DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
ICD-10-PCS Topics
September 14, 2021

Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: September 14, 2021: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.
- Day 2: September 15, 2021: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.

To minimize feedback to the maximum extent possible, join the meeting using only **ONE** of the options listed below.

Option 1: Remote participants (attendees wishing to both view slides and ask questions during the Q&A portions of the meeting) must join the Zoom Webinar via the web. To join this Zoom Webinar conference from a PC, MAC, iPad, iPhone or Android device as well as, connect to the audio portion of the conference:

Click the following URL:
https://cms.zoomgov.com/s/1611807597?pwd=dnB1TWxkRW1HbDRWUytzTURrcUZaQT09

Passcode: 649118

Option 2: Dial-in access is available for listen-only participants. Listen-only participants are participants who wish to only listen to the meeting and do not wish to comment or ask questions during the Q&A portions of the meeting.

1. From your phone, dial U.S.*: 669-254-5252 or 646-828-7666 or 833-568-8864 (Toll Free)
2. Enter the webinar ID: 161 180 7597

*If dialing in from outside of the U.S., visit https://cms.zoomgov.com/u/aOk65TJ24 for a list of Zoom International Dial-in Numbers.

Option 3: To join this Zoom Webinar conference from an H.323/SIP room system:

1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
2. Enter the webinar ID: 161 180 7597
   Passcode: 649118

   SIP: 1611807597 @sip.zoomgov.com
   Passcode: 649118

If you experience technical difficulties during the meeting, please contact Marvelyn Davis for assistance at marvelyn.davis1@cms.hhs.gov or 410-786-2580 Option 7.

Those participating in the Zoom Webinar may ask questions during the Q&A portions of the meeting using the "Raise Your Hand" feature. If time does not permit you to comment or ask a question during the Q&A session, you may submit comments and questions at any time using the "Q&A" feature. All comments and questions submitted using the "Q&A" feature, along with CMS' responses to them, will be posted as soon as possible after the meeting in the "Downloads" section of the CMS web page located at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

Note: Proposals for diagnosis code topics will be led by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled to begin following completion of the CMS procedure code proposals on September 14, 2021. Remaining diagnosis code topics will continue to be presented on September 15, 2021. Please visit CDC's website for the Diagnosis agenda located at the following address: http://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.

Registration for the meeting:
Information on registering can be found at: https://www.eventbrite.com/e/icd-10-coordination-and-maintenance-committee-meeting-tickets-167332278349
***Please note that registration is not required to attend the Zoom Webinar. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes.**

Registration for the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting opened on Monday, August 9, 2021, and closed on Thursday, September 9, 2021.

For questions about the registration process, please contact Mady Hue at 410-786-4510 or marilu.hue@cms.hhs.gov or Andrea Hazeley at 410-786-3543 or andrea.hazeley@cms.hhs.gov.

Instructions for joining the ICD-10 Coordination and Maintenance Committee Meetings Govdelivery Subscriber List

To sign up go to CMS website:
https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12420

To sign up for updates or to access your subscriber preferences, please enter your contact information below.

1. Email Address

Submit

2. A new subscriber screen will appear. Confirm your primary email address.
3. Select an Email delivery preference.
4. Enter an optional password to add password protection to your subscriber preferences.
5. Check privacy box confirming your consent to our data privacy. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
6. You should receive a SUCCESS message that states (your email address) has been successfully subscribed to ICD-10 Coordination and Maintenance
7. Click on the Finish button at bottom of screen.
8. You should now be on the Welcome Quick subscribe page. You can subscribe to receive information from a list of topics of your choice from our partner organizations by checking the boxes; unsubscribe by unchecking the boxes.
9. Scroll down to the bottom of the page. Check the data privacy policy box and click on Submit. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
10. You should have now reached the SUCCESS page confirming that you have been successfully subscribed. Click on Finish. ☺

Introductions & Overview April 1 Implementation Discussion 9:00 AM - 9:30 AM	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics: 1. Administration of Fostamatinib[1, 2] Pages 14-16	Mady Hue, CMS
2. Administration of Broad Consortium Microbiota-based Live Biotherapeutic Suspension[1] Pages 17-20	Andrea Hazeley, CMS
3. Pressure-controlled Intermittent Coronary Sinus Occlusion Pages 21-23 9:30 AM - 9:45 AM	Mady Hue, CMS Gregg W Stone, MD Director of Academic Affairs Mount Sinai Heart Health System
4. Measurement of Exhaled Nitric Oxide (FeNO) Pages 24-27 9:45 AM - 10:00 AM	Andrea Hazeley, CMS Jorge Pascual Retuerta International Sales Manager Eversens SL José María Olaguibel Rivera Medical Director Severe Asthma Unit Navarra Hospital Complex
5. Histotripsy of Liver Pages 28-30 10:00 AM - 10:15 AM	Andrea Hazeley, CMS Paul Laeseke MD., PhD Asst. Professor of Radiology University of Wisconsin UW Health Barb Peterson President/CEO Emerson Consultants

6. Replacement of Meniscus with Synthetic Substitute[(1)] Pages 31-36 10:15 AM - 10:30 AM	Mady Hue, CMS Wayne Gersoff, MD Orthopedic Surgery and Sports Medicine Advanced Orthopedics and Sports Medicine Specialists Denver, CO Erik Harris, MHA VP Global Market Access and Reimbursement Active Implants, LLC
7. Section X Updates Pages 37- 40 10:30 AM - 11:00 AM	Mady Hue, CMS
8. Addenda and Key Updates Pages 41- 49 11:00 AM - 11:30 AM	Andrea Hazeley, CMS
9. **Closing Remarks** Pages 50-53	Mady Hue, CMS

LUNCH BREAK 12:30 PM to 1:30 PM

(1) Requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2023.

(2) Request is for an April 1, 2022 implementation date.

Continuing Education Credits:
Continuing education credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Calls, Meetings and Webcasts.

Continuing Education Information for American Academy of Professional Coders (AAPC)
If you have attended or are planning to attend a CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Call, you should be aware that CMS does not provide certificates of attendance for these calls. Instead, the AAPC will accept your e-mailed confirmation and call description as proof of participation. Please retain a copy of your e-mailed confirmation for these calls as the AAPC will request them for any conference call you entered into your CEU Tracker if you are chosen for CEU verification. Members are awarded one (1) CEU per hour of participation.

Continuing Education Information for American Health Information Management Association (AHIMA)
AHIMA credential-holders may claim 1 CEU per 60 minutes of attendance at an educational program. Maintain documentation about the program for verification purposes in the event of an audit. A program does not need to be pre-approved by AHIMA, nor does a CEU certificate need to be provided, in order to claim AHIMA CEU credit. For detailed information about AHIMA's CEU requirements, see the Recertification Guide on AHIMA's web site.

Please note: The statements above are standard language provided to CMS by the AAPC and the AHIMA. If you have any questions concerning either statement, please contact the respective organization, not CMS.

Contact Information

Comments on the procedure code proposals presented at the ICD-10 Coordination and Maintenance Committee meeting should be sent to the following email address: ICDProcedureCodeRequest@cms.hhs.gov

Mady Hue
(410) 786-4510
Marilu.hue@cms.hhs.gov

Andrea Hazeley
(410) 786-3543
Andrea.hazeley@cms.hhs.gov

ICD-10 TIMELINE

A timeline of important dates in the ICD-10 process is described below:

September 14-15, 2021	The September 2021 ICD-10 Coordination and Maintenance Committee Meeting is fully virtual by zoom and dial-in.
September 2021	Recordings and slide presentations of the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2021	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd10cm.htm **Procedure addendum –** https://www.cms.gov/Medicare/Coding/ICD10/
October 15, 2021	**Deadline for receipt of public comments on proposed new codes discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2022.**
November 2021	Any new ICD-10 codes required to capture new diseases or technology that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2022 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 15, 2021	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 14-15, 2021 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2022.**

December 3, 2021	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and to NCHS for diagnoses by this date.** Requestors should indicate if they are submitting their code request for consideration for an October 1, 2022 implementation date, or an April 1, 2023 implementation date.
January 2022	The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2022 implementation date or an April 1, 2023 implementation date. Federal Register notice for the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 2022	Tentative agenda for the Procedure portion of the March 8, 2022 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage as follows: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the March 9, 2022 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage as follows: https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
February 1, 2022	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
February 1, 2022	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
February 1, 2022	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/

February 1, 2022	**On-line registration opens for the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting at: https://www.cms.gov/events** Please note that this meeting will be conducted virtually and registration is not required to attend. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes. The on-line registration will be available through March 1, 2022.
March 8-9, 2022	ICD-10 Coordination and Maintenance Committee Meeting.
March 2022	Recordings and slide presentations of the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2022	Any new ICD-10 codes will be implemented on April 1, 2022.
April 8, 2022	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2022**.
April 2022	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by Public Law 99-509. This notice will include references to the FY 2023 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/AcuteInpatientPPS/IPPS/list.asp
May/June 2022	Final addendum posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/icd10cm.htm **Procedure addendum -** https://www.cms.gov/Medicare/Coding/ICD10/index.html

June 10, 2022	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting, must have their requests submitted to CMS for procedures and NCHS for diagnoses.**
July 2022	Federal Register notice for the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
August 1, 2022	Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Public Law 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2022. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html
August 2022	Tentative agenda for the Procedure portion of the September 13, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the September 14, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at - https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm
August 12, 2022	**On-line registration opens for the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting at: https://www.cms.gov/events** Please note that this meeting will be conducted virtually and registration is not required to attend. However, we are providing the ability to register on-line for those required to provide proof of attendance for continuing education purposes. The on-line registration will be available through September 12, 2022.
September 13-14, 2022	The September 2022 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
September 2022	Recordings and slide presentations of the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages:

	Diagnosis code portion of the recording and related materials– https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2022	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addendum available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd10cm.htm **Procedure addendum –** https://www.cms.gov/Medicare/Coding/ICD10/
October 14, 2022	**Deadline for receipt of public comments on proposed new codes discussed at the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2023.**
November 2022	Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2023 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd10cm.htm https://www.cms.gov/Medicare/Coding/ICD10/
November 15, 2022	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2023.**

Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee meeting is a public forum on ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the meetings
  - CMS has lead responsibility on procedure issues
  - CDC has lead responsibility on diagnosis issues
- Coding proposals requested by the public are presented and public given opportunity to comment

Code Proposals

- ICD-10-PCS code proposals being considered for implementation on April 1, 2022 and October 1, 2022
- No final decisions are made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment during the meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - October 15, 2021 for codes being considered for April 1, 2022 implementation
  - November 15, 2021 for codes being considered for October 1, 2022 implementation
- Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2021 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2021 C&M meeting
- August 2021 – Final rule with links to final codes to be implemented October 1, 2021
  - Includes any additional codes approved from March 9-10, 2021 C&M meeting
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

Addendum

- May/June 2021 – Final code updates and addendum posted
  - FY 2022 ICD-10-PCS (Procedures) http://www.cms.gov/Medicare/Coding/ICD10/index.html
  - FY 2022 ICD-10-CM (Diagnoses) http://www.cdc.gov/nchs/icd/icd10cm.htm

Public Participation

- For this virtual meeting, the public may participate in the following ways:
  - Participate via Zoom Webinar.
  - Listen to proceedings through free conference lines
  - Listen to recordings and view slide presentations

- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - October 15, 2021 for codes being considered for April 1, 2022 implementation
  - November 15, 2021 for codes being considered for October 1, 2022 implementation
  - Procedure comments to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for April 1, 2022 or October 1, 2022 implementation

March 8-9, 2022 C&M Code Requests

- December 3, 2021 – Deadline for submitting topics for March 8-9, 2022 C&M meeting
  - Procedure requests to CMS ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis requests to NCHS nchsicd10cm@cdc.gov

Administration of Fostamatinib

Issue: There are currently no unique ICD-10-PCS codes to describe the administration of fostamatinib.

New Technology Application? A request for Emergency Use Authorization (EUA) is under review by the U.S. Food and Drug Administration (FDA) for the treatment of hospitalized COVID-19 patients. If approved by the FDA under its COVID-19 EUA, fostamatinib will become eligible for the New COVID-19 Treatment Add-on Payment (NCTAP).[1] The NCTAP policy became effective November 2, 2020, and was established by CMS under the interim final rule for additional policy and regulatory revisions in response to the COVID-19 Public Health Emergency (PHE). The requestor is seeking an April 1, 2022 implementation date.

Food & Drug Administration (FDA) Approval? Fostamatinib is marketed in the U.S. as TAVALISSE (fostamatinib disodium hexahydrate) tablets, and is approved in the U.S., Europe, and Canada as a treatment for adult chronic immune thrombocytopenia (ITP). If EUA is granted for fostamatinib by the FDA, the commercially available formulation of TAVALISSE will be made available to hospitals for the treatment of hospitalized COVID-19 patients.

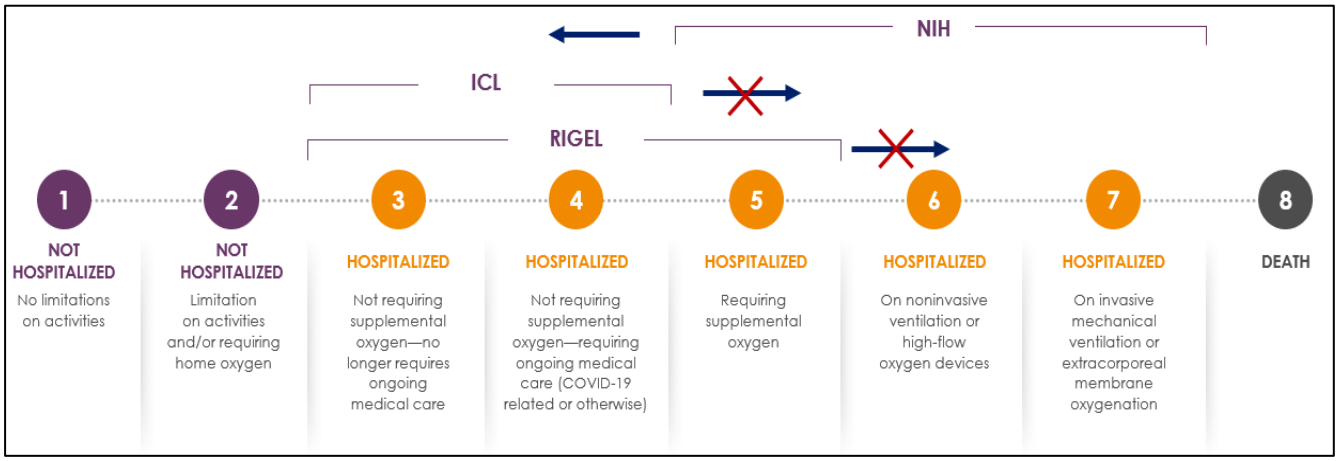
Background: COVID-19 is the infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). SARS-CoV-2 primarily infects the upper and lower respiratory tract and can lead to acute respiratory distress syndrome (ARDS). Additionally, some patients develop other organ dysfunction including myocardial injury, acute kidney injury, shock resulting in endothelial dysfunction and subsequently micro and macrovascular thrombosis.[2] Much of the underlying pathology of SARS-CoV-2 is thought to be secondary to a hyperinflammatory immune response associated with increased risk of thrombosis.[3]

Description and Mechanism of Action for Fostamatinib
Fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor, is under investigation for the treatment of hospitalized COVID-19 patients. SYK is involved in the intracellular signaling pathways of many different immune cells. According to the requestor, SYK inhibition may improve outcomes in patients with COVID-19 via inhibition of key Fc gamma receptor (FcγR) and c-type lectin receptor (CLR) mediated drivers of pathology, such as inflammatory cytokine release by monocytes and macrophages, production of neutrophil extracellular traps (NETs) by neutrophils, and platelet aggregation.[4,5,6] Fostamatinib has been shown to inhibit NETosis, a unique form of cell death that is associated with mortality in COVID-19 and differentiates fostamatinib from other

[1] https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap
[2] Rigel press release, July 14, 2020. https://www.rigel.com/investors/news-events/press-releases/
[3] Becker RC. COVID-19 Update: COVID-19 associated coagulopathy. Journal of Thrombosis and Thrombolysis May 15, 2020
[4] Hoepel W. et al. Anti-SARS-CoV-2 IgG from severely ill COVID-19 patients promotes macrophage hyper-inflammatory responses. bioRxiv July 13, 2020.
[5] Sung P-S and Hsieh S-L (2019) CLEC2 and CLEC5A: Pathogenic Host Factors in Acute Viral Infections. Front. Immunol. 10:2867.
[6] Behnen M. Immobilized Immune Complexes Induce Neutrophil Extracellular Trap Release by Human Neutrophil Granulocytes via Fcγ RIIIB and Mac-1. The Journal of Immunology July 2014.

immunomodulators in COVID-19 trials.[7] Furthermore, SYK inhibition in neutrophils and platelets may lead to decreased thromboinflammation, alleviating organ dysfunction in critically ill patients with COVID-19.

World Health Organization (WHO) Ordinal Scale
A special WHO committee arrived at the ordinal scale that measures illness severity over time for a randomized multi-center adaptive trial to evaluate the efficacy and safety of investigational therapeutic agents in combination with standard of care (SOC) for the treatment of hospitalized patients with COVID-19. The 8-point ordinal scale is being used in fostamatinib clinical studies to assess hospitalized COVID-19 patients pre- and post-treatment with fostamatinib.



Adapted from Ordinal Scale for Clinical Improvement, WHO 2020.

Inpatient Administration of Fostamatinib
Fostamatinib was administered to hospitalized COVID-19 patients in the Phase 2 clinical trial by a twice daily oral dose of 150 mg for 14 days plus SOC. The study protocol provided for dose reduction to 100 mg daily, if necessary, because of adverse events (AEs). The study protocol also specified that patients unable to swallow the oral tablets would receive dosing through enteral feeding. In the Phase 2 study, enteral feeding of fostamatinib was administered via nasogastric (NG) tube. No patients were administered fostamatinib via gastrostomy tube, although this method of enteral feeding would not be contraindicated. FDA review is underway; an approved fostamatinib EUA Fact Sheet for Healthcare Providers will not be available until EUA approval.

Fostamatinib will be available to hospitals immediately upon EUA approval as it has received full FDA approval and is commercially available under the brand name, TAVALISSE, for a non-COVID, chronic, outpatient indication: treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

While these 60-count commercially available SKUs will be available for access by the hospitals, the requestor is also working on the manufacturer of SKUs specific to use of fostamatinib under EUA:

[7] Strich JR, et al., Fostamatinib Inhibits Neutrophils Extracellular Traps Induced by COVID-19 Patient Plasma: A Potential Therapeutic. *Journal of Infectious Disease*, 2020.

- 150 mg tablets: bottles of 30 tablets for use under EUA (NDC 71332-002-05)
- 100 mg tablets, bottles of 30 tablets for use under EUA (NDC 71332-001-05)

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of fostamatinib. Facilities can report the oral or enteral administration of fostamatinib using one of the following codes:

3E0DXGC	Introduction of other therapeutic substance into mouth and pharynx, external approach
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial opening
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the oral or enteral administration of fostamatinib. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the oral or enteral administration of fostamatinib.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
D Mouth and Pharynx	**X** External	**ADD R** Fostamatinib	**7** New Technology Group 7
G Upper GI **H** Lower GI	**7** Via Natural or Artificial Opening	**ADD R** Fostamatinib	**7** New Technology Group 7

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Administration of Broad Consortium Microbiota-Based Live Biotherapeutic Suspension

Issue: There are no unique ICD-10-PCS codes to describe the rectal administration of RBX2660, a broad consortium microbiota-based live biotherapeutic suspension.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2023 consideration.

Food & Drug Administration (FDA) Approval? No. The FDA has granted RBX2660 the following designations: Fast Track status (2013), Breakthrough Therapy status (2015), and amended Orphan Drug status (2017). The requestor will be seeking approval for a Biologics License Application (BLA).

Background: *C. difficile* is a bacterium that causes diarrhea and colitis, with complications ranging from dehydration and electrolyte imbalance to toxic megacolon, sepsis, and death.[1,2,3,4,5,6,7,8] *C. difficile* infection (CDI) is a common healthcare-associated infection and a significant cause of morbidity and mortality, especially among elderly, hospitalized patients.[1,2,9,10] Infection recurs in more than 1 in 3 patients (≤35%) treated for an initial episode of CDI and nearly 2 in 3 patients (≤65%) with multiple, prior recurrences.[1,11] The causes of recurrent CDI (rCDI) are not completely understood, although dysbiosis, which is a disruption of the gut's microbial community, is thought to play a major role. In addition to higher readmission rates, rCDI is associated with longer hospital stays, increased mortality, and fewer treatment options than an initial case of CDI.[2,12,13,14]

Standard-of-care antibiotic pharmacotherapy for initial and recurrent episodes of CDI is a predominant risk factor for dysbiosis and is associated with high rates of recurrence.[15,16] In addition to antibiotic treatment, dysbiosis may also be triggered by genetic predisposition, diet, stress, or other causes,[4,11] leaving the intestinal microenvironment susceptible to opportunistic bacterial infection, such as those caused by *C. difficile*.[17] Alternative treatments for rCDI such

[1] Smits WK, Lyras D, Lacy DB, Wilcox MH, Kuijper EJ. *Clostridium difficile* infection. *Nat Rev Dis Primers*. 2016;2:16020.
[2] Arbel LT, Hsu E, McNally K. Cost-effectiveness of fecal microbiota transplantation in the treatment of recurrent *Clostridium difficile* infection: a literature review. *Cureus*. 2017;9(8):e1599.
[3] Yacyshyn B. Pathophysiology of *Clostridium difficile*-associated diarrhea. *Gastroenterol Hepatol (N Y).* 2016;12(9):558-560.
[4] Depestel DD, Aronoff DM. Epidemiology of *Clostridium difficile* infection. *J Pharm Pract*. 2013;26(5):464-475.
[5] Fernández-García L, Blasco L, López M, Tomás M. *Clostridium difficile* infection: pathogenesis, diagnosis, and treatment. In: Enany S, ed. *Clostridium difficile—A Comprehensive Overview*. InTech; 2017.
[6] Antharam VC, Li EC, Ishmael A, et al. Intestinal dysbiosis and depletion of butyrogenic bacteria in *Clostridium difficile* infection and nosocomial diarrhea. *J Clin Microbiol*. 2013;51(9):2884-2892.
[7] Ofosu A. *Clostridium difficile* infection: a review of current and emerging therapies. *Ann Gastroenterol.* 2016;29(2):147-154.
[8] Chandrasekaran R, Lacy DB. The role of toxins in *Clostridium difficile* infection. *FEMS Microbiol Rev*. 2017;41(6):723-750.
[9] Centers for Disease Control and Prevention (CDC). Antibiotic resistance threats in the United States, 2019. US Department of Health and Human Services, CDC; 2019. Accessed May 10, 2021. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
[10] Reveles KR, Lee GC, Boyd NK, Frei CR. The rise in *Clostridium difficile* infection incidence among hospitalized adults in the United States: 2001–2010. *Am J Infect Control*. 2014;42(10):1028-1032.
[11] Leffler DA, Lamont JT. *Clostridium difficile* infection. *N Engl J Med*. 2015;372(16):1539-1548.
[12] Olsen MA, Yan Y, Reske KA, Zilberberg MD, Dubberke ER. Recurrent *Clostridium difficile* infection is associated with increased mortality. *Clin Microbiol Infect*. 2015;21(2):164-170.
[13] Shah DN, Aitken SL, Barragan LF, et al. Economic burden of primary compared with recurrent *Clostridium difficile* infection in hospitalized patients: a prospective cohort study. *J Hosp Infect*. 2016;93(3):286-289.
[14] Zilberberg MD, Shorr AF, Jesdale WM, Tjia J, Lapane K. Recurrent *Clostridium difficile* infection among Medicare patients in nursing homes: a population-based cohort study. *Medicine (Baltimore)*. 2017;96(10):e6231.
[15] McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for *Clostridium difficile* infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clin Infect Dis*. 2018;66(7):e1-e48.
[16] Kelly CP. Can we identify patients at high risk of recurrent *Clostridium difficile* infection? *Clin Microbiol Infect*. 2012;18(Suppl 6):21-27.
[17] Bien J, Palagani V, Bozko P. The intestinal microbiota dysbiosis and *Clostridium difficile* infection: is there a relationship with inflammatory bowel disease? *Therap Adv Gastroenterol*. 2013;6(1):53-68.

as fecal microbiota transplant (FMT) attempt to treat dysbiosis but have multiple limitations with safety and consistency.[11,18,19,20]

Description of RBX2660

RBX2660 is a nonantibiotic, live biotherapeutic intended to reduce the recurrence of CDI.[21] RBX2660 contains a broad consortium of diverse spore-forming and non-spore-forming bacteria, including *Bacteroides*, which closely mirror that of the healthy human gut microbiome.[22] The standardized donor protocol and quality control process for RBX2660 were established in collaboration with the FDA to reduce the risk of transmissible disease to recipients, including emerging threats such as COVID-19. Donors undergo regular, rigorous blood and stool screening. All donations are quarantined until the specimen passes screening and quality control testing. The donor testing protocol is part of the Chemistry, Manufacturing, and Controls information that will be included in the BLA for RBX2660 and will be reviewed by the FDA as part of the approval process.

Mechanism of Action

The exact mechanism of action for RBX2660 is not fully understood, but it is thought to involve restoration of the composition and diversity of the gut microbiome to suppress *C. difficile* outgrowth and rCDI.[22] Treatment success was associated with a shift of the gut microbiome from dysbiosis, characterized by decreased diversity, to a composition and diversity similar to those of healthy individuals.[22] RBX2660 administration was also associated with a shift in gut bile acid compositions to secondary bile acid predominance,[23] which has been associated with suppression of *C. difficile* outgrowth and rCDI in animal studies.

The safety and efficacy of RBX2660 were evaluated in 6 clinical trials involving more than 1,000 patients. Study participants received a minimum of 1 dose and a maximum of 4 total doses of RBX2660. Duration of follow-up ranged from 6 to 24 months. Treatment with RBX2660 has demonstrated the following:

- In a phase 3 trial, CDI-associated diarrhea remained absent at 8 weeks in 70.4% of patients treated with RBX2660 compared to 58.1% of patients treated with placebo[24]
- In a phase 2 open-label trial, 79.9% of patients were CDI recurrence-free at 8 weeks after RBX2660 treatment[25]
    - Of the patients evaluable for long-term follow-up:

[18] Wilcox MH, Gerding DN, Poxton IR, et al; for the MODIFY I and MODIFY II investigators. Bezlotoxumab for prevention of recurrent *Clostridium difficile* infection. *N Engl J Med*. 2017;376(4):305-317.
[19] Gerding DN, Kelly CP, Rahav G, et al. Bezlotoxumab for prevention of recurrent *Clostridium difficile* infection in patients at increased risk for recurrence. *Clin Infect Dis*. 2018;67(5):649-656.
[20] Tariq R, Pardi SD, Bartlett MG, Khanna S. Low cure rates in controlled trials of fecal microbiota transplantation for recurrent *Clostridium difficile* infection: a systematic review and meta-analysis. *Clin Infect Dis*. 2019;68(8):1351-1358.
[21] Ferring Pharmaceuticals Inc. Ferring and Rebiotix present landmark phase 3 data demonstrating superior efficacy of investigational RBX2660 versus placebo to reduce recurrence of *C. difficile* infection. May 21, 2021. Accessed June 9, 2021. https://www.ferring.com/ferring-and-rebiotix-present-landmark-phase-3-data-demonstrating-superior-efficacy-of-investigational-rbx2660-versus-placebo-to-reduce-recurrence-of-c-difficile-infection/
[22] Blount KF, Shannon WD, Deych E, Jones C. Restoration of bacterial microbiome composition and diversity among treatment responders in a phase 2 trial of RBX2660: an investigational microbiome restoration therapeutic. *Open Forum Infect Dis*. 2019;6(4):ofz095.
[23] Papazyan R. Rapid restoration of bile acid compositions after treatment with investigational microbiota-based therapeutic RBX2660 for recurrent *Clostrioides difficile* infection. Presented at: IDWeek 2020; October 21-25, 2020; virtual meeting.
[24] Lee C. Beyond FMT: a pragmatic approach to microbiome therapies: RBX2660 study. Presented at: Digestive Disease Week 2021; May 21-23, 2021; virtual meeting.
[25] Orenstein R, Mische S, Blount D, et al. A long-time coming: final 2-year analysis of efficacy, durability, and microbiome changes in a controlled open-label trial of investigational microbiota-based drug RBX2660 for recurrent *Clostridioides difficile* infections. IDWeek 2019 late breaker oral abstract LB5. *Open Forum Infect Dis*. 2019;6(Suppl 2):S994-S995.

    - 97.2% remained CDI recurrence-free at 6 and 12 months[26,27]
    - 91.6% remained CDI recurrence-free at 24 months[25]
- The biodiversity of the gut microbiome for patients treated with RBX2660 changed to become more similar to the composition of RBX2660[22]
- The microbiome of patients who received RBX2660 experienced more significant and longer-lasting shifts toward donor-like configurations compared to patients who received placebo[28,29]

A total of 188 adverse events (AEs) were reported in 28 participants in the open-label phase 2 PUNCH CD trial. Gastrointestinal (GI)-related AEs were the most common and included mild to moderate diarrhea (24.3%), flatulence (14.0%), abdominal pain/cramping (13.1%), and constipation (13.1%). AEs declined over time, with the majority (72.9%) occurring in the first 30 days. Over half (58.5%) of the AEs were related to CDI. None of the 20 serious AEs reported were related to RBX2660 or its administration; several were related to preexisting conditions.[30]

During the blinded portion of the phase 2b PUNCH CD2 trial, 379 AEs were reported in 82 (64.1%) participants. There were no differences in the number or rate of AEs among blinded treatment groups. The most common AEs were GI disorders. Of the serious AEs reported during the blinded and open-label portions of the study, 31.1% were related to CDI, and 77.8% were related to a preexisting condition. None were related to the rectal administration procedure.[31] Preliminary safety data including the rate of AEs in a phase 3 clinical trial are consistent with those found in phase 2 studies.[24]

Administration of RBX2660
RBX2660 is provided in a prepackaged, single-dose bag with a ready-to-use delivery system for rectal administration. Each dose contains ≥3 billion colony-forming units (CFUs) per 150 mL. The product is shipped frozen to the clinical site in a kit containing 1 bag of frozen RBX2660 and components for administration. RBX2660 must be thawed completely prior to use. To administer RBX2660, the healthcare provider must insert a lubricated tube into the patient's rectum about 12 cm (5 inches). Once the product is fully instilled, the assembly should be removed, and the patient should remain in the administration position for at least 15 minutes. RBX2660 may be administered by a healthcare provider in multiple care settings including inpatient hospital, outpatient hospital clinics, and physician offices, without a requirement for bowel preparation, colonoscopy, or conscious sedation.

Current Coding: There are no unique ICD-10-PCS codes to describe the rectal administration of RBX2660. Facilities can report the rectal administration of RBX2660 with the following ICD-10-PCS code:

3E0H7GC Introduction of other therapeutic substance into lower GI, via natural or artificial opening

[26] Garcia-Diaz J, Jones C, Karathia H, Fanelli B, Hasan NA, Blount K. Response to microbiota-based drug RBX2660 is associated with reduction in antimicrobial resistance genes in patients with recurrent *Clostridioides difficile* infections. Presented at: ASM Microbe 2019; June 20-24, 2019; San Francisco, CA.
[27] Jones C, Mische S, Blount K, Shannon B. Twelve-month durability of microbiota-based therapy RBX2660 for prevention of recurrent *Clostridium difficile* infection. IDWeek 2019 poster abstract 669. *Open Forum Infect Dis*. 2019;6(Suppl 2):S306.
[28] Kwak S, Choi J, Hink T, et al; CDC Prevention Epicenter Program. Impact of investigational microbiota therapeutic RBX2660 on the gut microbiome and resistome revealed by a placebo-controlled clinical trial. *Microbiome*. 2020;8(1):125.
[29] Langdon A, Schwartz DJ, Bulow C, et al; CDC Prevention Epicenter Program. Microbiota restoration reduces antibiotic-resistant bacteria gut colonization in patients with recurrent *Clostridioides difficile* infection from the open-label PUNCH CD study. *Genome Med*. 2021;13(1):28.
[30] Orenstein R, Dubberke E, Hardi R, et al. Safety and durability of RBX2660 (microbiota suspension) for recurrent *Clostridium difficile* infection: results of the PUNCH CD study. *Clin Infect Dis*. 2016;62(5):596-602.
[31] Dubberke ER, Lee CH, Orenstein R, Khanna S, Hecht G, Gerding DN. Results from a randomized, placebo-controlled clinical trial of a RBX2660-A microbiota-based drug for the prevention of recurrent *Clostridium difficile* infection. *Clin Infect Dis*. 2018;67(8):1198-1204.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the rectal administration of RBX2660. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the rectal administration of RBX2660.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
H Lower GI	**7** Via Natural or Artificial Opening	**ADD X** Broad Consortium Microbiota-based Live Biotherapeutic Suspension	**8** New Technology Group 8

CMS Recommendation: Option 2.

Interim Coding Advice: Continue using current codes as listed in current coding.

Pressure-controlled Intermittent Coronary Sinus Occlusion

Issue: There is currently no ICD-10-PCS code to describe treatment with pressure-controlled intermittent coronary sinus occlusion in patients with acute myocardial infarction (AMI).

New Technology Application: Not at this time. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2024.

FDA Approval: No. The PiCSO® Impulse System was granted a Breakthrough Device designation by the FDA on August 8, 2019 for the treatment of ST-elevated myocardial infarction (STEMI) patients. An IDE clinical study is anticipated to begin in the United States in 2022.

Background: The introduction of percutaneous coronary interventions, including angioplasty, atherectomy, and coronary artery stents, greatly advanced the treatment of ST-elevation myocardial infarction (STEMI). However, despite optimized stenting techniques, improvements in imaging, and advances in pharmacology, clinical outcomes post-AMI, including mortality rates, have plateaued over the last ten years. In addition, de novo heart failure is diagnosed in about 13% of patients at 30 days and in 20%-30% of patients at one-year post-discharge.[1] These suboptimal outcomes have turned the cardiology community's attention to the role of the heart's microvasculature.

As in all other muscles, the myocardial cells of the heart must be provided with oxygenated blood and deoxygenated blood must be removed. Oxygenated blood is supplied by the large coronary arteries, specifically the left main, left anterior descending, left circumflex, and right coronary arteries. Deoxygenated blood is removed by the coronary veins, with the majority draining into the coronary sinus. These large vessels are visible on the epicardial surface of the heart. However, keeping all regions and depths of heart muscle supplied with blood requires an intricate network of ever-smaller branches with interfaces between the smallest arterioles and venules. This network is referred to as the heart's microvasculature or microcirculation. The role of obstruction in the large coronary arteries is apparent in AMI but recent clinical understanding attributes a far greater role to the heart's microcirculation than had previously been recognized. Beyond the large coronary arteries, obstruction and delayed perfusion within the heart's microvasculature is associated with poor outcomes in treatment of AMI.[2]

Pressure-controlled intermittent coronary sinus occlusion (PiCSO) is a percutaneous coronary intervention currently performed as an adjunct to coronary artery stenting during treatment of AMI. After the obstructed large coronary artery has been re-opened by dilation, atherectomy or other techniques and blood flow has been restored, the physician accesses the femoral vein and advances the PiCSO catheter through the inferior vena cava and into the right atrium. The catheter's balloon is then positioned in the coronary sinus to begin treatment. As the PiCSO catheter cyclically inflates and deflates (for few seconds at a time) within the coronary sinus, controlled by an

[1] Jenča, D., et al. Heart failure after myocardial infarction: incidence and predictors. ESC Heart Failure, 2021. 8(1): p. 222-237.
[2] Xie F and Qian L et al. Circ Cardiovasc Imaging. 2020. https://www.ahajournals.org/doi/10.1161/CIRCIMAGING.119.010091

extracorporeal console, the physician returns to placing the stent through the area of obstruction that was previously opened in the large coronary artery. The PiCSO catheter continues its cycle of inflation and deflation in the coronary sinus concurrently with stent deployment and for a period afterward, usually totaling between 20 and 90 minutes with an average duration of 30 minutes.[3]

Placement of the stent maintains the patency of the large coronary artery after the obstruction is opened. According to the requestor, concurrent PiCSO balloon inflation and deflation within the coronary sinus has two effects in the microcirculation: it reduces infarct size and improves circulation within the heart muscle tissue.

During the balloon inflation phase, drainage of blood out of the coronary sinus is blocked. The resulting increase in pressure within the coronary sinus forces the blood to be pushed back and redistributed to the areas around the central infarct zone. That is, the heart tissue located around the occlusion in the large coronary artery inevitably dies, but at-risk areas that circle the infarct core can be saved by the forced reperfusion of blood. Infarct size is strongly linked to mortality and hospitalization for heart failure[4] and this redistribution of blood reduces the size of the infarct.

During the balloon deflation phase, the sudden drop in pressure creates a gradient shift with a suction effect. Following AMI, the blood contains noxious biochemical byproducts of cell death as well as microdebris created by the stent placement itself, a paradoxical phenomenon known as reperfusion injury. Although the stent maintains patency of the newly re-opened large coronary artery, the microdebris can embolize downstream and cause obstructions in the microvasculature. The suction effect washes out the noxious agents and clears the obstructions to improve the viability of the microcirculation, which is strongly linked to improved outcomes.[5]

The requestor states that by reducing infarct size and clearing the microcirculation of noxious agents and obstructions, PiCSO addresses key factors in improving outcomes from AMI, with potential applications in related areas such as heart failure and represents a new form of percutaneous accessory treatment.

Current Coding: There are no unique ICD-10-PCS codes to identify pressure-controlled intermittent coronary sinus occlusion performed as an adjunct to coronary artery stenting for treatment of acute MI. Code the coronary angioplasty and stenting procedure using the appropriate code(s) in table 027, Dilation of Heart and Great Vessels.

[3] Egred M, Bagnall A, Spyridopoulos I, Purcell IF, Das R, Palmer N, Grech ED, Jain A, Stone GW, Nijveldt R, McAndrew T, Zaman A. Effect of Pressure-controlled intermittent Coronary Sinus Occlusion (PiCSO) on infarct size in anterior STEMI: PiCSO in ACS study. Int J Cardiol Heart Vasc. 2020 May 15;28:100526. doi: 10.1016/j.ijcha.2020.100526

[4] Stone, G. W., Selker, H. P., Thiele, H., Patel, M. R., Udelson, J. E., Ohman, E. M., Maehara, A., Eitel, I., Granger, C. B., Jenkins, P. L., Nichols, M., & Ben-Yehuda, O. (2016). Relationship Between Infarct Size and Outcomes Following Primary PCI. Journal of the American College of Cardiology, 67(14), 1674–1683. https://doi.org/10.1016/j.jacc.2016.01.069

[5] Carrick, D., Haig, C., Ahmed, N., Carberry, J., Yue May, V. T., McEntegart, M., Petrie, M. C., Eteiba, H., Lindsay, M., Hood, S., Watkins, S., Davie, A., Mahrous, A., Mordi, I., Ford, I., Radjenovic, A., Oldroyd, K. G., & Berry, C. (2016). Comparative Prognostic Utility of Indexes of Microvascular Function Alone or in Combination in Patients With an Acute ST-Segment–Elevation Myocardial Infarction. Circulation, 134(23), 1833–1847. https://doi.org/10.1161/circulationaha.116.022603

Coding Options

Option 1. Do not create new ICD-10-PCS codes for pressure-controlled intermittent coronary sinus occlusion. Continue coding coronary angioplasty and stenting procedures as described in current coding.

Option 2. In table 5A0 of section 5, Extracorporeal or Systemic Assistance and Performance, create new function value 6 Perfusion and new qualifier value E Intermittent Coronary Sinus Occlusion, applied to the body system value Circulatory and the duration value Intraoperative, to identify pressure-controlled intermittent coronary sinus occlusion performed as an adjunct to coronary artery stenting.

Section **5** Extracorporeal or Systemic Assistance and Performance *Body System* **A** Physiological Systems *Operation* **0** Assistance: Taking over a portion of a physiological function by extracorporeal means			
Body System	*Duration*	*Function*	*Qualifier*
2 Cardiac	**1** Intermittent **2** Continuous	**1** Output	**0** Balloon Pump **5** Pulsatile Compression **6** Other Pump **D** Impeller Pump
5 Circulatory	**1** Intermittent **2** Continuous	**2** Oxygenation	**1** Hyperbaric **C** Supersaturated
5 Circulatory	**A** Intraoperative	**ADD 6** Perfusion	**ADD E** Intermittent Coronary Sinus Occlusion

Option 3. Create new codes in section X table X2A Assistance of Cardiovascular System, to identify pressure-controlled intermittent coronary sinus occlusion.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **A** Assistance: Taking over a portion of a physiological function by extracorporeal means			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 7 Coronary Sinus	**3** Percutaneous	**ADD 5** Intermittent Coronary Sinus Occlusion	**8** New Technology Group 8

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Measurement of Exhaled Nitric Oxide (FeNO)

Issue: There are currently no unique ICD-10-PCS codes to describe the measurement of the fraction exhaled of Nitric Oxide (FeNO).

New Technology Application? No.

Food and Drug Administration (FDA) Approval? Yes. The following devices/systems have been cleared for marketing by the FDA:

- The NIOX Breath Nitric Oxide Test System® received 510(K) approval on April 30, 2003.
- The NIOX MINO® a handheld, portable device, received 510(K) approval on March 3, 2008.
- The Apieron INSIGHT™ eNO System received 510(K) approval on March 14, 2008.
- The NIOX VERO® was cleared for marketing by the FDA in 2014.
- The RTube Exhaled Breath Condensate collection system, which has a proprietary gas-standardized pH assay, is registered with the FDA as a Class I device that collects expired gas.
- On February 13, 2019, the FDA gave 510(k) clearance to the Fenom Pro™ Nitric Oxide Test as a class II medical device cleared for individuals aged 7 or older to be used in a point-of-care healthcare setting under professional supervision to measure FeNO in human breath. The FDA noted it should not be used in critical care, emergency care or in anesthesiology.

Background: Asthma is defined as a chronic inflammatory disease of the respiratory tract characterized by variable and recurring respiratory symptoms, airflow limitation or obstruction, bronchial hyperresponsiveness and/or airway inflammation.[1] It is a syndrome that includes several clinical phenotypes that share similar clinical manifestations. Asthma is diagnosed with a patient history and physical examination supplemented by conventional tests such as peak flow and spirometry. Sometimes the diagnosis can be difficult because of a lack of clear symptoms or signs of the disease. As a consequence, asthma can be misdiagnosed or underdiagnosed.

Although the clinical spectrum of asthma is variable, the presence of airway inflammation is a common feature. In most asthmatic patients, the inflammatory pattern includes an increase in the number of cells that release the mediators responsible for causing disease symptoms. Structural airway cells also produce inflammatory mediators that contribute to the persistence of the inflammation.[1]

The measurement of the fraction of exhaled nitric oxide (FeNO), when used in conjunction with established clinical and laboratory assessments of asthma, can enhance the ability of the clinician to correctly diagnose and effectively treat the various types of asthma. The American Thoracic Society (ATS) strongly recommends the use of FeNO measurement to aid in the assessment, management, and long-term monitoring of asthma.[2]

[1] GEMA, Executive Committee of the. GEMA 4.4: Spanish Guide for the Management of Asthma. Madrid: Luzán 5, 2019. ISBN: 978- 84-17372-51-4.S

[2] Dweik RA, Boggs PB, Erzurum SC, et al on behalf of the American Thoracic Society Committee on Interpretation of Exhaled Nitric Oxide Levels (FeNO) for Clinical Applications. An official ATS clinical practice guideline: interpretation of exhaled nitric oxide levels (FeNO) for clinical applications. Am J Respir Crit Care Med. 2011;184:602-615

Technology

Fractional exhaled nitric oxide (FeNO) is an objective measurement of antigen-specific T-helper cells type 2 (T2) or allergic/eosinophilic inflammation and is a quantitative, noninvasive, simple, and safe complementary tool to measure airway disease in asthma patients. During T2 airway inflammation, higher-than-normal levels of nitric oxide (NO) are released from epithelial cells of the bronchial wall.[3] FeNO can help identify allergic/eosinophilic inflammation, and can thereby support a diagnosis of asthma when other objective evidence is lacking.[4] FeNO predicts the likelihood of corticosteroid responsiveness more consistently than spirometry, bronchodilator response, peak flow variation, or airway hyperresponsiveness to methacholine.[5,6,7]

FeNO test devices/systems are intended to measure fractional nitric oxide in human breath by combining the detection of nitric oxide with a pneumotachograph, display, and dedicated software. The technology can be based in three different measuring methods, chemiluminescence, electrochemical and chemical field-effect. Chemiluminescence is the gold standard technique because of its high analytical performance features. The electrochemical method is implemented in point-of-care devices, which convert gas concentration into electrical signals and the chemical field-effect method measures nitrogen dioxide to convert the value into nitric oxide.

Procedure Description

The steps involved in the performance of the procedure are the following:

1. The medical practitioner analyzes the patient's symptoms (e.g. cough, chest pressure).
2. The medical practitioner studies the patient's medical history (e.g. asthma exacerbations).
3. A spirometry test is carried out in order to know the respiratory capacity, flow, volume and resistance.
4. The FeNO test is performed to give the medical practitioner more information about possible inflammation of the airways.
    a. The medical practitioner selects the operation mode in the FeNO analyzer. The test can be performed on children (older than 4 years old), who must exhale for six seconds or on adults, who must exhale for 10 seconds, both with a constant flow of 50ml/s.*
    b. The patient inhales either ambient air or through the mouthpiece*.
    c. The patient exhales through the mouthpiece of the device.
    d. Once the exhalation has been done, the results are obtained in a period of 5-60 seconds (depending on the FeNO device/system).
    e. Once the data have been recorded, the interpretation can be made according to the following table (Table 1) which is based on the official guidelines of clinical

[3] Van Den Toorn LM, Overbeek SE, De Jongste JC, Leman K, Hoogsteden HC, Prins J-B. Airway inflammation is present during clinical remission of atopic asthma. *Am J Respir Crit Care Med.* 2001;164:2107-2113.

[4] Dweik RA, Boggs PB, Erzurum SC, et al; on behalf of the American Thoracic Society Committee on Interpretation of Exhaled Nitric Oxide Levels (FeNO) for Clinical Applications. An official ATS clinical practice guideline: interpretation of exhaled nitric oxide levels (FeNO) for clinical applications. Am J Respir Crit Care Med. 2011;184:602-615.

[5] Knuffman JE, Sorkness CA, Lemanske RF Jr, et al; for the Childhood Asthma Research and Education Network of the National Heart, Lung, and Blood Institute. Phenotypic predictors of long-term response to inhaled corticosteroid and leukotriene modifier therapies in pediatric asthma. J Allergy Clin Immunol. 2009;123:411-416.

[6] Szefler SJ, Martin RJ, King TS, et al; for the Asthma Clinical Research Network of the National Heart, Lung, and Blood Institute. Significant variability in response to inhaled corticosteroids for persistent asthma. J Allergy Clin Immunol. 2002;109:410-418.

[7] Smith AD, Cowen JO, Brassett KP, et al. Exhaled nitric oxide: a predictor of steroid response. Am J Respir Crit Care Med.2005;172:453-459. 4. Morice AH, Fontana GA, Sovijarvi ARA, et al on behalf of the ERS Task Force. The diagnosis and management of chronic cough. Eur Respir J. 2004;24:481-492.

practice published by the ATS[8].

*The exhalation time and the way in which the pre-exhalation is performed depends on the FeNO measuring device/system used.

	FeNO <25 (<20 ppb in children)	**FeNO 25-50 (20–35 ppb in children)**	**FeNO > 50 (>35 ppb in children)**
	DIAGNOSIS		
Symptomatic patient	1. Eosinophilic airway inflammation unlikely. 2. Alternative diagnoses. a. Other pulmonary/airway causes: i. Rhinosinusitis. ii. Non-eosinophilic asthma. iii. Reactive airways dysfunctionsyndrome. iv. C.O.P.D. v. Bronchiectasis. vi. Cystic fibrosis, primary ciliarydyskinesia. vii. Extended post-viral bronchial hyperresponsiveness syndrome. viii. Vocal cord dysfunction. b. Non-pulmonary/airway causes: i. Anxiety-hyperventilation. ii. Gastroesophageal reflux disease. iii. Cardiac disease/pulmonary hypertension/pulmonary embolism. 3. Other factors: a. Smoking. b. Obesity. 4. Unlikely to benefit from ICS.	1. Be cautious. 2. Evaluate clinical context. 3. Monitor change in FeNO over time.	1. Eosinophilic airway inflammation present: • Atopic asthma. • Eosinophilic bronchitis. • COPD with mixed inflammatory phenotype. 2. Likely to benefit from ICS.

Table 1. FeNO interpretation for asthma diagnosis

Current Coding: The measurement of exhaled nitric oxide (FeNO) is not reported separately for inpatient hospital coding.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the measurement of exhaled nitric oxide (FeNO).

[8] An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications. Raed A. Dweik, Peter B. Boggs, Serpil C. Erzurum, Charles G. Irvin, Margaret W. Leigh, Jon O. Lundberg Anna-Carin Olin, Alan L. Plummer, D. Robin Taylor, on behalf of the American Thoracic Society Committee on Interpretation of Exhaled Nitric Oxide Levels. 602-615, s.l. : Am J Respir Crit Care Med, 2011, Vol. 184. DOI: 10.1164/rccm.912011ST.

Option 2. In table 4A0 of section 4, Measurement and Monitoring, create new function value A Inflammation, applied to the body system value Respiratory and the approach value External, to identify measurement of exhaled nitric oxide (FeNO).

Section	**4** Measurement and Monitoring		
Body System	**A** Physiological Systems		
Operation	**0** Measurement: Determining the level of a physiological or physical function at a point in time		
Body System	*Approach*	*Function / Device*	*Qualifier*
9 Respiratory	**7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**1** Capacity **5** Flow **C** Rate **D** Resistance **L** Volume **M** Total Activity	**Z** No Qualifier
9 Respiratory	**X** External	**ADD A** Inflammation	**Z** No Qualifier

Option 3. Create new codes in section X table XXE, Measurement, to identify measurement of exhaled nitric oxide (FeNO).

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**E** Measurement: Determining the level of a physiological or physical function at a point in time		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
B Respiratory	**X** External	**ADD 3** Exhaled Nitric Oxide	**8** New Technology Group 8

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Histotripsy of Liver

Issue: There are currently no unique ICD-10-PCS codes to describe histotripsy of the liver.

New Technology Application? No.

Food and Drug Administration (FDA) Approval? No. HistoSonics received approval of an Investigational Device Exemption (IDE) from the FDA in October 2020 to begin a clinical study to evaluate the safety and efficacy of the HistoSonics System. The study is a multi-center, open label, non-randomized, single arm trial planned to enroll up to 45 patients.

Background: Hepatocellular carcinoma (HCC) is the most common primary malignancy of the liver, accounting for 70-90% of cases of primary liver cancer. Despite the availability of multiple treatment options, the incidence of HCC in the US has more than tripled since 1980, and the five-year survival rate is at just 17%. Primary liver tumors were the third leading cause of tumor related death worldwide in 2020, with approximately 906,000 new cases and 830,000 deaths globally, and 5-year survival rates less than 18%. Additionally, the liver is second only to lymph nodes as the most common site of metastatic tumors.

Surgical resection is a first-line treatment, but surgical resection is recommended only for 10-30% of patients with liver tumors due to the presence of multiple tumors, underlying poor liver function, or general health issues limiting the success of surgery. HCC tumors are chemotherapy resistant, so chemotherapy alone has limited efficacy. Current liver ablation methods including radiofrequency ablation (RFA) and high intensity focused ultrasound (HIFU) are primarily thermal-based, however possess inherent limitations such as inconsistent ablation, inability to treat larger or multi-nodular tumors, limited or no real-time imaging feedback and heat sink effect (cooling effect from the blood flow near major blood vessels) through the densely vascular liver. Other treatment options include irreversible electroporation (IRE), which is a non-thermal tissue ablation technique in which micro to millisecond electrical pulses are delivered to undesirable tissue to produce cell death through irreversible cell membrane permeabilization, however according to the requestor this therapy can cause transient and self-limiting abnormalities in liver function. Histotripsy is an alternative therapy to treat liver tissue non-invasively and the requestor states that it may provide benefits to patients due to its unique non-thermal and non-ionizing destructive capabilities without the potential complications seen with conventional therapies such as bleeding, infection, or pain from surgery.

Technology
Histotripsy of the liver is an automated external beam therapy that mechanically destroys targeted tissue without incisions, ionizing radiation or heat, through the precise targeting of acoustic cavitation using an image-guided device designed for the local treatment of focal liver tumors. HistoSonics' non-invasive platform combines advanced imaging and proprietary software to deliver patient specific treatments and uses the science of histotripsy to mechanically destroy targeted tissues at sub-cellular levels. According to the requestor, the novel mechanism of action of the HistoSonics System, which is intended to avoid thermal necrosis and ionizing radiation, may provide significant advantages to patients, including the

ability of the treatment site to recover and resolve quickly, as well as providing physicians the unique ability to monitor the destruction of tissue under continuous real-time visualization and control.

Procedure Description
The steps involved to perform histotripsy of the liver using the HistoSonics System are simulation, planning, dose calculation, treatment delivery and ongoing imaging to assess the effect. To begin, physicians' contour and plan treatments according to the shape and size of the target. Then, a therapy transducer delivers short pulses of ultrasound to a focal zone, resulting in acoustic cavitation (a bubble cloud). The rapid expansion and collapse of the bubble cloud mechanically destroys the targeted tissue. The entire procedure is controlled by the physician, who monitors in real-time while the system automatically moves the bubble cloud through the treatment plan. The key elements that differentiate histotripsy from other procedures are:

- High-amplitude, short-pulses (microsecond) of focused ultrasound is directed at the soft tissue target to destroy tissue at the sub-cellular level
- Negative pressure created by this process creates a cavitation "bubble cloud", which is the rapid expansion and collapse of gas microbubbles, in the targeted tissue
- The resulting strain on the tissue produced by the bubble cloud causes a mechanical disruption of the cells

Currently, there is an approved IDE study (#HOPE4LIVER US Study) that is enrolling patients in the US with primary or metastatic tumors located in the liver. The first patient in the #HOPE4LIVER US Study was treated in the first quarter of 2021. There has also been a small OUS study focused on safety and technical success. There were no significant adverse events and there was 100% technical success in destroying the targeted tissue (malignant liver tumors).

Current Coding: There are currently no unique ICD-10-PCS codes to identify extracorporeal histotripsy of targeted liver tissue using ultrasound-guided cavitation. Code the procedure using the appropriate body part value in table 0F5, Destruction of Hepatobiliary System and Pancreas, with approach value 3 Percutaneous and the qualifier value Z No Qualifier.

Section	**0** Medical and Surgical		
Body System	**F** Hepatobiliary System and Pancreas		
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent		
Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**F** Irreversible Electroporation **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for extracorporeal histotripsy of targeted liver tissue using ultrasound-guided cavitation. Continue coding as described in current coding.

Option 2. In table 0F5, Destruction of Hepatobiliary System and Pancreas, create new qualifier value G Ultrasound-guided Cavitation, applied to the liver body part values and the approach

value X External, to identify extracorporeal histotripsy of targeted liver tissue using ultrasound-guided cavitation.

Section	**0** Medical and Surgical		
Body System	**F** Hepatobiliary System and Pancreas		
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent		
Body Part	*Approach*	*Device*	*Qualifier*
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**Z** No Device	**F** Irreversible Electroporation **Z** No Qualifier
0 Liver **1** Liver, Right Lobe **2** Liver, Left Lobe	**ADD X** External	**Z** No Device	**ADD G** Ultrasound-guided Cavitation

Option 3. Create new codes in section X table XF5, Destruction of Hepatobiliary System and Pancreas, to identify extracorporeal histotripsy of targeted liver tissue using ultrasound-guided cavitation.

Section	**X** New Technology		
Body System	**F** Hepatobiliary System and Pancreas		
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD 0 Liver **ADD 1** Liver, Right Lobe **ADD 2** Liver, Left Lobe	**X** External	**ADD 0** Ultrasound-guided Cavitation	**8** New Technology Group 8

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

1. Chen X, Ren Z, Zhu T, Zhang X, Peng Z, Xie H, Zhou L, Yin S, Sun J, Zheng S. Electric ablation with irreversible electroporation (IRE) in vital hepatic structures and follow-up investigation. Sci Rep. 2015;5:16233. doi: 10.1038/srep16233.
2. Vlaisavljevich E, Kim Y, Allen S, Owens G, Pelletier S, Cain C, Ives K, Xu Z. Image-guided non-invasive ultrasound liver ablation using histotripsy: feasibility study in an in vivo porcine model. Ultrasound Med Biol. 2013;39(8):1398-409. PMCID: 3709011.
3. Vlaisavljevich E, Owens G, Lundt J, Teofilovic D, Ives K, Duryea A, Bertolina J, Welling TH, Xu Z. Non-Invasive Liver Ablation Using Histotripsy: Preclinical Safety Study in an In Vivo Porcine Model. Ultrasound Med Biol. 2017;43(6):1237-51.
4. Kim Y, Vlaisavljevich E, Owens GE, Allen SP, Cain CA, Xu Z. In vivo transcostal histotripsy therapy without aberration correction. Phys Med Biol. 2014;59(11):2553-68.
5. Smolock AR, Cristescu MM, Vlaisavljevich E, Gendron-Fitzpatrick A, Green C, Cannata J, Ziemlewicz TJ, Lee FT, Jr. Robotically Assisted Sonic Therapy as a Noninvasive Nonthermal Ablation Modality: Proof of Concept in a Porcine Liver Model. Radiology. 2018;287(2):485-93.
6. Vlaisavljevich E, Greve J, Cheng X, Ives K, Shi J, Jin L, Arvidson A, Hall T, Welling TH, Owens G, Roberts W, Xu Z. Non-Invasive Ultrasound Liver Ablation Using Histotripsy: Chronic Study in an In Vivo Rodent Model. Ultrasound Med Biol. 2016;42(8):1890-902. PMCID: PMC4912895
7. Kim Y, Hall TL, Xu Z, Cain CA. Transcranial Histotripsy Therapy: A Feasibility Study. IEEE Trans Ultrason Ferroelectr Freq Control. 2014;61(4):582-93

Replacement of Meniscus with Synthetic Substitute

Issue: There are currently no unique ICD-10-PCS codes to describe replacement of the medial or lateral meniscus with a synthetic substitute for the knee joint.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2023 consideration.

Food and Drug Administration (FDA) Approval? The NUsurface® Meniscus Implant (NUsurface) received FDA Breakthrough Designation in September 2019. The NUsurface randomized clinical trial submission is currently undergoing FDA review for De Novo market authorization, and is proposed to be indicated for[1]:

1. Mild or greater symptomatic medial compartment knee pain caused by a dysfunctional medial meniscus either related to a previous medial meniscus surgery and/or a clinically significant medial meniscal tear, as determined by patient history, diagnostic imaging, and/or validated knee pain measurement tool.

2. Revision of symptomatic previous medial meniscus surgery, including an exchange of a previously implanted NUsurface device.

Background: The meniscus consists of a c-shaped fibrocartilaginous structure that is composed of 70% water and 30% collagen. Between 10% to 30% of the outer portion of the meniscus is vascular[2] and is commonly referred to as the "red" zone. The inner two-thirds of the meniscus has no blood supply and is referred to as the "white" zone[3]. The medial meniscus is located on the inner side of the knee joint, and the lateral meniscus is located on the outer side of the knee. The meniscus is one of the most crucial structures of the knee.[4]

The meniscus plays a pivotal role in the biomechanical function and stability of the knee. It is critical for preserving the articulating surfaces of the knee joint[5] and is vital for shock absorption and load distribution while walking and other activities.[6]

As a result of increased awareness of the vital functions of the meniscus and the increased likelihood of early onset osteoarthritis in the absence of the meniscus, surgeons have shifted their management goal from meniscectomy to preservation, repair, and reconstruction of the meniscus.

---

[1] Proposed indications; to be updated with final indications upon receipt of FDA market authorization

[2] Rao AJ, Erickson BJ, Cvetanovich GL, Yanke AB, Bach BR Jr, Cole BJ. The Meniscus-Deficient Knee: Biomechanics, Evaluation, and Treatment Options. *Orthop J Sports Med*. 2015 Oct 23;3(10):2325967115611386. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4714576/

[3] American Academy of Orthopaedic Surgeons. OrthoInfo: Meniscus Tears. Retrieved on May 3, 2021 from https://www.drronakpatel.com/pdf/meniscus-tears-orthoinfo-aaos.pdf

[4] Bhan K. Meniscal Tears: Current Understanding, Diagnosis, and Management. *Cureus*. 2020 Jun 13;12(6) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7359983/

[5] Matar HE, Duckett SP, Raut V. Degenerative meniscal tears of the knee: evaluation and management. *Br J Hosp Med* (Lond). 2019 Jan 2;80(1):46-50. https://pubmed.ncbi.nlm.nih.gov/30592671/

[6] Englund M, Guermazi A, Lohmander SL. The role of the meniscus in knee osteoarthritis: a cause or consequence? *Radiol Clin North Am.* 2009 Jul;47(4):703-12. https://pubmed.ncbi.nlm.nih.gov/19631077/

Types of Tears
A dysfunctional meniscus can result from an acute traumatic injury (e.g., tear), which often occurs during sports,[2] or can result from deterioration as a result of the normal aging process.[7] Common tears include bucket handle, flap and radial tears[8] with locations in vascular (red-zone) or non-vascular regions (white-zone)[9].

Treatment of Tears
According to the requestor, physicians recommend treatment based on type of meniscus dysfunction and/or location of tear or degeneration, the type of tear, extent of injury, patient's age, health, and activity level. Surgeons correlate clinical information with MRI images and develop an individualized treatment plan for patients with a meniscal tear.[10]

In some cases, conservative care may be appropriate for patients as a first course of treatment for a small meniscal tear. Small tears located in the highly vascular red/red zones of the meniscus or "peripheral 30% of the medial meniscus and 25% of the lateral meniscus" are often first treated with conservative treatment[1] (i.e., rest, physical therapy, unloader bracing, corticosteroid injections, hyaluronic acid injections, and pharmacological therapy ranging from NSAIDS to opioids).

For other types of tears, including those in the "white" zone, surgery is often indicated, including meniscus repair and meniscectomy. Approximately 760,000 meniscectomies are performed annually in the hospital outpatient setting. Meniscectomy "can alter the joint biomechanics and overload the articular cartilage, which may contribute to degenerative changes and the need for knee replacement."[11]

As stated above, meniscal degeneration occurs with age, which in turn can result in meniscal tears. As individuals age, even moderate injuries may cause meniscal tears. Degenerative tears often have frayed edges on the inner rim, where the meniscus is thinnest. If frayed parts of the meniscus become trapped in the joint, the surgeon may perform a partial or complete meniscectomy. Some patients who have had a previous partial meniscectomy may have to undergo an additional meniscectomy(ies) to trim additional fraying. The removal of additional meniscal tissue often results in worsening pain and function.

Published literature suggests that meniscal injuries "have accelerated cartilage wear, leading to early onset osteoarthritis." [10] A meta-analysis found that over 10 years, patients who underwent meniscus repair, meniscectomy and nonoperative (conservative) treatments had 53.0%, 99.3%, and 95.1% rates of osteoarthritis, respectively, and 33.5%, 51.5%, and 45.5% rates of total knee

---

[7] Greis PE, Bardana DD, Holmstrom MC, Burks RT. Meniscal injury: I. Basic science and evaluation. *J Am Acad Orthop Surg.* 2002 May-Jun;10(3):168-76. https://pubmed.ncbi.nlm.nih.gov/12041938/
[8] Labbe C. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Spotlight on Research: Physical Therapy to Treat Torn Meniscus Comparable to Surgery for Many Patients. Retrieved on May 3, 2021 from https://www.niams.nih.gov/newsroom/spotlight-on-research/physical-therapy-treat-torn-meniscus-comparable-surgery-many
[9] American Academy of Orthopedic Surgeons. Diseases and Conditions: Meniscus Tears. Retrieved on May 2, 2021 from https://orthoinfo.aaos.org/en/diseases--conditions/meniscus-tears/
[10] Feeley BT, Lau BC. Biomechanics and Clinical Outcomes of Partial Meniscectomy. *J Am Acad Orthop Surg.* 2018 Dec 15;26(24):853-863. https://pubmed.ncbi.nlm.nih.gov/30247309/
[11] McKeon BP, Zaslav KR, Alfred RH, et al. Preliminary Results from a US Clinical Trial of a Novel Synthetic Polymer Meniscal Implant. Ortho J of Sports Med. 8(9). https://pubmed.ncbi.nlm.nih.gov/33062765/

replacement, respectively. [12]

When meniscal tears occur in younger patients, some surgeons may recommend a meniscal replacement, while for older patients a unicompartmental or total knee replacement. According to the requestor, these surgeries are invasive, risky, and require substantial pre-habilitation and rehabilitation. Until recently, however, these two surgeries were often the last resort at reducing a patient's pain and improving their function.[13]

Technology
According to the requestor, the NUsurface® Implant is an implantable, "discoid" anatomic-shaped device that is femoral-conforming due to its manufacture from the combination of Bionate® thermoplastic polycarbonate-urethane (PCU), a biostable medical grade plastic, reinforced for circumferential structural stability with embedded Dyneema Purity® ultra high molecular weight polyethylene fibers. The implant is manufactured using injection molding processes. As a result of its unique polymer materials, and its composite structure and design, the implant is implanted between the femur and tibia without fixation to bone or soft tissues. The requestor maintains that the implant's mechanism of action mimics the function of the natural meniscus, reducing pain by redistributing stressful loads transmitted across the knee joint during full range of knee motion, and helping to protect the femoral cartilage due to matched compliance to native cartilage tissue properties.

Procedure Description
Under anesthesia, the knee is positioned for arthroscopy according to the surgeon's preference (e.g., tourniquet is applied above the knee; a bolster is placed to support the heel when the leg is bent during surgery). The leg is prepped, draped, and positioned for a knee arthroscopy. An arthroscopy is performed to evaluate joint condition, confirm Outerbridge Grade and the size and location of any bony lesions.

Using an arthroscopic approach, a limited synovectomy and patellar fat pad resection are performed for visualization of the intercondylar notch. Medial compartment tightness is addressed by pie-crusting the medial collateral ligament, as needed. Meniscal tissue excision and remodeling is initiated with the posterior meniscus using instruments to achieve a 2 mm posterior meniscal rim with a vertical wall (i.e., meniscoplasty). Then, using a specialized probe instrument, the surgeon carefully measures and confirms a posterior 2 mm vertical, stable meniscal rim. An intercondylar medial femoral notchplasty and/or roofplasty is performed using radiofrequency ablation and/or burrs; osteophytes are excised as needed. To create adequate spacing for the implant, a specialized rasp instrument is used to refine the anterior, middle, and posterior intercondylar notch and roof, as needed. This completes the initial arthroscopic portion of the procedure, and the arthroscope is removed.

A 5 cm medial parapatellar arthrotomy dissecting tissue to expose the medial compartment is performed exposing the medial compartment. Under direct visualization, the anterior medial

[12] Faucett SC, Geisler BP, Chahla J, Krych AJ, Kurzweil PR, Garner AM, Liu S, LaPrade RF, Pietzsch JB. Meniscus Root Repair vs Meniscectomy or Nonoperative Management to Prevent Knee Osteoarthritis After Medial Meniscus Root Tears: Clinical and Economic Effectiveness. *Am J Sports Med.* 2019 Mar;47(3):762-769. https://pubmed.ncbi.nlm.nih.gov/29517925/
[13] John Hopkins Medicine. Health: Meniscal Transplant Surgery. Retrieved on May 2, 2021 from https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/meniscal-transplant-surgery#:~:text=Replacing%20your%20meniscus%20may%20provide,invasive%20than%20knee%20replacement%20surgery

meniscus is excised and remodeled using a scalpel and other instruments, as needed, to complete and establish the fully circumferential 2mm meniscal rim with a vertical wall (i.e., meniscoplasty). The surgeon addresses any medial compartment tightness by pie-crusting the medial collateral ligament, as needed, and inserts the trial into the medial compartment abutting the prepared 2 mm medial meniscus rim.

Utilizing the C-arm, fluoroscopic images evaluate correct placement of the trial and correct trial sizing and/or implant motion through full range of flexion and extension. Using a shaver or burr, the anterior, middle, and posterior intercondylar notch and roof are further refined, as needed. The arthroscope is reinserted into the knee joint to re-evaluate under both arthroscopic magnification and direct visualization to determine the need for further refinement of the notchplasty and roofplasty, and to confirm proper size of the trial. If there is no trial impingement or dislodgement (lift-off) during range of motion testing, the trial is removed. The definitive meniscus implant is positioned and implanted.

Range of motion, positioning and stability are again tested under direct visualization. The arthrotomy and arthroscopic portals are closed with appropriate sutures. A sterile dressing is applied. A dressing and straight-knee immobilizer are applied.

Current Coding: There are no unique ICD-10-PCS codes for replacement of the medial or lateral meniscus of the knee with a synthetic substitute. Code the meniscus replacement procedure using the appropriate code in table 0SR, Replacement of Lower Joints.

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**J** Synthetic Substitute	**9** Cemented **A** Uncemented **Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for replacement of the medial or lateral meniscus of the knee with a synthetic substitute. Continue coding as listed in current coding.

Option 2. In table 0SR, Replacement of Lower Joints, create new qualifier values D Medial Meniscus and E Lateral Meniscus, applied to the knee body part values and the device value Synthetic Substitute, to identify replacement of the medial or lateral meniscus of the knee with a synthetic substitute. In addition, add the corresponding new values to tables 0SP, Removal of Lower Joints and 0SR, Revision of Lower Joints as shown.

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open	**J** Synthetic Substitute	**9** Cemented **A** Uncemented **ADD D** Medial Meniscus **ADD E** Lateral Meniscus **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**J** Synthetic Substitute	**C** Patellar Surface **ADD D** Medial Meniscus **ADD E** Lateral Meniscus **Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device*	*Qualifier*
C Knee Joint, Right **D** Knee Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**J** Synthetic Substitute	**C** Patellar Surface **ADD D** Medial Meniscus **ADD E** Lateral Meniscus **Z** No Qualifier

Option 3. Create new codes in section X table XRR, Replacement of Joints, to identify replacement of the medial or lateral meniscus of the knee with a synthetic substitute. In addition, add the corresponding new values to tables XSP, Removal of Joints and XSR, Revision of Joints as shown.

Section	**X** New Technology
Body System	**R** Joints
Operation	**R** Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD G Knee Joint, Right **ADD H** Knee Joint, Left	**0** Open	**ADD L** Synthetic Substitute, Lateral Meniscus **ADD M** Synthetic Substitute, Medial Meniscus	**8** New Technology Group 8

Section	**X** New Technology
Body System	**R** Joints
Operation	**P** Removal: Taking out or off a device from a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD G Knee Joint, Right **ADD H** Knee Joint, Left	**0** Open	**ADD L** Synthetic Substitute, Lateral Meniscus **ADD M** Synthetic Substitute, Medial Meniscus	**8** New Technology Group 8

Section	**X** New Technology
Body System	**R** Joints
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD G Knee Joint, Right **ADD H** Knee Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**ADD L** Synthetic Substitute, Lateral Meniscus **ADD M** Synthetic Substitute, Medial Meniscus	**8** New Technology Group 8

CMS Recommendation: Option 3, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Section X Update
September 2021 ICD-10 Coordination and Maintenance Committee Meeting

Background:
At the September 11-12, 2018 ICD-10 C&M Committee Meeting we announced our plans to begin analyzing the frequency of the New Technology Group 1 codes within Section X as it has been 3 years since the implementation of these codes. We stated that we would consider the following during our review.

- Was the procedure code related to a new technology add-on payment application (NTAP)?
- If yes, was the technology approved for the NTAP?
- What is the frequency (total number of cases) of this procedure code as reported in the data for FYs 2016, 2017 and 2018?
- Based on review of the data and the clinical aspects of each procedure code, we will propose one of the options below
    1. Leave the code in Section X (e.g. procedure codes related to the administration of a specific medication)
    2. Reassign the code to the Med/Surg or other section of ICD-10-PCS and delete from Section X (e.g. NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the main Med/Surg section)
    3. Delete the Section X code (e.g. the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact)

For the March 2019 ICD-10 C&M meeting we provided the findings from our initial analysis with regard to the frequency in which the New Technology Group 1 codes had been reported in the data.

At the September 2019 meeting we did not propose any changes to the New Technology Group 1 codes and stated we would continue to monitor the data.

For the March 2020 ICD-10 C&M meeting we shared the results of our analysis for the New Technology Group 2 codes within Section X as it has been 3 years since the implementation of those codes. We provided the frequency (total number of cases) of the New Technology Group 2 procedure codes as reported in the data for FYs 2017, 2018, and 2019. We also updated the data for the New Technology Group 1 codes to include the frequency of the codes for FY 2019.

We revised the format in which we display the findings from our analyses. We created an Excel spreadsheet with 2 specific tabs labeled accordingly as Group 1 Codes and Group 2 Codes. On each tab is the list of ICD-10-PCS codes, code description, frequency by fiscal year and if the technology was approved for the NTAP.

At the September 2020 ICD-10 C&M meeting we reviewied the updated analysis results in more detail and encouraged participants to consider the options listed above while reviewing the data for discussion. Commenters suggested adding another option for consideration.

At the March 2021 ICD-10 C&M meeting we proposed changes based on the public comments received and discussed a new approach to consider for future proposals.

For this September 2021 ICD-10 C&M meeting we are reviewing the finalized changes based on the public comments received and sharing our analysis results for the Group 3 Codes from FY 2018, 2019 and 2020.

Fourth Option Issue
We received overall support for the addition of the fourth option for the Section X codes which was described as creating a unique code in another section of ICD-10-PCS and deleting the existing section X code. As a result, based on review of the data and the clinical aspects of each section X procedure code, we will continue to propose one of the four options listed below

1. Leave the code in Section X (e.g. procedure codes related to the administration of a specific medication)
2. Reassign the code to the Med/Surg or other section of ICD-10-PCS and delete from Section X (e.g. NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the main Med/Surg section)
3. Delete the Section X code (e.g. the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact)
4. Create a new code in Med/Surg or other section of ICD-10-PCS and delete the code from Section X. (e.g. NTAP has expired, data analysis and clinical review justifies uniquely identifying the technology in the Med/Surg section)

We also received support for

- establishing guiding principles in connection with the fourth option
- adding another column to the far right to identify the CMS recommendation
- reminding requestors that Section X codes are temporary and may be subject to one of the four listed options at a future meeting
- CMS continuing to present recommendations for the Section X codes and allowing the public to comment versus having the public submit specific requests

Based on prior discussions for Section X codes, we agreed that for the September meetings we would share the findings from our analysis, however, we would provide additional updates to the analysis and the actual proposals using one of the 4 options at the March meeting. The reason for doing this is because it allows us to incorporate the most recent fiscal year's data and a more complete data set for the prior fiscal year. So it will be at the March 2022 meeting where CMS will include the column indicating our recommendation for each of the Group 3 Section X codes. We will also include the proposed Index and Substance Key entries where applicable.

During the March 2021 meeting we also decided to Table a few of the Section X Group 2 codes so we will be providing the updated analysis and recommendations for this set of codes at the March 2022 meeting also.

Section X_September 2021 Update
Group 3

ICD-10-PCS Code	Code Description	FY 2018		FY 2019		FY 2020		
		Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Frequency	Approved as a New Technology?	Total Frequency Procedure Code Reported
XK02303	Introduction of concentrated bone marrow aspirate into muscle, percutaneous approach, new technology group 3	17	NO	39	NO	15	NO	71
XRG00F3	Fusion of occipital-cervical joint using radiolucent porous interbody fusion device, open approach, new technology group 3	0	NO	0	NO	0	NO	0
XRG10F3	Fusion of cervical vertebral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	15	NO	17	NO	21	NO	53
XRG20F3	Fusion of 2 or more cervical vertebral joints using radiolucent porous interbody fusion device, open approach, new technology group 3	46	NO	94	NO	65	NO	205
XRG40F3	Fusion of cervicothoracic vertebral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	5	NO	1	NO	3	NO	9
XRG60F3	Fusion of thoracic vertebral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	3	NO	1	NO	1	NO	5
XRG70F3	Fusion of 2 to 7 thoracic vertebral joints using radiolucent porous interbody fusion device, open approach, new technology group 3	0	NO	2	NO	0	NO	2
XRG80F3	Fusion of 8 or more thoracic vertebral joints using radiolucent porous interbody fusion device, open approach, new technology group 3	0	NO	0	NO	0	NO	0
XRGA0F3	Fusion of thoracolumbar vertebral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	3	NO	1	NO	0	NO	4
XRGB0F3	Fusion of lumbar vertebral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	41	NO	129	NO	94	NO	264

XRGC0F3	Fusion of 2 or more lumbar vertebral joints using radiolucent porous interbody fusion device, open approach, new technology group 3	18	NO	57	NO	57	NO	132
XRGD0F3	Fusion of lumbosacral joint using radiolucent porous interbody fusion device, open approach, new technology group 3	21	NO	59	NO	42	NO	122
XW033A3	Introduction of bezlotoxumab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 3	8	YES	23	YES	16	NO	47
XW033B3	Introduction of cytarabine and daunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3	214	NO	202	YES	167	YES	583
XW033C3	Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3[1]	19	NO	37	YES	55	YES	111
XW033F3	Introduction of other new technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 3	13	YES	34	YES	295	NO	342
XW043A3	Introduction of bezlotoxumab monoclonal antibody into central vein, percutaneous approach, new technology group 3	3	YES	5	YES	5	NO	13
XW043B3	Introduction of cytarabine and daunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3	418	NO	415	YES	367	YES	1200
XW043C3	Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3[1]	94	NO	208	YES	354	YES	656
XW043F3	Introduction of other new technology therapeutic substance into central vein, percutaneous approach, new technology group 3	4	YES	6	YES	39	NO	49
XY0VX83	Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3	74	NO	78	NO	48	NO	200

[1] ICD-10-PCS code has been deleted effective October 1, 2021.

ICD-10-PCS Index Addenda

Lttr	A	
Main	Add	Abdominal cavity use Peritoneal Cavity

Lttr	B	
Main	Add	Breyanzi(R) use Lisocabtagene Maraleucel Immunotherapy[(2)]

Lttr	C	
Main		Change device in Intestinal Tract
	Delete	Lower 0D2DXUZ
	Delete	Upper 0D20XUZ
	Add	Lower Intestinal Tract 0D2DXUZ
	Add	Upper Intestinal Tract 0D20XUZ
Main	Add	Continent ileostomy 0D1B

Lttr	D	
Main	Delete	DynaNail Mini(R)
	Delete	use Internal Fixation Device, Sustained Compression in 0RG
	Delete	use Internal Fixation Device, Sustained Compression in 0SG
Main	Delete	DynaNail(R)
	Delete	use Internal Fixation Device, Sustained Compression in 0RG
	Delete	use Internal Fixation Device, Sustained Compression in 0SG
Main	Add	DynaClip(R) (Forte)
	Add	use Internal Fixation Device, Sustained Compression in 0RG
	Add	use Internal Fixation Device, Sustained Compression in 0SG
Main	Add	DynaNail(R) (Hybrid) (Mini)
	Add	use Internal Fixation Device, Sustained Compression in 0RG
	Add	use Internal Fixation Device, Sustained Compression in 0SG

Lttr	F	
Main		Feeding Device
		Change device in
	Delete	Lower 0D2DXUZ
	Delete	Upper 0D20XUZ
	Add	Lower Intestinal Tract 0D2DXUZ
	Add	Upper Intestinal Tract 0D20XUZ

(2) Request is for an April 1, 2022 implementation date.

		Removal of device from Intestinal Tract
	Delete	Lower 0DPD
	Delete	Upper 0DP0
	Add	Lower Intestinal Tract 0DPD
	Add	Upper Intestinal Tract 0DP0
		Revision of device in Intestinal Tract
	Delete	Lower 0DWD
	Delete	Upper 0DW0
	Add	Lower Intestinal Tract 0DWD
	Add	Upper Intestinal Tract 0DW0
Main		Insertion of device in Intestinal Tract
	Delete	Lower 0DHD
	Delete	Upper 0DH0
	Add	Lower Intestinal Tract 0DHD
	Add	Upper Intestinal Tract 0DH0
Main		Inspection Intestinal Tract
	Delete	Lower 0DJD
	Delete	Upper 0DJ0
	Add	Lower Intestinal Tract 0DJD
	Add	Upper Intestinal Tract 0DJ0
Main		Removal of device from Intestinal Tract
	Delete	Lower 0DPD
	Delete	Upper 0DP0
	Add	Lower Intestinal Tract 0DPD
	Add	Upper Intestinal Tract 0DP0
Main		Revision of device in Intestinal Tract
	Delete	Lower 0DWD
	Delete	Upper 0DW0
	Add	Lower Intestinal Tract 0DWD
	Add	Upper Intestinal Tract 0DW0
Lttr	R	
Main	Add	RYBREVANT(tm) use Amivantamab[(2)]

(2) Request is for an April 1, 2022 implementation date.

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical

Axis 4 Body Part

Row Add

Term Add Peritoneal Cavity

Includes Add Abdominal cavity

ICD-10-PCS Device Key Addenda

Axis 6 Device

Row

Term Internal Fixation Device, Sustained Compression for Fusion in Lower Joints

Includes Delete DynaNail Mini(R)

Includes Delete DynaNail(R)

Includes Add DynaClip(R) (Forte)

Includes Add DynaNail(R) (Hybrid) (Mini)

Row

Term Internal Fixation Device, Sustained Compression for Fusion in Upper Joints

Includes Delete DynaNail Mini(R)

Includes Delete DynaNail(R)

Includes Add DynaClip(R) (Forte)

Includes Add DynaNail(R) (Hybrid) (Mini)

ICD-10-PCS Substance Key Addenda

Section X New Technology

Axis 6 Device / Substance / Technology

Row Add

Term Add Amivantamab(2)

Includes Add RYBREVANT(tm)

Row Add

Term Add Lisocabtagene Maraleucel Immunotherapy(2)

Includes Add Breyanzi(R)

(2) Request is for an April 1, 2022 implementation date.

ICD-10-PCS Table Addenda

Medical and Surgical Section
Axis 6 Device

Infusion Device in Head and Facial Bones

Source	Description	Code specification
2021, public request with CMS internal review	In the Head and Facial Bones body system of the Medical and Surgical section, add the device value 3 Infusion Device to the root operation tables Removal 0NP and Revision 0NW, for the body part value 0 Skull, to enable capture of removal or revision procedures on a previously inserted infusion device such as the Ommaya reservoir.	Add: 0NP0[034X]3Z (4 codes) 0NW0[034X]3Z (4 codes)

EXAMPLES

Section	**0** Medical and Surgical		
Body System	**N** Head and Facial Bones		
Operation	**P** Removal: Taking out or off a device from a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Skull	**0** Open	**0** Drainage Device **ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **N** Neurostimulator Generator **S** Hearing Device	**Z** No Qualifier
0 Skull	**3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
0 Skull	**X** External	**0** Drainage Device **ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Drainage Device **4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**X** External	**0** Drainage Device **4** Internal Fixation Device **M** Bone Growth Stimulator	**Z** No Qualifier

Section	**0** Medical and Surgical		
Body System	**N** Head and Facial Bones		
Operation	**W** Revision: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device		
Body Part	*Approach*	*Device*	*Qualifier*
0 Skull	**0** Open	**0** Drainage Device **ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **N** Neurostimulator Generator **S** Hearing Device	**Z** No Qualifier
0 Skull	**3** Percutaneous **4** Percutaneous Endoscopic **X** External	**0** Drainage Device **ADD 3** Infusion Device **4** Internal Fixation Device **5** External Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator **S** Hearing Device	**Z** No Qualifier
B Nasal Bone **W** Facial Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External	**0** Drainage Device **4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **M** Bone Growth Stimulator	**Z** No Qualifier

Medical and Surgical Section
Axis 7 Qualifier

Embolization of the Prostatic Arteries

Source	Description	Code specification
2021, public request with CMS internal review	In the Lower Arteries body system of the Medical and Surgical section, create new qualifier values V Prostatic Artery, Right and W Prostatic Artery, Left, and add to the root operation Occlusion table 04L for the body part values E Internal Iliac Artery, Right and F Internal Iliac Artery, Left. These changes enable capture of detail for procedures such as prostatic artery embolization.	Add: 04LE[034][CDZ]V (9 codes) 04LF[034][CDZ]W (9 codes)

EXAMPLE

Section	**0** Medical and Surgical		
Body System	**4** Lower Arteries		
Operation	**L** Occlusion: Completely closing an orifice or the lumen of a tubular body part		
Body Part	*Approach*	*Device*	*Qualifier*

E Internal Iliac Artery, Right	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**T** Uterine Artery, Right **ADD V** Prostatic Artery, Right **Z** No Qualifier
F Internal Iliac Artery, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**C** Extraluminal Device **D** Intraluminal Device **Z** No Device	**U** Uterine Artery, Left **ADD W** Prostatic Artery, Left **Z** No Qualifier

Index/Body Part Key entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr P
Main Add Prostatic artery use Internal Iliac Artery, Right
use Internal Iliac Artery, Left
Lttr S
Main Add Superior vesical artery use Internal Iliac Artery, Right
use Internal Iliac Artery, Left

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical
Axis 4 Body Part

Row Add
Term Add Internal Iliac Artery, Left
Includes Add Prostatic artery
Includes Add Superior vesical artery
Term Add Internal Iliac Artery, Right
Includes Add Prostatic artery
Includes Add Superior vesical artery

Bladder Augmentation

Source	Description	Code specification
2021, public request with CMS internal review	In the Gastrointestinal body system of the Medical and Surgical section, create new qualifier value B Bladder and add to the root operation Transfer table 0DX for the body part values 8 Small Intestine and E Large Intestine. These changes enable capture of detail for procedures such as bladder augmentation using an isolated segment of small or large intestine that is still connected to its vascular and nervous supply.	Add: 0DX8[04]ZB (2 codes) 0DXE[04]ZB (2 codes)

EXAMPLE

Section *Body System* *Operation*	**0** Medical and Surgical **D** Gastrointestinal System **X** Transfer: Moving, without taking out, all or a portion of a body part to another location to take over the function of all or a portion of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
6 Stomach	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus
8 Small Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **ADD B** Bladder
E Large Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **7** Vagina **ADD B** Bladder

Ileal Ureter

Source	**Description**	**Code specification**
2021, public request with CMS internal review	In the Gastrointestinal body system of the Medical and Surgical section, create new qualifier values C Ureter, Right, D Ureter, Left, and F Ureters, Bilateral, and add to the root operation Transfer table 0DX for the body part value 8 Small Intestine. These changes enable capture of detail for procedures such as the ileal ureter procedure that uses an isolated segment of small intestine connected to its vascular and nervous supply to take over the function of part or all of both ureters.	Add: 0DX8[04]Z[CDF] (6 codes)

EXAMPLE

Section *Body System* *Operation*	**0** Medical and Surgical **D** Gastrointestinal System **X** Transfer: Moving, without taking out, all or a portion of a body part to another location to take over the function of all or a portion of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
6 Stomach	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus
8 Small Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **ADD C** Ureter, Right **ADD D** Ureter, Left **ADD F** Ureters, Bilateral
E Large Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **7** Vagina

Administration Section
Axis 6 Substance

Genetically Modified Autologous Hematopoietic Stem/Progenitor Cells

Source	Description	Code specification
2021, public request with CMS internal review	In the Administration section, create four new substance values: • 0 Hematopoietic Stem/Progenitor Cells, Genetically Modified, In Vivo Gene Therapy; • D Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, ADA Gene Therapy; • E Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, ARSA Gene Therapy; and • F Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, WASP Gene Therapy, and add to the root operation Transfusion table 302. In addition, revise existing substance value: Revised from C Hematopoietic Stem/Progenitor Cells, Genetically Modified; Revised to C Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, Unspecified Gene Therapy These changes enable capture of additional detail for administration of genetically modified autologous hematopoietic stem/progenitor cells.	Add: 302[34]3[0DEF]0 (8 codes) Revise: 302[34]3C0 (2 codes)

EXAMPLE

Section	**3** Administration		
Body System	**0** Circulatory		
Operation	**2** Transfusion: Putting in blood or blood products		
Body System / Region	*Approach*	*Substance*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD 0** Hematopoietic Stem/Progenitor Cells, Genetically Modified, In Vivo Gene Therapy	**0** Autologous
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**A** Stem Cells, Embryonic	**Z** No Qualifier
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**REVISE FROM C** Hematopoietic Stem/Progenitor Cells, Genetically Modified **REVISE TO C** Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, Unspecified Gene Therapy **ADD D** Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, ADA Gene Therapy **ADD E** Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, ARSA Gene Therapy **ADD F** Hematopoietic Stem/Progenitor Cells, Genetically Modified Ex Vivo, WASP Gene Therapy	**0** Autologous

New Technology Section(2)
Axis 6 Device / Substance / Technology

Source	Description	Code specification
2021, CMS internal review	In New Technology Section table XW0, Introduction, create new substance values V COVID-19 Vaccine Dose 3, and W COVID-19 Vaccine Booster to identify the administration of COVID-19 Vaccine Dose 3, and COVID-19 Vaccine Booster to enable the efficient tracking of these substances when used to protect against COVID-19.	Add: XW0[12]3[VW]7 (4 codes)

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
1 Subcutaneous Tissue	**3** Percutaneous	**ADD V** COVID-19 Vaccine Dose 3 **ADD W** COVID-19 Vaccine Booster	7 New Technology Group 7
2 Muscle	**3** Percutaneous	**ADD V** COVID-19 Vaccine Dose 3 **ADD W** COVID-19 Vaccine Booster	7 New Technology Group 7

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr C
Main Add COVID-19 Vaccine Booster XW0
Main Add COVID-19 Vaccine Dose 3 XW0

Lttr N
Main New Technology
Add COVID-19 Vaccine Booster XW0
Add COVID-19 Vaccine Dose 3 XW0

(2) Request is for an April 1, 2022 implementation date.

Closing Remarks

1. Links

The links for the following ICD-9-CM code files have been moved to the ICD-10 webpage to allow all code files to be located in one area on the CMS website at: https://www.cms.gov/medicare/coding/icd10

ICD-9-CM Diagnosis and Procedure Codes: Abbreviated and Full Code Titles

Updates and Revisions to ICD-9-CM Procedure Codes (Addendum)

2. New Grouper Release

A new ICD-10 MS-DRG Grouper software release, V39.1, will be made available by February 1, 2022 effective with discharges on and after April 1, 2022 that includes a new Medicare Code Edit. Additional information can be found in the FY 2022 IPPS/LTCH PPS final rule at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps

3. New System to Process Code Requests for Updates to the ICD-10-PCS Classification and to Submit MS-DRG Classification Changes Requests

CMS is working with a contractor to build a system called Medicare Electronic Application Request Information System™ (MEARIS™). MEARIS™ is a secure web-based platform that will receive and process applications specific to Medicare coding and MS-DRGs. Users type in a designated URL on their web browser and sign in with a unique user name and password. CMS anticipates that we will collect information we currently collect by email for ICD-10-PCS code requests and MS-DRG requests in this system in 2022. We will provide more information on the CMS website and via the ICD-10 Coordination and Maintenance Subscriber List as we get closer to launching this system.

April 1 Code Implementation Discussion

At the March 2021 ICD-10 Coordination and Maintenance Committee meeting, the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention's National Center for Health Statistics (CDC/NCHS), announced our consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current October 1 annual update for ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. We stated that this April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(K)(vii) of the Social Security Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We noted that under our contemplated process, requestors would indicate if they are submitting their code request for consideration for an April 1 implementation date, if adopted, or an October 1 implementation date. The ICD-10 Coordination and Maintenance Committee would make efforts to accommodate the requested implementation date for each request submitted, however, the Committee would determine which requests would be presented for consideration for an April 1 implementation date or an October 1 implementation date.

We asked for feedback on the possible adoption of this April 1 implementation date, including how it may impact your current business processes. We also sought input on what factors the Committee should consider when determining which requests should be considered for either an April 1 or October 1 implementation date. We stated the earliest date for which we would consider an April 1 code update option is April 1, 2022, and provided a Sample Timeline.

We also stated we would use our established process to implement an April 1 code update, which would include presenting proposals for April 1 consideration at the September ICD-10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments, consistent with the new Grouper release information. The code update process for an April 1 implementation date would also involve the release of new code files, coding guidelines, and coding advice on the use and reporting of new codes through AHA's *Coding Clinic for ICD-10-CM/PCS* publication.

CMS would assign the codes approved for the April 1 update to an MS-DRG(s) using its established process for Grouper assignments for new diagnosis and procedure codes. CMS would list the codes approved for an April 1 update in the annual IPPS proposed rule, along with their proposed Grouper assignments beginning October 1 of the next fiscal year. These Grouper assignments include the Major Diagnostic Category (MDC), Medicare Severity Diagnosis Related Group (MS-DRG), severity level designations for diagnosis codes of a major complication or comorbidity (MCC), a complication or comorbidity (CC) or a non-complication or comorbidity (NonCC), and the designation of procedure codes as either operating room (O.R.) procedures or non-operating room (non-O.R.) procedures. We would make these assignments available in tables 6A. – New Diagnosis Codes and 6B. – New Procedure Codes, associated with each proposed rule, at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/

We also provided a discussion in the FY 2022 IPPS/LTCH PPS proposed and final rules regarding this April 1 announcement in association with the March ICD-10 C&M meeting.

Comments submitted in response to both the ICD-10 C&M meeting and the proposed rule discussion consisted of support for the April 1 update stating it would allow for more timely and specific capture and recognition of diseases and procedures for data collection, research, and advancing public health. Other comments acknowledged processes are already in place and would lessen some of the burden of the October update. Some stated an April 1 option is important to recognize transformative therapies, including novel cell and gene therapies, such as CAR T-cell therapies. Specific comments in response to the proposed rule also referenced advantages that could be realized under the MS-DRGs, however, we are unable to discuss payment or MS-DRGs at this meeting, therefore, we encourage those of you who may be interested, to review the information in the IPPS rules.

We had also asked for feedback on what criteria or factors should be taken into consideration for determining whether to consider a code request for an April 1 or October 1 implementation date. Some commenters stated CMS should consider new codes that are related to new therapies that will be up for regulatory approval, or for diagnoses that are new and important to public health (such as those from the COVID-19 PHE). The commenters stated it is better to have coding in place before, and certainly as soon as, a product is approved, and sooner rather than later when an emerging public health issue is identified. Other commenters suggested aligning with regulatory approval dates. Some commenters suggested that CMS consider limiting the number of codes approved with respect to adoption of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current October 1 annual update since although the coding changes associated with COVID-19 under the PHE have demonstrated it is possible to implement more frequent coding updates that are limited in number, significant adjustments were needed to incorporate the updates and resulted in operational issues for hospitals.

With regard to how business processes may be affected, commenters stated that, initially, there may be some increased work to ensure that the April 1 codes released (and the MS-DRG grouping assignments) are up to date in their systems. The commenters stated this effort would include checking with software vendors to ensure that they are also updating their software for the new codes and groupings. A commenter stated that the benefits of adding the new release cycle, however, will be well worth the time and resource investment at the beginning.

Other commenters opposed consideration of the April 1 implementation date in addition to the October 1 annual update, stating it will be a work intensive process in terms of systems updates, training time, and data comparison. Some commenters expressed concerns about increased costs related to the production and purchase of additional code books or software, however, we do not believe there is a specific need for publishers to produce new code books. We have stated that our intent is to utilize a phased in approach with limited code updates. With regard to new software, we were not and have not been made aware of any significant challenges encountered by vendors or programmers during the public health emergency (PHE) with the additional GROUPER releases that were made available. Lastly, we were also informed of potential operational issues for which we intend to work with stakeholders and identify how we can improve processes.

After consideration of all the public comments received, we are adopting the April 1 implementation date, in addition to the annual October 1 update, effective FY 2022. We emphasize that the intent of this April 1 implementation date is to allow flexibility in the ICD-10 code update process for the reasons previously discussed, as outlined in rulemaking and based on the feedback received by commenters.

As shown in the **Federal Register** notice and on the CMS webpage in the meeting materials, we identified in advance the requests for which an April 1 implementation is being considered. It is a limited amount and consistent with the basis for which we adopted this option. We will continue to follow the timeline that outlines the process for an April 1 implementation and communicate announcements by the dates provided, if not sooner. We understand that this is a new and evolving process. We look forward to continuing communications and encourage you to provide feedback on what other materials or information may be helpful to you regarding the April 1 implementation. If your concerns involve MS-DRG or payment, Grouper logic issues, please submit those to the MSDRGClassificationChange@cms.hhs.gov mailbox and for specific code related information, those inquiries should continue to be submitted to the ICDProcedureCodeRequest@cms.hhs.gov mailbox.