C3 for E43 is higher than that of E44.0. Therefore, we believe that it is counterintuitive that E44.0, Moderate protein-calorie malnutrition, be an MCC and E43 would be a CC. Consequently, we believe that E44.0 should remain a CC. Given the C1 metric for E43 and the volume of cases that this represents, we agree that E43 be a CC.

Recommendation: ACDIS recommends that E42 remain an MCC; that E43 transition from an MCC to a CC; and that E44.0 remain a CC.

Pancytopenia

Position: The new IPPS rules indicate that pancytopenia will be downgraded from an MCC to a CC status. We feel that this new CC status does not reflect the severity of pancytopenia which is a deficiency of all cellular elements of the blood.

Rationale: Emergencies associated with pancytopenia include neutropenia, symptomatic anemia, thrombocytopenia, DIC, severe aplastic anemia as well as metabolic emergencies.[4]

[4] www.uptodate.com

Conversely, the neutropenia category (D70.-) is being upgraded from non-CC to CC status. Neutropenia is usually defined as an absolute neutrophil count (ANC) <1500 or 1000 cells/microL.[5] The Infectious Diseases Society of America defines fever in neutropenic patients as a single oral temperature of ≥38.3°C (101°F) or a temperature of ≥38.0°C (100.4°F) sustained over a one-hour period.[6]

Review of neutropenic cases without pancytopenia codes may have skewed conclusions inaccurately formed from that study. There is an excludes 1 note under D61 (the pancytopenia category) to code only neutropenia. This note has caused confusion and inconsistent coding practices. According to *Coding Clinic,* Fourth Quarter 2014, page 22, pancytopenia and neutropenia with fever may co-exist and are clinically different processes. However, the excludes 1 note prohibits assigning codes for both conditions. Although at the time of that publication the National Center for Health Statistics (NCHS) had planned to address the issue of the excludes 1 note at a future ICD-10-CM Coordination and Maintenance Committee (C&M) meeting, *Coding Clinic* has not published clarification since then and no revision of the instructional note has been done. This is an ongoing issue which may potentially be addressed at some point in the future and in turn generate code assignments that more accurately reflect the true nature and severity of the patient's clinical condition.

Recommendation: We urge CMS to consider maintaining the current MCC status of certain pancytopenia codes (e.g., due to cancer chemotherapy or other drugs) as we feel that they are appropriately designated as such.

Sickle Cell Anemia

Position: ACDIS believes that CMS's analyses of Medicare expenditures for sickle cell disease with crisis, acute chest syndrome, and splenic sequestrations do not support its proposal to transition the MCC status of most of these codes to a non-CC status. We believe that Medicare's own data supports that all of these codes should at least be a CC with those involving splenic sequestration or acute chest syndrome being ranked at the MCC level. ACDIS also believes that patients admitted with sickle-cell crisis and acute chest syndrome should allow for the acute chest syndrome as a principal diagnosis to serve as its own CC or MCC.

Rationale: CMS's publication of its "C1-C2-C3" methodology for sickle cell disease is as follows:

ICD-10-CM Diagnosis Code	Code Description	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current Severity Designation	Proposed Severity Designation
D57.00	Hb-SS disease with crisis, unspecified	1173	2.167	1948	2.7715	1748	3.3077	MCC	**Non-CC**
D57.01	Hb-SS disease with acute chest syndrome	78	2.4887	101	3.0304	372	3.4576	MCC	**Non-CC**
D57.02	Hb-SS disease with splenic sequestration	2	3.2392	6	3.2134	8	3.684	MCC	**Non-CC**

[5] https://www.uptodate.com/contents/overview-of-neutropenic-fever-syndromes
[6] https://www.uptodate.com/contents/overview-of-neutropenic-fever-syndromes

D57.211	Sickle-cell/Hb-C disease with acute chest syndrome	2	0.6576	6	1.6682	20	3.3282	MCC	**Non-CC**
D57.212	Sickle-cell/Hb-C disease with splenic sequestration	NA	NA	NA	NA	NA	NA	MCC	**MCC**
D57.219	Sickle-cell/Hb-C disease with crisis, unspecified	46	1.3153	95	2.3769	64	3.164	MCC	**Non-CC**
D57.411	Sickle-cell thalassemia with acute chest syndrome	2	2.162	6	2.8861	20	3.7543	MCC	**Non-CC**
D57.412	Sickle-cell thalassemia disease with splenic sequestration	NA	NA	NA	NA	NA	NA	MCC	**MCC**
D57.419	Sickle-cell thalassemia with crisis, unspecified	54	2.9334	84	2.6242	82	3.2085	MCC	**Non-CC**
D57.811	Other sickle-cell disorders with acute chest syndrome	5	2.7655	3	0.7726	19	3.5038	MCC	**Non-CC**
D57.812	Other sickle-cell disorders with splenic sequestration	1	1.4045	0	0	1	1.9698	MCC	**Non-CC**
D57.819	Other sickle-cell disorders with crisis, unspecified	34	2.4267	40	3.0056	40	3.1165	MCC	**Non-CC**

ACDIS believes that a better analysis of resource utilization should be performed on the Medicaid population, given that splenic sequestration syndrome occurs more often in children that may not be on Medicare. ACDIS emphasizes that CMS's MS-DRG methodology is used by many Medicaid programs and private insurers, thus while its calculations may not impact the Medicare population, its downstream impact on Medicaid and privately insured patients must be acknowledged and considered.

First, ACDIS notes that CMS plans to keep D57.212, Sickle-cell/Hb-C disease with splenic sequestration and D57.412, Sickle-cell thalassemia disease with splenic sequestration, both defined sickle cell disease with splenic sequestration, as MCCs but will not allow D57.02, Hb-SS disease with splenic sequestration, to serve as even a CC.

We refer CMS to a review article that demonstrate the seriousness of this condition, the fact that there is a fall of hemoglobin of at least 2 g/dl associated with the condition, the need for massive blood transfusions, and the fact that all of these interventions are expensive. While splenectomy is a treatment that prevents further attacks, it creates an immunocompromised state, thus there is some thought that there is no proof that splenectomy increases survival over transfusion therapy. These articles are:

- Owusu-Ofori S, Remmington T. Splenectomy versus conservative management for acute sequestration crises in people with sickle cell disease. Cochrane Database Syst Rev. 2017 Nov; 2017 (11). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6486322/.
- Others are available at the following link - https://www.ncbi.nlm.nih.gov/pubmed/?term=%22splenic+sequestration%22

ACDIS would like to point out that D57.02's C1 value is 3.24 and C2 value is 3.21, both of which are at the level of an MCC. We wish that CMS had published the C1-C2-C3 values for D57.212 and D57.412, but it did not; given that CMS is proposing to keep these as MCCs, we believe that the C1 value is 3.0 or higher, much like that of D57.02. While D57.812 is not at the same levels at the other splenic sequestration codes, the volume of records for this population is so low that it, along with D57.02, should be allowed to have the same MCC status as D57.212 and D57.412 that CMS plans to keep at the MCC level.

Second, ACDIS notes that CMS's analyses of sickle cell patients with acute chest syndrome have C1-C2-C3 metrics that qualify this diagnosis to be at least a CC, if not an MCC. Please view your C1-C2-C3 analyses for the various ICD-10-CM codes representing sickle cell disease with acute chest syndrome:

ICD-10-CM Diagnosis Code	Code Description	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current Severity Designation	Proposed Severity Designation
D57.01	Hb-SS disease with acute chest syndrome	78	2.4887	101	3.0304	372	3.4576	MCC	**Non-CC**
D57.211	Sickle-cell/Hb-C disease with acute chest syndrome	2	0.6576	6	1.6682	20	3.3282	MCC	**Non-CC**
D57.411	Sickle-cell thalassemia with acute chest syndrome	2	2.162	6	2.8861	20	3.7543	MCC	**Non-CC**
D57.811	Other sickle-cell disorders with acute chest syndrome	5	2.7655	3	0.7726	19	3.5038	MCC	**Non-CC**

Note how D57.01 C1 is 2.4887, which is well above the value of a CC, that C2 is 3.03, which is very much the value of an MCC, and that C3 is very much above the value of 3.0, which means it adds significantly to the value of the other MCC. The C1 value of 2.4887 on its own without any other CC demonstrates that D57.01 should be an MCC, given its significant impact on resource utilization.

Finally, regarding sickle cell disease with crisis but without splenic sequestration or acute chest syndrome, CMS's C1-C2-C3 data is as follows:

ICD-10-CM Diagnosis Code	Code Description	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current Severity Designation	Proposed Severity Designation
D57.00	Hb-SS disease with crisis, unspecified	1173	2.167	1948	2.7715	1748	3.3077	MCC	**Non-CC**
D57.219	Sickle-cell/Hb-C disease with crisis, unspecified	46	1.3153	95	2.3769	64	3.164	MCC	**Non-CC**
D57.419	Sickle-cell thalassemia with crisis, unspecified	54	2.9334	84	2.6242	82	3.2085	MCC	**Non-CC**
D57.819	Other sickle-cell disorders with crisis, unspecified	34	2.4267	40	3.0056	40	3.1165	MCC	**Non-CC**

Please note that for D57.00 that the C1 value is at 2.167 and that the C2 and C3 values are much higher than that of a CC or MCC respectively. We believe that this Medicare data suggests that sickle cell disease in crisis without acute chest syndrome or splenic sequestration should at least be a CC based on the C1 methodology and a MCC if using the C2 methodology. We also believe that if you evaluated Medicaid data, particularly in states with a high percentage of at-risk populations, you will find that sickle cell disease in crisis meets the level of an MCC.

Recommendation: ACDIS recommends that CMS maintain MCC status for sickle cell disease with acute chest syndrome and splenic sequestration and that sickle cell disease in crisis alone be at MCC or, alternative, a CC. ACDIS also recommends that CMS analyze Medicaid data prior to making its final decisions.

STEMI/NSTEMI

Position: We appreciate and acknowledge that the CMS data analysis indicates that the ICD 10 CM codes for STEMI and subsequent STEMI and NSTEMI do not consistently demonstrate a MCC type of impact as a secondary impact. However, our members believe that the data analysis for I21.01 (STEMI involving left main coronary artery) does not have a sufficient analysis population to achieve statistical validity.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
I21.01 (ST elevation (STEMI) myocardial infarction involving left main coronary artery).	2	1.2010	17	2.9902	38	3.0195	MCC	CC.
I21.02 (ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery).	149	0.9326	322	1.6565	754	3.3157	MCC	CC.
I21.09 (ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall).	583	1.2201	1,288	2.2225	3,744	3.1094	MCC	CC.
I21.11 (ST elevation (STEMI) myocardial infarction involving right coronary artery).	175	1.8486	326	2.0867	581	3.1141	MCC	CC.
I21.19 (ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall).	913	1.5054	1,940	2.2641	4,081	3.1996	MCC	CC.
I21.21 (ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery).	30	0.9445	56	2.4160	117	2.9965	MCC	CC.
I21.29 (ST elevation (STEMI) myocardial infarction involving other sites).	162	1.0143	417	2.2401	1,048	3.3341	MCC	CC.
I21.3 (ST elevation (STEMI) myocardial infarction of unspecified site).	1,271	1.6587	3,876	2.2420	10,168	3.2432	MCC	CC.
I22.0 (Subsequent ST elevation (STEMI) myocardial infarction of anterior wall).	10	0.9199	74	1.2558	165	2.6794	MCC	CC.
I22.1 (Subsequent ST elevation (STEMI) myocardial infarction of inferior wall).	4	0.0000	81	1.6022	143	3.3056	MCC	CC.
I22.2 (Subsequent non-ST elevation (NSTEMI) myocardial infarction).	94	2.1034	352	2.1291	1,916	3.0157	MCC	CC.
I22.8 (Subsequent ST elevation (STEMI) myocardial infarction of other sites).	5	2.2963	18	2.0589	53	3.1306	MCC	CC.
I22.9 (Subsequent ST elevation (STEMI) myocardial infarction of unspecified site).	27	1.7140	87	1.8737	293	2.9627	MCC	CC.

Rationale: ACDIS is concerned about the low number of cases that were analyzed for the assessment of MCC status for I21.01 (NSTEMI left main). The C1 group included only 2 cases, the C2 group included only 17 cases and the C3 group included only 38 cases. These low numbers do not provide our members with a high level of confidence in the analysis of the behavior of I21.01 as a secondary diagnosis. ACDIS also believes that the left main STEMI does have the characteristics of a major complicated comorbidity in the Medicare population. This is demonstrated by a documented in-hospital mortality rate of 39.2% with the significant predictor of mortality being older age[7].

[7] Yeo, K, Left *Main Coronary Artery ST-Elevation Myocardial Infarction: Clinical Characteristics and Outcomes From a Multicenter Registry.* Journal of the American College of Cardiology, vlm 6, issue 12 Supplement, April 2014.

Recommendation: ACDIS proposes that ICD-10 CM code I21.01 for STEMI of the left main coronary artery maintain its MCC status. We agree with the demotion of the other defined STEMI/NSTEMIs as listed in the table above.

Conclusion

We appreciate that CMS is bound by mandate to a program of cost control and the reduction of health care expenditures. Recognizing the increasing burden of health care upon our economic well-being, we share in this goal. To the extent that we can help serve as clinical, coding, and documentation advisors to your effort, we would be delighted to work with you and your process. We feel that increased participation in the development of the proposed rules, rather than only joining in response, will result in a smoother, more proactive, and better accepted process of rule-making. Please take advantage of what we can offer to your work.

Thank you for the opportunity to comment on the proposed FY 2020 IPPS rule. On behalf of ACDIS, 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.

Best,

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