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

CENTER FOR MEDICARE

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

CMS modified the approach for presenting the new technology add-on payment (NTAP) related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting, due to the high volume of NTAP applications and corresponding procedure code requests being considered for FY 2022. Consistent with the requirements of section 1886(d)(5)(K)(iii) of the Social Security Act, applicants submitted requests to create a unique procedure code to describe the administration of a therapeutic agent, such as the option to create a new code in Section X within the ICD-10-PCS procedure code classification. In order to accommodate all of the requests received for the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting, CMS only displayed the Agenda and related materials associated with the following six NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent.

The six NTAP related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent are:

1. Administration of Trilaciclib
2. Administration of ZEPZELCA™ (lurbinectedin)
3. Administration of ENSPRYNG™ (satralizumab-mwge)
4. Administration of Ciltacabtagene Autoleucel (cilta-cel)
5. Administration of Amivantamab
6. Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC)*

*On pages 21 and 22 of the Agenda packet, two typographical errors were noted in the coding options for Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC).

In Option 2, the approach value 0 Open, was inadvertently included.

In Option 3, the root operation 2 Transfusion was displayed, rather than root operation 1 Transfusion.

We are correcting the coding options for consideration of this request to the following.

Option 2. Create new codes in section 3, Administration, to identify the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC).

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 D** Pathogen Reduced Cryoprecipitated Fibrinogen Complex	1 Nonautologous

Option 3. Create new codes in section X, New Technology, to identify the transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC).

Section **X** New Technology *Body System* **W** Anatomical Regions *Operation* **1** Transfusion: Putting in blood or blood products			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD D** Pathogen Reduced Cryoprecipitated Fibrinogen Complex	**7** New Technology Group 7

QUESTIONS & ANSWERS

Below we provide the CMS responses to questions or comments that were submitted in advance of the March 9, 2021 ICD-10 Coordination and Maintenance Committee Meeting for the six procedure code topics to ICDProcedureCodeRequest@cms.hhs.gov.

Question: In reviewing the ICD-10-PCS procedure code request for administration of trilaciclib, the slides indicate that this drug is administered in both the inpatient and outpatient setting. Approximately, how often is this drug administered in the inpatient setting versus the outpatient setting?

CMS Response: Patients treated with trilaciclib are generally treated per FDA label with 4 cycles of 21 days each, where days 1-3 of the cycle involve chemotherapy with a dose of trilaciclib administered in conjunction with the chemotherapy. This is followed by an 18-day treatment holiday such that the inpatient hospitalization is only expected to span one cycle. Therefore, roughly translated about 25 percent of the patient's total administered vials will be in the inpatient setting.

Question: The manufacturer's website states "ENSPRYNG™ is intended for home use or elsewhere under the guidance of a healthcare provider. After proper training, an adult patient or caregiver may inject ENSPRYNG™." The slides for C&M mention that this drug will be administered in both the inpatient and outpatient settings. But if this drug is intended for home use and can be self-administered, approximately how often would it be administered in a hospital inpatient setting?

CMS Response: ENSPRYNG™ is a prescription medicine used to treat neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4 (AQP4)

antibody positive. NMOSD is a rare, inflammatory, potentially life-threatening autoimmune central nervous system (CNS) disorder characterized primarily by severe, unpredictable relapses of optic neuritis and/or acute longitudinally extensive transverse myelitis (LETM). Due to the severity of relapses, relapse prevention is a key disease management priority. Patients who relapse are often admitted to hospital for acute treatment. With every relapse, patients are at risk of becoming blind or paralyzed, and thus it is critical to minimize the risk of future relapses by initiating maintenance treatment in a timely manner while the patient is still admitted.

Only a patient's initial dose of ENSPRYNG™ (or doses, depending on their length of stay) is anticipated to be administered in the hospital inpatient setting, unless they are subsequently re-admitted to hospital having been started on ENSPRYNG™ and then discharged. After their discharge from hospital and having received adequate training on how to perform the injection, an adult patient/caregiver may administer all subsequent doses of ENSPRYNG™ at home if the treating physician determines that it is appropriate and the adult patient/caregiver can perform the injection technique. This gives patients the option to continue the therapy initiated in the hospital in the convenience of their own home, with reduced disruption of daily life for themselves and their caregivers.