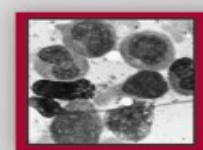
Chimeric Antigen Receptor T-Cell Therapy Category III CPT Codes

Advisory Panel on Hospital Outpatient Payment Panel
(HOP Panel)

August 20-21, 2018

Submitted By: The American Society of Blood and Marrow Transplantation



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Presentation Checklist

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- Recommendation/rationale – slides 8 - 10
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Financial Relationships

- Stephanie Farnia, MPH, Policy Director at the ASBMT
- Jugna Shah, MPH, President Nimitt Consulting Inc.; paid consultant of the ASBMT

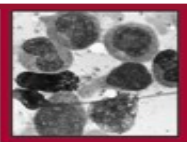
CPT/HCPCS and APC Codes

This presentation involves the following Category III CPT® codes and APCs

CY 2019 OPPS Proposed Rule Status Indicator and APC Assignment				
HCPCS Code	**Short Descriptor**	**CI**	**SI**	**APC**
05X1T	Bld drv t lymphcyt car-t cll	NP	B	
05X2T	Bld drv t lymphcyt prep trns	NP	B	
05X3T	Receipt&prep car-t cll admn	NP	B	
05X4T	Car-t cll admn autologous	NP	B	

Description of Issue

- **Chimeric Antigen Receptor T – Cell (CAR-T) Therapy** requires drawing blood from each patient and separating out the T cells which are then genetically engineered to produce receptors on their surface called chimeric antigen receptors, or CARs to fight cancer cells. The FDA stated upon approval of the first CAR-T that we are entering a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer.
- There are **currently no CPT codes** to report the following services associated with CAR-T:
  - Collection of autologous cells when collected in the outpatient setting and administration occurs in the inpatient setting which is by and large what is happening today
  - Preparation of cells to/from the manufacturer
  - Administration of cells in the outpatient setting if the service is performed outpatient or in the inpatient setting and reporting by the physician of his/her service
- Per the AMA CPT instruction *"Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the approximate unlisted procedure or service code."*



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Description of Issue (Cont.)

- The American Medical Association (AMA) has approved four new Category III CPT codes for use starting January 1, 2019
- In Addendum B of the CY 2019 OPPS Proposed Rule CMS has assigned status indicator B to all four of these codes which indicates a different code should be reported
- We do not understand what different/better code CMS intends providers to report for services that are rendered to registered hospital outpatients
  - This is especially true for some CAR-T services that are provided to hospital outpatients many days prior to other CAR-T services being provided inpatient where HCPCS codes are not reported at all
  - It is also true when one hospital provides the cell collection service to a patient and another hospital provider infuses the CAR-T cells whether inpatient or outpatient

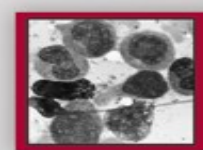
Consider the following examples:

Description of Issue (Cont.)

- Ex 1: Patients cells are collected in the outpatient setting and prepared to send to the manufacturer. When the cells are ready, infusion of the CAR-T product occurs in the inpatient setting a week or more later.
  - The hospital needs to be able to bill for the collection of the cells which occurred in the outpatient setting days in advance of the inpatient administration
- Ex 2: CAR-T cells are administered to a patient in the outpatient setting and providers need a way to report the infusion of the cells
- Ex 3: Provider A performs the cell collection on a patient and sends the cells to the manufacturer. Provider B performs the infusion of the CAR-T cells in either the inpatient or outpatient setting. Each provider needs a way to report the individual services they performed.

Recommendations

- The ASBMT respectfully requests the HOP panel to recommend to CMS that it change the status indicators assigned to the new Category III CPT codes for CAR-T services from “B” to separately payable status indicators.
- Since these are new codes representing these new services, we believe it would be appropriate to cross-walk these codes to existing transplant APCs as shown in the table on the next slide; this represents the best/closest approximation at present.
- We recommend CMS revisit the APC assignment of these services once more data is available.



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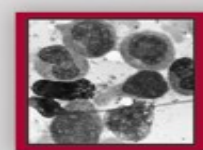
Recommendations (Cont.)

- The ASBMT requests the HOP Panel recommend to CMS that it use the following status indicators and APC assignments for the new Category III CAR-T CPT codes

CY 2019 OPPS Proposed Rule Status Indicator and APC Assignment					Recommended Status Indicators and APC Assignments and Payments Based on Using the Transplant Codes as a Cross-Walk				
HCPCS Code	**Short Descriptor**	**CI**	**SI**	**APC**	**HCPCS Code**	**Short Descriptor**	**SI**	**APC**	**APC Payment**
05X1T	Bld drv t lymphcyt car-t cll	NP	B		38206	Harvest auto stem cells	S	5242	$1,222.97
05X2T	Bld drv t lymphcyt prep trns	NP	B		38207	Cryopreserve stem cells	S	5241	$383.39
05X3T	Receipt&prep car-t cll admn	NP	B		38208	Thaw preserved stem cells	S	5241	$383.39
05X4T	Car-t cll admn autologous	NP	B		38241	Transplt autol hct/donor	S	5242	$1,222.97



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Rationale for Recommendations

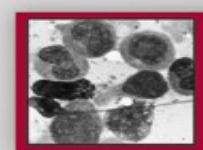
- Making these changes will allow hospitals to bill and be paid appropriately for the services they provide to their patients
- The OPPS payment system is designed such that the services performed at each separate outpatient encounter be billed on individual claims with the date that the service was provided with HCPCS codes
- The most clinically appropriate codes to represent these services are the AMA-approved new Category III CPT codes (1/1/19)
- CAR-T services and hospital charges associated with these services will ONLY be identifiable on claims for future rate-setting purposes if the Category III codes are approved and mapped to payable APCs.

Expected Outcome

- Hospitals will be able to separately report outpatient encounters with codes for the outpatient services which occur many days in advance of the usual inpatient admission for infusion of the CAR-T cells
  - Would not have to use unlisted or codes that are not clinically appropriate
- If more than one provider is involved in the clinical CAR-T process, each will be able to appropriately bill for its services
- CMS would have clear data for tracking and rate-setting purposes

Potential Consequences if Not Changed

- Until AMA approved Category III CPT codes go into effect for CAR-T services starting January 1, 2019, providers have no choice but to use unlisted CPT codes
  - Hospitals are prohibited by CPT and HIPAA transaction sets from selecting an approximate CPT code to represent a service
- Confusion will remain on how hospitals are supposed to report CAR-T services that are performed on outpatients and
- CMS will not receive consistent or accurate claims data for future outpatient rate setting
- Per our previous comments to CMS regarding the existing CAR-T HCPCS Q codes, we continue to recommend that it change the code structures and exclude any clinical services so they can be appropriately reported by the corresponding provider, as standard for all current coding practices.



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