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

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
March 17-18, 2020

QUESTIONS & ANSWERS

CMS responses to questions or comments submitted for procedure code topics using the "Chat" feature or the "Q & A" feature during the March 17th, 2020 ICD-10 Coordination and Maintenance Committee Meeting.

Question: Where is the download for today's presentations?
CMS Response: The meeting materials for the procedure code issues discussed on March 17th are available at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials

Question: Will clinical presentation PowerPoint slides be available as a handout?
CMS Response: Slides and all other files that were utilized for the procedure code issues discussed on March 17th are available at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials

Question: Where is the raise hand feature?
CMS Response: The raise hand feature is located at the bottom of the Participants Panel*. Once your question has been addressed, please lower the raised hand. *Attendees must be logged into the WebEx via the detailed instructions provided in order to utilize the raise hand feature.

Question: I raised my hand a couple of times during the Q&A segment of the last proposal, but you apparently didn't see it?
CMS Response: We were unable to address all raised hands during the meeting. Your additional questions, if not addressed during the meeting, can be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure

codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Question: Does TERLIVAZ® (terlipressin) work in hepatorenal syndrome type 2 (HRS-2)?

CMS Response: Mallinckrodt is seeking FDA approval for terlipressin for the proposed indication of hepatorenal syndrome type 1 (HRS-1). Results from the CONFIRM study demonstrated that terlipressin is effective in improving renal function and achieving hepatorenal syndrome (HRS) reversal in patients with HRS-1 and progressive advanced liver disease. HRS-2 is a relapsing-remitting type of renal dysfunction, whereas HRS-1 is an acute severe renal dysfunction. Finding from previous investigations show that treatment with terlipressin is effective in improving kidney function and inducing reversal of HRS-2. It should be noted that based on recent revised guidelines, the concepts of HRS-1 and HRS-2 have evolved to introduce the definition of acute kidney injury (AKI) where patients with cirrhosis are treated based on magnitude of change in renal function, not as HRS-1 or HRS-2.

Question: ICD-10-CM only has generic diagnosis codes for HRS... there is no differentiation of type 1 or type 2. Would we need granularity of ICD-10-CM to justify the medical necessity for this pharmaceutical? If not, then medical necessity would require documentation that results in K76.7 and N17.8, not just N17.9, since N17.9 is unspecified and does not point to the AKI as due to HRS.

CMS Response: The CDC maintains the ICD-10-CM diagnosis code set. Requests/suggestions for updates to the diagnosis classification can be directed to nchsicd10cm@cdc.gov.

Question: Did CMS consider just changing the last character of the current codes to represent the TERLIVAZ® (terlipressin) instead of creating more codes in the new tech section or even leaving as is?

CMS Response: Thank you for your comments which we will carefully consider. Your comments can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Question: Are there other CAR T-cell therapies for mantle cell lymphoma (MCL) besides KTE-X19?

CMS Response: Currently, no CAR T-cell therapies are approved for the treatment of relapsed / refractory (r/r) MCL. If approved by the FDA, KTE-X19 would be the first CAR T-cell therapy approved for the treatment of r/r MCL. Data from one non-pivotal cohort of 17 patients with r/r MCL treated with

JCAR017 within the TRANSCEND-NHL-001 trial (Juno Therapeutics, a Bristol Myers Squibb company) were presented at the 2019 ASCO (American Society of Clinical Oncology) Annual Meeting (Wang et al., abstract #7516).

Comment: Regarding the coding options for bacterial autofloresescence detection, we support Option 3. Use of the procedure has identified the unique patient outcomes related to the anatomical location. Having the procedure code will greatly aid outcome capture of patients related to their conditions. This would be used both inpatient and outpatient.

CMS Response: Thank you for indicating your support of Option 3. Your comments should also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov for consideration. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Question: Has the implantable fracture reduction system (SpineJack® Expansion Kit) been tested in those who have compression fractures from other causes (e.g. accident) not osteoporosis?

CMS Response: At present, the SpineJack® system has received FDA 510(k) clearance for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs). In the United States, the SpineJack® device is contraindicated for use in the treatment of patients presenting with traumatic or tumoral vertebral fractures and is considered off-label use for those indications in the U.S. market.

There are publications from Europe that provide data on the use of the SpineJack® system for the treatment of traumatic or tumoral VCFs. In the European market, the SpineJack® system is indicated for use in the reduction of mobile fractures that may result from osteoporosis, trauma (type A fractures according to the Magerl classification), and malignant lesions (myeloma or osteolytic metastasis).

Question: In the SAKOS trial of the implantable fracture reduction system (SpineJack® Expansion Kit), what were the results regarding anterior, posterior height and cobb angle?

CMS Response: Stryker makes no claims of clinically significant improvements in anterior vertebral body height, posterior vertebral body height and Cobb angle with SpineJack® system use. The SpineJack® system was shown to be non-inferior to balloon kyphoplasty (BKP) on these particular measures in the SAKOS pivotal trial. The treatment of osteoporotic VCFs with BKP have historically focused on anterior wall height restoration and Cobb angle improvement, but did little for mid-vertebral body height due to the lack of a permanent implant with BKP to maintain the restoration of the fracture after balloon removal and before bone cement administration. Based upon the

SAKOS trial results, the SpineJack® system has demonstrated superiority to BKP in mid-vertebral body height restoration.

Question: In the SAKOS trial of the implantable fracture reduction system (SpineJack® Expansion Kit), what were the pain results at the 12-month time between BKP and SpineJack®?

CMS Response: Stryker makes no claims of clinically significant improvement at 12 months post-procedure for the reduction of pain scores with SpineJack® system use. Per the SAKOS trial results, the SpineJack® system was found to be non-inferior to BKP in the reduction of pain scores at 12 months. Clinically significant pain score reductions were found at 1 month and 6 months with the SpineJack® system compared to BKP in the SAKOS trial, which suggests faster pain symptom resolution. In addition, fewer patients were taking pain medication including opiates at 5 days after surgery with the SpineJack® system compared to BKP.

Comment: Just an input. I agree with Option 1 to not add new codes for the covered stents. I believe this would cause bigger issues across the board with collecting data and data being documented.

CMS Response: Thank you for indicating your support of Option 1. Your comments should also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Comment: I wanted to raise a comment on the OTL-101 presentation. I believe option 2 is good but had a question I'd like to ask out loud if possible about ex-vivo vs. in-vivo.

CMS Response: Thank you for indicating your support of Option 2. Your additional questions on this topic, if not addressed during the meeting, can be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Comment: I think continuing to use the ICD-10-PCS new technology codes is not scalable or sustainable with all the different drugs and biologic products that are due to be FDA approved and which apply for NTAP. Rather, per the National Uniform Billing Committee, CMS could require hospitals to report the HCPCS codes on inpatient claims and/or the National Drug Code as it did for VABOMERE.

CMS Response: Thank you for your comment which we will carefully consider. Your comment can also be submitted via the CMS ICD-10 Procedure Code

Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Comment: Also, for the two CAR T-cell products, the third character in the new technology administration says zero and states "except blood products" and CAR T-cells are blood derived products.

CMS Response: Thank you for your comment which we will carefully consider. Your comment can also be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov. As a reminder, April 17, 2020 is the deadline for receipt of public comments on proposed new procedure codes and revisions discussed at the March 17, 2020 ICD-10 Coordination and Maintenance Committee meeting for implementation on October 1, 2020.

Question: Is Soliris administered during the acute episode of neuromyelitis?

CMS Response: Soliris is FDA-approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. In clinical practice, Soliris has been administered in the acute setting.