

Administration of Non-CAR-T Cell Immune Effector Cell Therapy

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Immune Effector Cell Therapies

- There are multiple types of immunotherapies currently being investigated in clinical trials in the United States, including immune effector cell therapies (also known as adoptive cell therapies).
- Immune effector cell therapies use a person's own genetically-engineered immune cells to treat disease.
- The majority of immune effector cell therapies being investigated are T-Cell specific¹. These include:
 - Chimeric Antigen Receptor T-Cell (CAR-T) Therapy
 - T-Cell Receptor-Engineered T-Cell (TCR-T) Therapy
 - T-Cell Antigen Coupler T-Cell (TAC-T) Therapy
 - Tumor-Infiltrating Lymphocyte (TIL) Therapy

FDA Approved Immune Effector Cell Therapies

- To date, the FDA has approved five CAR-T immune cell effector therapies for the treatment of cancer², and each unique product has a unique ICD-10-PCS code assigned³.
 - Axicabtagene Ciloleucel Immunotherapy (XW033H7 and XW043H7)
 - Tisagenlecleucel Immunotherapy (XW033J7 and XW043J7)
 - Idecabtagene Vicleucel Immunotherapy (XW033K7 and XW043K7)
 - Brexucabtagene Autoleucel Immunotherapy (XW033M7 and XW043M7)
 - Lisocabtagene Maraleucel Immunotherapy (XW033N7 and XW043N7)

ICD-10-PCS codes for Investigational CAR-T Immune Effector Cell Therapy

- Several “generic” CAR-T-related ICD-10-PCS codes have been created and allow for accurate reporting of qualified investigational CAR-T therapies when provided in the inpatient setting³.
 - XW033C7- Introduction of *Autologous* Engineered Chimeric Antigen Receptor T-cell Immunotherapy into *Peripheral Vein*, Percutaneous Approach, New Technology Group 7
 - XW033G7- Introduction of *Allogeneic* Engineered Chimeric Antigen Receptor T-cell Immunotherapy into *Peripheral Vein*, Percutaneous Approach, New Technology Group 7
 - XW043C7- Introduction of *Autologous* Engineered Chimeric Antigen Receptor T-cell Immunotherapy into *Central Vein*, Percutaneous Approach, New Technology Group 7
 - XW043G7- Introduction of *Allogeneic* Engineered Chimeric Antigen Receptor T-cell Immunotherapy into *Central Vein*, Percutaneous Approach, New Technology Group 7

ICD-10-PCS codes for Investigational Non-CAR-T Immune Effector Cell Therapy

- There are six product-specific ICD-10-PCS codes available to report the provision of investigational non-CAR-T immune effector cell therapies when provided in the inpatient setting³.
 - XW03368- Introduction of Afamitresgene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 8
 - XW04368- Introduction of Afamitresgene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 8
 - XW033L7*- Introduction of Lifileucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7
 - XW043L7*- Introduction of Lifileucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7
 - XW03378- Introduction of Tabelecleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 8
 - XW04378- Introduction of Tabelecleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 8

*On Feb. 16, 2024 the Food and Drug Administration granted accelerated approval to Lifileucel

Investigational Non-CAR-T Immune Effector Cell Therapy Clinical Trials in the U.S.^{1,4}

T-Cell Receptor Therapies (TCRs)

Sponsor	Treatment	Indication	NCT #
Adaptimmune	MAGE-A4c1032T-cells	Solid tumors	NCT03132922
Adaptimmune	AFPc332T-cells	HCC, NSCLC, melanoma, head and neck cancer, urothelial carcinoma	NCT03132792; NCT02592577; NCT02989064
Adaptimmune	MAGE A10c796T-cells	Solid Tumors	NCT02989064
Adaptimmune	NYSEO-1c259T-cells	Ovarian cancer; Melanoma	NCT01567891; NCT01350401
Bellicum Pharmaceuticals	BPX-701 (PRAME-TCR) infusion	AML, myelodysplastic syndrome, uveal melanoma	NCT02743611
GlaxoSmithKline	Anti-NY-ESO-1/LAGE-1a infusion	Neoplasms	NCT03709706
GlaxoSmithKline	NY-ESO-1c259 transduced T-cell infusion	Synovial sarcoma	NCT01343043
GlaxoSmithKline	GSK3377794 infusion	Solid tumors	NCT03967223
TCR2 Therapeutics	TC-210 T-cells	Solid tumors	NCT03907852

T-Cell Antigen Coupler T-Cell Therapies (TAC-Ts)

Sponsor	Treatment	Indication	NCT#
Triumvira Immunologics, Inc.	AC01-HER2	Relapsed HER2-Positive Solid Tumors	NCT04727151
Triumvira Immunologics, Inc.	TAC01-CLDN18.2	Locally Advanced or Metastatic Claudin 18.2+ Solid Tumors	NCT05862324

Tumor-Infiltrating Lymphocyte Therapies (TILs)

Sponsor	Treatment	Indication	NCT#
lovance	LN-145/LN-145-S1	Head and Neck Squamous Cell; Metastatic NSCLS, cervical carcinoma	NCT03083873; NCT04614103; NCT03108495
Instil Bio	ITIL-168	Advanced cutaneous melanoma	NCT05050006
lovance	IOV-4001	unresectable or metastatic melanoma or Stage III or IV NSCLC	NCT05361174
Turnstone Biologics, Corp.	TBio-4101	Advance solid tumors	NCT05576077

New ICD-10-PCS Code Request

- UCHealth has received requests to provide inpatient services for seven qualified, non-CAR-T clinical trials.
- We are kindly requesting the addition of new “generic” ICD-10-PCS codes to report the use and administration of investigational non-CAR-T immune effector cell therapies on inpatient claims.
- The addition of new “generic” ICD-10-PCS codes will create coding consistency between CAR-T and non-CAR-T investigational therapies as they are both immune effector cell therapies.
- It will provide hospital coding teams with more specific codes for investigational non-CAR-T claims and help to reduce coding errors.

References

1. Zhang P, Zhang G, Wan X. Challenges and new technologies in adoptive cell therapy. J Hematol Oncol. 2023 Aug 18;16(1):1-55.
2. Chen Y-J, Abila B, Kamel YM. CAR-T: What is Next?. Cancers (Basel) 2023 Jan 21: 15(3):1-20.
3. CMS.gov ICD-10-CM/PCS MS-DRG v39.0 Definitions Manual. DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies. https://www.cms.gov/icd10m/version39-fullcode-cms/fullcode_cms/P0038.html
4. <https://clinicaltrials.gov/>