



Chimeric Antigen Receptor T Cell Therapy Category III CPT Codes

Advisory Panel on Hospital Outpatient Payment Panel (HOP Panel)

August 19-20, 2019

Submitted By: The American Society of Transplantation and Cellular Therapy

Presentation Checklist

- Financial relationship – slide 3
- CPT codes and APCs involved – slides 4
- Description of issue – slides 5 -8
- Recommendation/rationale – slide 9-10
- Expected outcome – slide 11
- Potential consequences of not making the change – slide 12

Financial Relationships

Alycia Maloney, JD, Government Relations and Policy Director at the ASTCT

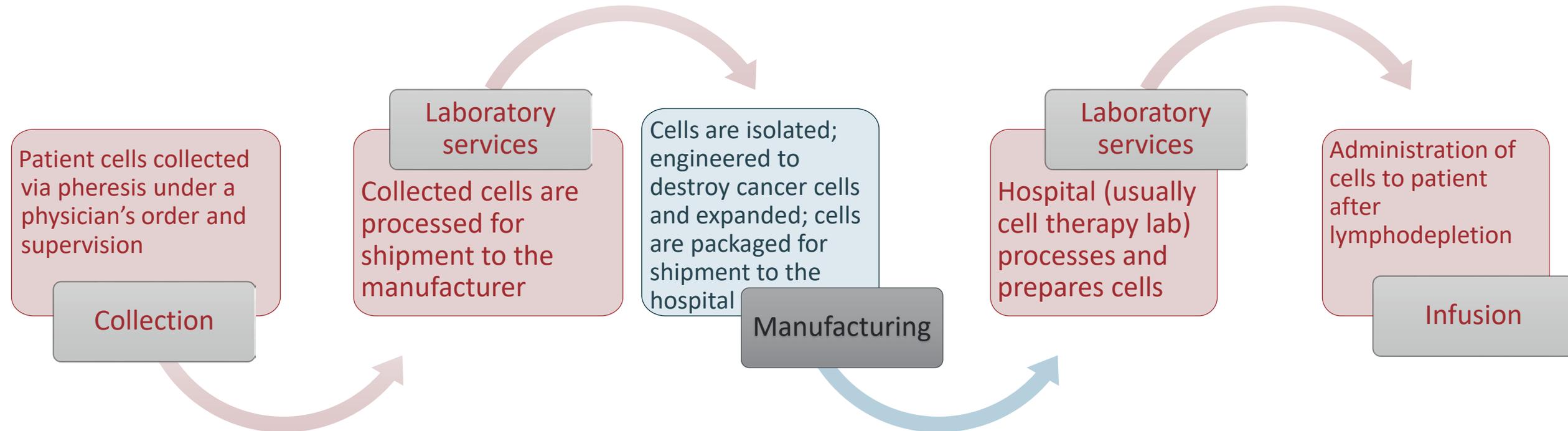
Jugna Shah, MPH, President Nimitt Consulting Inc.; Paid consultant of the ASTCT

CPT/HCPCS Codes and APC Groups the Presentation Covers

Addendum B.-Proposed OPPS Payment by HCPCS Code for CY 2020					
HCPCS Code	Short Descriptor	CI	SI	APC	Payment Rate
0537T	Bld drv t lymphcyt car-t cll		B		
0538T	Bld drv t lymphcyt prep trns		B		
0539T	Receipt&prep car-t cll admn		B		

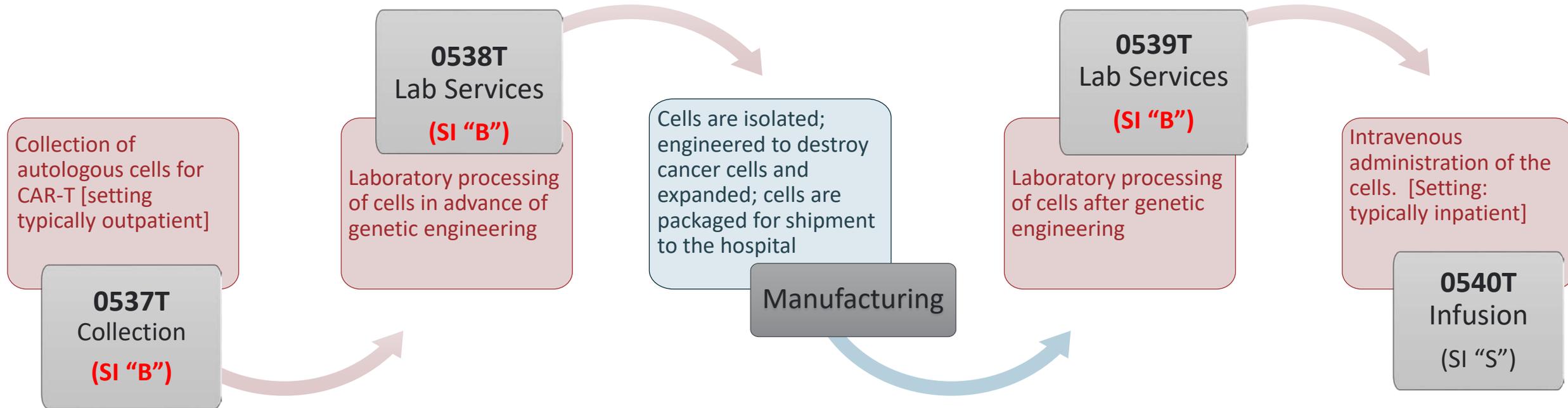
CPT codes and descriptions only are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply. Dental codes (D codes) are copyright 2018 American Dental Association. All Rights Reserved.

Description of the Issue: Clinical Summary



Chimeric Antigen Receptor T – Cell (CAR-T) Therapy requires hospital services, ordered by treating clinicians to be provided before and after the cells/drug is prepared by the manufacturer

Description of the Issue: Codes Assigned to the Clinical Services



- CMS' continued assignment of Status Indicator (SI) "B" is problematic
- The "B" results in a rejection of these charges when reported by providers on claims
 - The hospital is "allowed to report" these codes on claims, but CMS does not accept them as covered charges which means they are not packaged/bundled into other hospital services furnished during the encounter

SI of “B” for Cell Collection and Cell Processing Means Charges Are Not Recognized or Packaged into Anything, Including Product Q-Codes



- Based on language in the CY 2019 OPPS Final Rule, it seems CMS continues to believe that the costs for cell collection and cell processing which are hospital outpatient department services are included in the payment for the product Q-codes and therefore does not recognize CPT codes 0537T, 0538T, or 0539T
 - Neither manufacturer pays hospitals for cell collection and cell processing, therefore their reported ASPs for the CAR-T cellular/drug products do not reflect dollars for these services
 - Given this, why does CMS continue to believe hospitals are paid for cell collection and cell processing through the ASP+6% product payment rates for Q2040 and Q2042?
- The only ways CMS can truly recognize hospital costs for cell collection and cell processing is by providing:
 - Separate payment as previously recommended by the HOP Panel (status indicator S)
 - Conditional payment (status indicator Q1)
 - Packaged payment (status indicator N)

The continued assignment of status indicator “B” to CPT codes 0537T, 0538T, or 0539T means these services are rejected resulting in CMS being unable to recognize the charges in its APC rate-setting system



CMS Provides Separate Payment for other Autologous Cellular Services



- CMS recognizes and has provided separate payment (SI = "S") for other collection/harvesting CPT codes: 38205, 38207, and 38208

AND

- In the CY 2020 OPPI Proposed Rule, CMS proposes separate conditional payment (SI = Q1) for the following new Category III CPT code, which also involves collection/harvesting of cells (in the form of tissue):
 - **05X3T** - Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation

Recommendation



- The ASTCT requests the HOP panel again recommend to CMS that it:
 - Change status indicator “B” assigned to CAR-T Category III CPT codes for cell collection and laboratory processing services to a payable indicator
 - At a minimum, status indicator “B” should change to “Q1” similar to the other new Category III CPT cell collection code 05X3T

Recommended Status Indicators, APCs, and Payment Rates for CY 2020					
HCPCS Code	Short Descriptor	CI	SI	APC	Payment Rate
0537T	Bld drv t lymphcyt car-t cll		Q1	5242	\$1,317.51
0538T	Bld drv t lymphcyt prep trns		Q1	5241	\$392.66
0539T	Receipt&prep car-t cll admn		Q1	5241	\$392.66

CPT codes and descriptions only are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply. Dental codes (D codes) are copyright 2018 American Dental Association. All Rights Reserved.

Rationale for Recommendation



- The OPPS payment system is designed such that the services performed at each separate outpatient encounter are to be billed on individual claims with the date that the service was provided and with most specific CPT/HCPCS code available
- Cell collection and cell processing meet the definition of covered outpatient hospitals services so CMS should recognize the codes and charges submitted and hospitals should be allowed to report these services as they do others following standard claims reporting practices
- Hospitals should receive some payment for the outpatient services that they provide to patients for which they incur a cost
- Additionally, the Agency will gain visibility into the cost of these services which it could then use for future rate-setting

Expected Outcome



- Hospital burden alleviated consistent with CMS' Patients Over Paperwork Initiative
 - Billing for CAR-T cell collection and cell processing would become incredibly straightforward and existing unnecessary operational burden alleviated
- Appropriate payment for covered Part B outpatient hospital services, even when administration of CAR-T occurs in the inpatient setting since payment for these is not already embedded/included in the product/drug payment
- Payment policy consistency with other procedures that hospitals perform on outpatients for which CMS provides payment

Potential Consequences if Not Changed



- Difficulty operationalizing the CAR-T cell therapy services revenue codes and the new CAR-T product revenue code
- Lack of transparency if providers begin embedding patient care service costs into their CAR-T drug/cell product charges and questions as to whether this is appropriate per coding and billing requirements that providers are required to follow
- Lack of consistent claims data for future use
- Without compensation for the services hospitals provide to their patients, a tipping point may be reached such that the financial losses cannot be absorbed resulting in program closures and even more patient access issues
- Confusion and operational burden associated with how hospitals are to report CAR-T cell collection and processing services will persist despite CMS' Special Edition Article (SE 19009)