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April 7, 2021

VIA ELECTRONIC MAIL

Mady Hue Centers for Medicare and Medicaid Services CMM, HAPG, Division of Acute Care Mail Stop C4-08-06 7500 Security Boulevard Baltimore, Maryland 21244-1850

Dear Ms. Hue:

The American Health Information Management Association (AHIMA) respectfully submits the following comments on the ICD-10-PCS code proposals presented at the ICD-10 Coordination and Maintenance (C&M) Committee meeting held on March 9.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and providers. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

Administration of Trilaciclib

AHIMA supports the creation of new codes in section X, New Technology, to identify intravenous infusion of trilaciclib.

We continue to urge CMS to adopt a drug terminology such as the National Drug Codes (NDCs) to identify the administration of specific drugs rather than creating unique ICD-10-PCS codes. We believe using NDC codes to identify the administration of a specific drug for purpose of applying the new technology add-on payment (NTAP) policy would be less burdensome than proposing, implementing, and assigning ICD-10-PCS codes.

Administration of ZEPZELCATM

AHIMA supports the creation of new codes in section X, New Technology, to identify intravenous infusion of ZEPZELCATM.

Administration of ENSPRYNGTM

AHIMA does **not** support the creation of codes for ENSPRYNG[™]. The proposal indicates that this drug is primarily self-administered, and we believe it is inappropriate to create ICD-10-PCS codes for self-administered drugs.

Administration of Ciltacabtagene Autoleucel

AHIMA supports option 3, the creation of new codes in section X New Technology, table XW0 Introduction, for intravenous administration of ciltacabtagene autoleucel (cilta-cel).

Administration of Amivantamab

We support the creation of new codes in section X New Technology, to identify the intravenous administration of amivantamab.

Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex

We support option 2, the creation of new codes in section 3 Administration, to identify the transfusion of pathogen reduced cryoprecipitated fibrinogen complex. Although this product represents new technology, we believe it would be preferable to add this procedure to section 3 rather than section X so that it is located in the same table as other similar transfusion procedures.

Administration of OTL-103

AHIMA does **not** support the creation of new codes for the administration of OTL-103 at this time. Since no NTAP application has been submitted and it is not anticipated that OTL-103 will be submitted to the Food and Drug and Administration (FDA) until the end of this year, it is premature to create new codes.

If CMS decides to create codes for the intravenous administration of OTL-103, we prefer that codes be added to table XW1 Transfusion. Administration of OTL-103 should be classified to the same root operation as administration of OTL-101.

Administration of OTL-200

We do **not** support the creation of new codes for the administration of OTL-200 at this time. Since no NTAP application has been submitted and it is not anticipated that OTL-200 will be submitted to the FDA until the end of this year, it is premature to create new codes.

Application of Topical Agent for Non-Excisional Eschar Removal

We support the creation of a new code for application of bromelain-enriched proteolytic enzyme for non-excisional eschar removal, but we recommend that the new code be created in section 3 Administration, table 3E0 Introduction, instead of in section X.

Application of Bioengineered Allogeneic Construct

AHIMA supports option 3, the creation of new device value L Nonautologous Tissue Substitute, Bioengineered, in table 0HR Replacement of Skin and Breast, applied to all available body parts and the approach value External, to identify skin replacement using StrataGraft bioengineered allogeneic construct. Although this procedure represents new technology, adding the codes to table 0HR would place them in the same table as existing codes for replacement of skin with nonautologous tissue substitute and the codes would distinguish full-thickness vs. partial-thickness burns (if this product is used for both types of burns either now or in the future).

Computer-Aided Assessment and Characterization Software for Head CT Scan

We do **not** support the creation of ICD-10-PCS codes for software analysis of computer tomography (CT) image data. The use of software to assist clinicians in interpretation of test results is not a distinct procedure that is appropriate for inclusion in ICD-10-PCS nor does it represent a service that should be reported separately for inpatient hospital coding.

Total Artificial Heart Systems

We do **not** support the creation of new codes for implantation of an autoregulated electrohydraulic total artificial heart at this time. Since the earliest an NTAP application is anticipated is for fiscal year 2024 consideration, it is premature to create new codes.

<u>Computer-Aided Triage and Notification Software for Computed Tomography Pulmonary</u> <u>Angiography</u>

AHIMA does **not** support the creation of ICD-10-PCS codes for software analysis of computed tomography pulmonary angiography to detect pulmonary embolism and notify clinicians. It is not appropriate to create ICD-10-PCS codes for artificial intelligence(AI)-based software tools for triage and notification. The use of these tools does not represent a distinct procedure that should be reported separately for inpatient hospital coding.

Transthoracic Echocardiography with Computer-Aided Image Acquisition

We do **not** support the creation of ICD-10-PCS codes for transthoracic echocardiography with AIguided image acquisition. The utilization of software to guide image acquisition for transthoracic echocardiography should not be reported separately for inpatient hospital coding.

Tissue Oxygen Saturation Imaging of GI Tract

We support a modified option 3. Rather than creating new codes for endoscopic imaging of tissue oxygen saturation levels of the gastrointestinal tract under both root operations Monitoring and Measurement in section X New Technology, we recommend only creating codes for the root operation Measurement. We agree with comments made during the C&M meeting that medical record documentation may not clearly indicate whether "measurement" or "monitoring" is the correct root operation, and so it would be simpler and less confusing to classify this procedure to only one root operation.

Computer-Aided Mechanical Aspiration Thrombectomy

AHIMA supports option 2, the creation of new codes for extirpation of matter from peripheral vessels using a computer-aided mechanical aspiration thrombectomy device in tables 02C Extirpation of Heart and Great Vessels, 04C Extirpation of Lower Arteries, 05C Extirpation of Upper Veins, and 06C Extirpation of Lower Veins. This option allows identification of the specific blood vessel.

Transcatheter Replacement of Pulmonary Valve

We support option 4, the creation of new qualifier values L In Existing Conduit and M Native Site, applied to the Pulmonary Valve body part, the approach value Percutaneous, and the device value Zooplastic Tissue, to identify transcatheter replacement of the pulmonary valve at a native site vs. at an existing conduit site.

Combined Thoracic Aortic Arch Replacement and Descending Thoracic Aorta Restriction

We support the creation of new codes to identify thoracic aortic arch replacement combined with restriction of the descending thoracic aorta, but recommend a different option from those proposed by CMS. We recommend creating new codes in tables 02R Replacement of Heart and Great Vessels and 02V Restriction of Heart and Great Vessels, rather than in section X. This approach would place these procedures with other similar "replacement" and "restriction" procedures.

We recommend that the device description be worded the same in both tables – Branched Synthetic Substitute with Intraluminal Device.

Coronary Intravascular Lithotripsy

We support the creation of new codes for coronary intravascular lithotripsy by adding body part values to table 02F Fragmentation of Heart and Great Vessels. However, **we also recommend that CMS consider adding a qualifier value for "ultrasonic**," similar to the codes that were created for intravascular ultrasound assisted thrombolysis.

Percutaneous Creation of an Arteriovenous Fistula

We support new codes to identify the percutaneous creation of an arteriovenous fistula using thermal resistance energy, but recommend a different option from those proposed by CMS. We recommend creating new codes in table 031 Bypass of Upper Arteries, rather than in section X, since this is the table where an alternative technology, the WavelinQTM EndoAVF System, is located.

Pharyngeal Electrical Stimulation

AHIMA supports option 2, the creation of a new code in table 0CH Insertion of Mouth and Throat, to identify the use of electrical pulses to stimulate sensory nerves in the oropharynx. However, based on the post-meeting Q&As, which indicated this procedure would not be performed endoscopically, we recommend that the new device value M Neurostimulator Lead not be applied to approach value 8 Via Natural or Artificial Opening Endoscopic.

Measurement of Flow in a Cerebral Fluid Shunt

We do **not** support the creation of a new code for the non-invasive assessment of cerebrospinal fluid (CSF) through an existing implanted CSF shunt. It is premature to create new codes since no NTAP application has been submitted yet, and it is anticipated that when an application is submitted, it will be for fiscal year 2023 consideration.

Colonic Irrigation for Colonoscopy

We do **not** support creation of new codes for colonic irrigation performed intraoperatively for colonoscopy procedures. Cleansing of the colon to ensure adequate visualization during a colonoscopy, whether done by the patient prior to the procedure or performed by the physician during the colonoscopy, is integral to the colonoscopy and should not be coded separately.

Mechanical Initial Specimen Diversion of Whole Blood Using Active Negative Pressure

We do **not** support the creation of a new code to identify a single-use blood collection device that diverts the initial specimen from the portion used for blood culture. Specimen collection systems are not captured in hospital inpatient coding and are outside the scope of ICD-10-PCS. In fact, there is no applicable root operation in ICD-10-PCS. The root operation Measurement, as proposed by CMS, is not appropriate because the use of an initial specimen diversion device is not a type of measurement.

Concurrent Measurement of mRNA, PCR test and Detection of Antibodies

AHIMA does **not** support the creation of new codes for the concurrent measurement of mRNA, PCR test and detection of antibodies from blood and nasal specimens. Laboratory testing is not captured in hospital inpatient coding. Additionally, documentation of these tests would be very difficult for coding professionals to find in order to assign a code.

Regional Anticoagulation for Renal Replacement Therapy

We do **not** support the creation of new codes for regional anticoagulation in an extracorporeal dialysis circuit with nafamostat. Anticoagulation during renal replacement therapy is not reported separately for inpatient hospital coding. Only the renal replacement therapy procedure should be coded.

Gene Expression Assay

We do **not** support the creation of a new code for SeptiCyte[®] RAPID molecular analysis of a blood specimen. The performance of gene expression assay of a blood specimen is not reported separately for inpatient hospital coding.

Single-use Intraluminal Closure System for Gastrointestinal Procedures

AHIMA does **not** support the creation of a new code to identify the utilization of a single-use intraluminal closure system in gastrointestinal procedures. Per longstanding coding guidelines, closure is integral to the procedure and not coded separately.

Patient Specific Intervertebral Body Fusion

We support the creation of a new code for the use of a patient-specific intervertebral body fusion device, but **recommend that the new code be created in tables 0RG Fusion of Upper Joints and 0SG Fusion of Lower Joints**, instead of in section X. Spinal fusions performed with interbody fusion devices would then be grouped together.

Section X Update

AHIMA fully supports the addition of a fourth option for handling section X codes, which would involve the creation of a unique code in another section of ICD-10-PCS and deleting the section X codes.

We agree that CMS should establish guiding principles in consideration of the fourth option for handling section X codes. However, we do not agree with the suggested guiding principle for drug administration procedures. We do not believe Alphabetic Index entries should be added for every drug, regardless of the volume of ICD-10-PCS codes reported. In some cases, there may be little or no public interest in continuing to code administration of these drugs with the code for the general drug class or category. We recommend that low-volume drug administration codes be deleted and not indexed to existing codes for the general drug class or category unless public comments support adding Index entries for administration of certain drugs.

We support the suggested principles for handling section X codes for surgical procedures.

We support the proposed addition of a column in the section X data analysis tables to identify CMS' recommendation for each code.

We also support including in communication with requesters information regarding the temporary nature of section X codes and the options these codes would be subject to once the three-year timeframe has expired.

While we agree that the public should have the opportunity to submit proposals regarding the disposition of section X codes, we recommend that CMS also continue to propose actions regarding section X codes that have reached the three-year timeframe. The public may not

always submit a proposal for each section X code, potentially resulting in codes being retained in section X indefinitely for lack of a proposal to take any action. We believe it is appropriate and worthwhile for CMS to continue to propose one of the options for handling each section X code when no proposal has been submitted by the public. The public would still have the opportunity to weigh in on CMS' proposal during the public comment period and raise any additional factors for CMS' consideration at that time.

Group 1 Codes

Orbital atherectomy: We support option 4 (creating unique codes in table 02C Extirpation of Heart and Great Vessels, and deleting the section X codes).

Monitoring of knee joint using intraoperative knee replacement sensor: We support option 3 (delete the section X code).

Introduction of drugs: We recommend option 3, unless there are specific drug administration codes for which the public has expressed interest in adding Index entries to direct users to codes for the general drug class or category.

Group 2 Codes

Cerebral embolic protection: At the September 2020 C&M meeting, the creation of a new code or codes for temporary intraoperative embolic protection was proposed. AHIMA continues to support option 2 presented at that meeting, which involved the creation of one code in table 5A0 Extracorporeal or Systemic Assistance and Performance. However, we recommended in our September C&M comment letter that CMS consider broadening the definition of the root operation Assistance, since embolic protection procedures do not fit within the current definition of this root operation. And there may be other procedures that represent a type of "assistance" but also don't fit within the definition of this root operation.

If CMS decides not to broaden the definition of the root operation Assistance, then we recommend that a new code for temporary intraoperative embolic protection be created under "Other Procedures" instead of "Assistance."

As stated in our September C&M comment letter, the existing section X codes for cerebral embolic filtration should be deleted, and these procedures should be reassigned to the new code for temporary intraoperative embolic protection to avoid creating a situation where there are multiple ways to code cerebral embolic protection.

We do not believe it is necessary to create qualifier values for the anatomic site because the code for the associated definitive surgical procedure would identify the procedural site.

We also do not believe it is necessary to create specific function values to identify the type of filter, as are currently included in the section X codes for cerebral embolic filtration.

Replacement of aortic valve: We recommend option 3.

Reposition of magnetically controlled growth rods: We support CMS' recommendation of option 2 (reassign the procedure to existing codes in other sections of ICD-10-PCS).

Fusion using nanotextured surface interbody fusion device: We support CMS' recommendation of option 2.

Replacement of skin using porcine liver derived skin substitute (this procedure wasn't listed under the Group 2 Codes Recap in the March C&M proposal packet, but it is a Group 2 code): We recommend option 2.

Addenda and Key Updates

We support the proposed ICD-10-PCS Addenda and Key modifications.

Other Comments

AHIMA continues to encourage CMS to explore alternative options for identifying services that are not distinct procedures, appear to be outside the scope of ICD-10-PCS, or are not typically coded in the hospital inpatient setting, including drug administration, laboratory tests, or AI or other software tools used to facilitate the performance of a procedure or interpretation of a test.

We recommend that CMS consider whether new root operation(s) should be created for some of the procedures currently classified to the root operation Introduction. This root operation encompasses a wide range of procedures, including an array of substances administered via multiple approaches and for a variety of purposes. For example, the proposal for application of topical agent for non-excisional eschar removal presented at the March C&M meeting describes a specialized type of procedure for a unique purpose that might perhaps be captured by a more precise root operation than grouping it with all of the other procedures classified to Introduction. We suggest that CMS analyze the procedures currently classified to the root operation Introduction to identify any emerging themes for potential new root operations.

Thank you for the opportunity to comment on the proposed ICD-10-PCS modifications presented at the March C&M meeting. If you have any questions, please feel free to contact Sue Bowman, Senior Director of Coding Policy and Compliance, at (312) 233-1115 or <u>sue.bowman@ahima.org</u>.

Sincerely,

Hyleai Higgs Harris

Dr. Wylecia Wiggs Harris, PhD, CAE Chief Executive Officer