DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
ICD-10-PCS Topics Clarifications, Questions and Answers
March 9, 2021

CORRECTIONS

Computer-Aided Mechanical Aspiration Thrombectomy

On pages 64 and 65 of the Agenda packet, typographical errors were noted in the coding options.

In Option 2, B Computer-aided Mechanical Aspiration was displayed in the 6th character Device column, rather than the 7th character Qualifier column.

We are correcting coding option 2 for consideration of this request to the following:

Option 2. Create new codes 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, to identify extirpation of matter from peripheral vessels using a computer-aided mechanical aspiration thrombectomy device.

Section	**0** Medical and Surgical		
Body System	**2** Heart and Great Vessels		
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part		
Body Part	*Approach*	*Device*	*Qualifier*
P Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Section	**0** Medical and Surgical		
Body System	**4** Lower Arteries		
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta 5 Superior Mesenteric Artery **9** Renal Artery, Right **A** Renal Artery, Left **C** Common Iliac Artery, Right **D** Common Iliac Artery, Left **E** Internal Iliac Artery, Right **F** Internal Iliac Artery, Left **H** External Iliac Artery, Right	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

J External Iliac Artery, Left **K** Femoral Artery, Right **L** Femoral Artery, Left **M** Popliteal Artery, Right **N** Popliteal Artery, Left **P** Anterior Tibial Artery, Right **Q** Anterior Tibial Artery, Left **R** Posterior Tibial Artery, Right **S** Posterior Tibial Artery, Left **T** Peroneal Artery, Right **U** Peroneal Artery, Left			

Section	**0** Medical and Surgical
Body System	**5** Upper Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
3 Innominate Vein, Right **4** Innominate Vein, Left **5** Subclavian Vein, Right **6** Subclavian Vein, Left **7** Axillary Vein, Right **8** Axillary Vein, Left **M** Internal Jugular Vein, Right **N** Internal Jugular Vein, Left	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**6** Lower Veins
Operation	**C** Extirpation: Taking or cutting out solid matter from a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Inferior Vena Cava **1** Splenic Vein **8** Portal Vein **C** Common Iliac Vein, Right **D** Common Iliac Vein, Left **F** External Iliac Vein, Right **G** External Iliac Vein, Left **M** Femoral Vein, Right **N** Femoral Vein, Left	**3** Percutaneous	**Z** No Device	**ADD B** Computer-aided Mechanical Aspiration **Z** No Qualifier

Coronary Intravascular Lithotripsy (IVL)

On page 74 of the Agenda packet, typographical errors were noted in the current coding options. In current coding, the word "table" was inadvertently included twice.

We are removing the extra occurrence of the word "table" from the current coding advice.

Current Coding: Currently, facilities report balloon angioplasty with or without stent insertion to treat calcified lesions in the coronary arteries with codes in table 027. The performance of coronary intravascular lithotripsy is not reported separately for inpatient hospital coding.

Fragmentation of Cerebral Artery

On page 105 of the Agenda packet, typographical errors were noted in the description of the proposed addenda update. The body part value G Cerebral Artery was displayed, rather than G Intracranial Artery.

We are correcting the description for this request to the following.

Source	Description	Code specification
2020, public comment & CMS internal review	In the Medical and Surgical section table 03F, Fragmentation of Upper Arteries, add body part value G Intracranial Artery, applied to the approach value Percutaneous, to identify procedures such as clot maceration performed in a cerebral artery using a microcatheter.	Add: 03FG3Z[0Z] (2 codes)

Hyperimmune Globulin or High-Dose Intravenous Immune Globulin for COVID-19

On page 109 of the Agenda packet, GAMUNEX-C and Octagam 10% were inadvertently listed as Hyperimmune Globulins.

We are correcting the proposed Index Addenda for these therapeutics to the following.

Lttr G
Main Add GAMUNEX-C, for COVID-19 treatment use High-Dose Intravenous Immune Globulin

Lttr O
Main Add Octagam 10%, for COVID-19 treatment use High-Dose Intravenous Immune Globulin

QUESTIONS & ANSWERS

Below we provide the CMS and clinical speaker responses to questions or comments submitted for the procedure code topics using the "Q&A" feature during the March 9, 2021 virtual ICD-10 Coordination and Maintenance Committee Meeting.

Question:	How rare is Wiskott-Aldrich syndrome?
Requestor Response:	The incidence of Wiskott-Aldrich syndrome (WAS) in the United States is estimated at 4 in 1,000,000 (or 0.4 in 100,000)
Question:	Is your plan to eventually request unique codes for all the other OTL products? If so, would OTL-101 remain with the more generic description, or is there a plan to create a specific code for that too?
Requestor Response:	Yes. While all of the OTL products use the same technology platform, mainly the ex vivo autologous gene therapy approach, each OTL product is a unique product encoding for one specific gene utilizing one specific promoter for one specific purpose. A unique code for each specific product may help track safety, adverse events, outcomes and claims data. OTL-101 is an ex vivo autologous gene therapy currently being investigated for the treatment of ADA-SCID. Once the investigation is complete, if the therapeutic is approved and granted a trade name and a brand name, a proposal can be presented at a future C&M meeting to revise the index and substance key entries for OTL-101.
Question:	I noted that the requestor has not submitted a New Technology Add-on Payment (NTAP) application for OTL-103 or OTL-200 at this time. Is that - something that would be pursued later, and therefore additional Section X codes are needed for NTAP recognition? Otherwise, it seems existing codes could be used. Is there another reason to create new codes, given that the national drug code (NDC) number could be reported?
CMS Response:	Thank you for your comments. OTL-103 and OTL-200 are both currently investigational autologous gene therapies which have not been approved by the U.S. Food and Drug Administration (FDA). The requestor has requested ICD-10-PCS procedure codes for these specific products for identification, tracking, and quantifying utilization, and outcome analysis. CMS continues to consider alternative options on how to best operationalize the reporting of the administration of a drug or therapeutic agent within our claims processing systems. Therefore, until such time when we have the ability to announce alternative options, we will not specifically address comments suggesting the use of NDCs.

Comment: While I agree with wanting to know information on the specific cell and gene therapies administered, I'm not sure that it's easier for providers to report Section X- codes and/or multiple codes, especially when CMS has indicated that NDCs can be reported on inpatient claims.

CMS Response: Thank you for your comments. As stated in the fiscal year 2016 proposed rule, CMS created Section X New Technology specifically to identify and describe new technologies and services. The Section X codes identify new services and technologies that are not usually captured in the inpatient setting, or that do not usually have the desired specificity within the current structure required to uniquely identify the use of these new services and technologies. CMS continues to consider alternative options on how to best operationalize the reporting of the administration of a drug or therapeutic agent within our claims processing systems. Therefore, until such time when we announce alternative options, we are unable to specifically address comments suggesting the use of NDCs.

Comment: I completely agree with the commenter for the OTL-200 proposal who suggested that NDCs should be used rather than ICD-10-PCS codes for identifying specific products.

CMS Response: Thank you for your comments. CMS continues to consider alternative options on how to best operationalize the reporting of the administration of a drug or therapeutic agent within our claims processing systems. Therefore, until such time when we announce alternative options, we are unable to specifically address comments suggesting the use of NDCs.

Comment: Just wanted to comment, back when the code in the transfusion table for OTL-101 was being proposed, some organizations did comment and ask for codes differentiating ex vivo and in vivo. This was not added, but could help with additional specificity.

CMS Response: Thank you for your comments which we will carefully consider. Your comments can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 9, 2021 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed during the March 9, 2021 virtual ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2021.

Question: The indication for NexoBrid is for thermal burns. Why not for chemical or radiation burns?

Requestor Response: NexoBrid has been studied in thermal burns. It is possible that the product is efficacious in burns caused by other sources, but it has not been studied. The pending NexoBrid BLA (Biologics License Application) is focused on patients with thermal burns.

Question:	The indication for StrataGraft also says "thermal" burns. What about chemical or radiation burns?
Requestor Response:	Mallinckrodt is seeking FDA approval of StrataGraft for the proposed indication of treatment of adult patients with severe thermal burns that contain intact dermal elements and for which surgical intervention is clinically indicated. The patient population in clinical studies conducted to support the biologics license application of StrataGraft was limited to adults with severe thermal burns. Both chemical and radiation burn patients present with a different pathology and often require modification of the standard of care used in thermal injury treatment. Because StrataGraft has not been investigated for the treatment of chemical or radiation burns, the indication statement for StrataGraft, per the FDA, will be limited to treatment of thermal burn injuries. Further studies may be done in other patient populations to support additional submissions to the FDA seeking approval to extend the types of wounds for which StrataGraft treatment may be indicated.
Question:	Just understanding and clarifying...the ASPECT software is to assist the radiology reading, not to substitute for it? The "frontline" doctor should not be put in the position of determining an invasive course of action based solely on the computer program.
Requestor Response:	Correct. Rapid ASPECTS assists frontline clinicians and radiologists to interpret CT scans and provide triage and appropriate care of stroke patients.
Question:	Would or could Rapid ASPECTS be performed along with the Rapid LVO or would Rapid LVO be separate?
Requestor Response:	Yes, Rapid ASPECTS can be used in conjunction with Rapid LVO. Rapid ASPECTS characterizes Alberta Stroke Program Early CT Score (ASPECTS) Regions of Interest (ROIs) using computed tomography (CT) image data. Rapid LVO received FDA clearance for detecting suspected large vessel occlusions (LVOs) using a vessel tracker.
Question:	When is FDA approval anticipated for the autoregulated electrohydraulic artificial heart?
Response:	FDA approval for the autoregulated electrohydraulic artificial heart is anticipated in 2024.
Comment:	Usually the abbreviation TAH used to represent total abdominal hysterectomy, not total artificial heart.
CMS Response:	Thank you for your comment. The Carmat TAH is an integrated autoregulated and electrohydraulically driven, biocompatible, pulsatile, system intended for full cardiac support, indicated as a bridge to heart transplant in patients suffering from end-stage

	biventricular heart failure. If TAH is documented and it is unclear if the abbreviation is referring to a total abdominal hysterectomy or a total artificial heart, the provider should be queried for clarification.
Comment:	I think this is an excellent plan!! COVID-19 pandemic has illustrated a need for this, just as AMA has been doing thru the entire rollout of the new vaccines/admins for COVID. Although I do understand the systems issues. We are currently doing this with the AMA too!
CMS Response:	Thank you for indicating your support of the ICD-10 Coordination and Maintenance Committee's consideration of an April 1 implementation date. Your comment can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, comments for the consideration of an April 1 implementation date are due May 7, 2021.
Question:	Does coronary intravascular lithotripsy (IVL) fragment the calcium? Or does it modify the calcified vessel?
Requestor Response:	IVL, in fact, does both. IVL modifies calcified lesions by fracturing (fragmenting) the calcium embedded within the arterial wall. This fragmentation, which results in modification, is the primary mechanism of action of IVL.
Question:	How long does coronary IVL take to perform, and is a balloon angioplasty always done?
Requestor Response:	Severely calcified lesions are associated with complex PCI. Procedure times are typically longer for complex PCI compared to non-calcified lesions. In the coronary IVL pivotal trial recently published in the Journal of the American College of Cardiology, the average IVL procedure time was 53-minutes[1]. Balloon dilation is routinely performed during the course of the procedure, as is stent implantation. Balloon dilation can be performed prior to IVL and in fact, IVL may be selected because the balloon cannot fully dilate. Following delivery of lithotripsy, the IVL catheter has an integrated balloon that is inflated that fully dilates at low, atraumatic pressures because lesion modification has occurred. Lastly, balloon dilatation may be performed after stent implantation to ensure proper stent apposition to the arterial wall.
Question:	Last year codes for fragmentation of peripheral vessels were created which included a qualifier value for "ultrasonic." Is the same qualifier needed for coronary vessels too?
CMS Response:	Thank you for your comments which we will carefully consider. Your comments can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at

[1] Hill, Jonathan M., et al. "Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease." Journal of the American College of Cardiology, vol. 76, no. 22, 2020, pp. 2635–2646., doi:10.1016/j.jacc.2020.09.603.

ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 9, 2021 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 9, 2021 virtual ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2021.

Question: Is pharyngeal electrical stimulation ever performed using an endoscopic approach?

Requestor Response: No, pharyngeal electrical stimulation (PES) is not performed using an endoscopic approach. No puncture, incision, or surgery is required for Phagenyx® catheter placement or during delivery of PES. The catheter is simply inserted intranasally and passes through the pharynx and esophagus until the distal end of the catheter is located within the stomach. The catheter incorporates an integrated oral positioning guide which can be directly visualized at the back of the throat by an oral exam to confirm correct electrode positioning for PES treatment delivery.

Comment: I liked the approach for the new technology add-on payment (NTAP) drugs.

CMS Response: Thank you for indicating your support of our approach to initially only display the Agenda and related materials associated with the NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent due to the high volume of NTAP applications and corresponding procedure code requests being considered for FY 2022.

Your comment can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 9, 2021 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 9, 2021 virtual ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2021.

GENERAL QUESTIONS

Question: I may have missed this at the beginning of the session this morning. Are the proposals presented today being considered for implementation on 10/1/2021?

CMS Response: Yes, the ICD-10-PCS code proposals presented on March 9, 2021 are being considered for implementation on October 1, 2021. If any portion of the meeting was missed, the recording from the procedure code portion of the March 9, 2021 ICD-10 Coordination and Maintenance Committee Meeting is now available at https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html.

As a reminder, April 9, 2021 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 9, 2021 ICD-10 Coordination and Maintenance Committee meeting.

During the meeting, CMS and CDC also discussed the ICD-10 Coordination and Maintenance Committee's consideration of an April 1 implementation date. The information regarding this announcement can be found in the March 2021 Final Agenda and Materials on page 50. Comments for this consideration are due May 7, 2021 to the CMS mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

Question: How do I join the ICD-10 Coordination and Maintenance Committee Meetings subscriber list?

CMS Response: Instructions for joining the ICD-10 Coordination and Maintenance Subscriber GovDelivery list are available in the Downloads section of https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-Coordination-and-Maintenance-Committee-Meetings.

Question: How do we get CEUs for attending today?

CMS Response: CMS does not provide certificates of attendance for ICD-10 Coordination and Maintenance (C&M) Committee Meetings. For additional information, please visit https://www.cms.gov/Medicare/Coding/ICD10/Continuing_Education_Credits.

Although registration was not required, if you did register for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting between Monday, February 1, 2021 and Monday, March 1, 2021, continuing education credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation. If you have any questions concerning obtaining your continuing education credits, please contact the respective organization.