

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053

Subject: Advanced Gene and Cellular Therapies

Effective Date: October 1, 2019

End Date:

Issue Date: February 24, 2025

Revised Date: February 2025

Date Reviewed: November 2024

Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☒

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

This policy is designed to provide direction on how the Cellular and Gene Therapies specified on this policy are reimbursed by the Plan when eligible and when the contract between Provider and the Plan does not have a stated reimbursement method for Cellular and Gene Therapies.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on Centers for Medicare and Medicaid (CMS) coverage guidelines for Commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

The scenarios outlined below are common examples that should be followed for all cell and gene therapies outlined in this policy, where applicable.

Professional (1500)

Professional reimbursement pricing methodology will be documented for applicability at a future date only at this time. Professional claims will be reimbursed at 100% of the CMS established professional rate.

If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC), or invoice cost.

Facility (UB)

Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018, to capture Chimeric Antigen Receptor T-cell (CAR-T) services and products. The 087X revenue code series must be included for services related to the therapy. Specifically, revenue codes 0874 and 0875 must be reported for the actual infusion or injection of the drug. The Plan is requiring revenue code 0891 be used to report the actual drug.

Value Code 90 with the invoice/acquisition cost needs to also be reported on any claim reporting revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. This Revenue code is more appropriate to bill for gene therapies.

Note: When drugs with Not Otherwise Classified (NOC) or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established Ambulatory Payment Classification (APC) rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition Cost (WAC), or invoice cost.

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department (HOPD) Setting

When administering the CAR-T drug in the hospital outpatient setting, report Current Procedural Terminology (CPT) code 0540T for the administration and Healthcare Common Procedure Coding System (HCPCS) Q-code Q2041 or Q2042 for the drug/biological. As discussed in the Calendar Year (CY) 2019 Outpatient Prospective Payment System Ambulatory Surgery Center (OPPS/ASC) final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPS.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11X) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – charges for modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

For facilities billing inpatient services, the drug payment will be included in their negotiated case rate.

Note: When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this policy.

APPLICABLE CELLULAR & GENE THERAPY PRODUCTS AND RELATED PLAN POLICIES:

HCPCs	Product Name	Related Highmark Medical Policies	
	Cellular Therapies: CAR-T & TCR Therapies	Commercial	Medicare Advantage
Q2041 Q2042 Q2053 Q2054 Q2055 Q2056 NOC	<ul style="list-style-type: none"> Yescarta (axicabtagene ciloleucel) Kymriah (tisagenlecleucel) Tecartus (brexucabtagene autoleucel) Breyanzi (lisocabtagene maraleucel) Abecma (idecabtagene vicleucel) Carvykti (ciltacabtagene autoleucel) Tecelra (afamitresgene autoleucel) 	<ul style="list-style-type: none"> I-180: Chimeric Antigen Receptor T-Cell & T-cell receptor (TCR) Therapies 	<ul style="list-style-type: none"> N-258: Chimeric Antigen Receptor T-Cell Therapy – NCD 110.24
	Other Cellular Therapies	Commercial	Medicare Advantage
Q2043	<ul style="list-style-type: none"> Provenge (sipuleucel-T)** 	<ul style="list-style-type: none"> I-26: Autologous Cellular Immunotherapy for Prostate Cancer S-11: Pheresis Therapy 	<ul style="list-style-type: none"> I-106: sipuleucel-T (Provenge) N-256: Autologous Cellular Immunotherapy Treatment – NCD 110.22
NOC	<ul style="list-style-type: none"> Omisirge (omidubicel-onlv) 	<ul style="list-style-type: none"> S-226: Placental/Umbilical Cord Blood as a Source of Stem Cells 	<ul style="list-style-type: none"> N/A
NOC	<ul style="list-style-type: none"> Lantidra (donislecel) 	<ul style="list-style-type: none"> S-144: Islet Cell Transplantation 	<ul style="list-style-type: none"> N/A
NOC	<ul style="list-style-type: none"> Amtagvi (Lifileucel) 	<ul style="list-style-type: none"> I-283: Lifileucel (Amtagvi) 	<ul style="list-style-type: none"> I-295: Lifileucel (Amtagvi)
	Gene Therapies	Commercial	Medicare Advantage

J3398	• Luxturna (voretigene neparvovec-rzyl)	• I-183: Voretigene Neparvovec-rzyl (Luxturna)	• I-183: Voretigene Neparvovec-rzyl (Luxturna)
J3399	• Zolgensma (onasemnogene abeparvovec-xioi)	• I-157: Treatment of Spinal Muscular Atrophy	• I-239: Treatment of Spinal Muscular Atrophy
J1411	• Hemgenix (etranacogene dezaparvovec)	• I-259: Etranacogene dezaparvovec (Hemgenix)	• I-269: Etranacogene dezaparvovec (Hemgenix)
J1412	• Roctavian (valoctocogene roxaparvovec-rvox)	• I-271: Valoctocogene Roxaparvovec-rvox (Roctavian)	• I-280: Valoctocogene Roxaparvovec-rvox (Roctavian)
J1413	• Elevidys (delandistrogene moxeparvovec)	• I-269: Delandistrogene moxeparvovec (Elevidys)	• N/A
J3393	• Zynteglo (betibeglogene autotemcel)	• I-253: Betibeglogene autotemcel (Zynteglo)	• N/A
NOC	• Skysona (elivaldogene autotemcel)	• I-258: Elivaldogene autotemcel (Skysona)	• N/A
NOC	• Casgevy (exagamglogene autotemcel)	• I-281: Exagamglogene autotemcel (Casgevy)	• I-290: Exagamglogene autotemcel (Casgevy)
J3394	• Lyfgenia (lovotibeglogene autotemcel)	• I-282: Lovotibeglogene autotemcel (Lyfgenia)	• I-291: Lovotibeglogene autotemcel (Lyfgenia)
NOC	• Lenmeldy (atidarsagene autotemcel)		• N/A
NOC	• Beqvez (fidanacogene elaparvovec-dzkt)	• I-284	
		• I-285	• I-296
J9325	• Imlygic (talimogene laherparepvec)**	• I-147: Talimogene Laherparepvec (Imlygic)	• I-147: Talimogene Laherparepvec (Imlygic)
J9029	• Adstiladrin (nadofaragene firadenovec)**	• I-264: Nadofaragene firadenovec-vncg (Adstiladrin)	• I-274: Nadofaragene firadenovec-vncg (Adstiladrin)
J3401	• Vyjuvek (beremeagene geperpavec-svdt)**	• G-49: Beremagene geperpavec-svdt (Vyjuvek)	• G-55: Beremagene geperpavec-svdt (Vyjuvek)
	RNA Therapies	Commercial	Medicare Advantage
J2326	• Spinraza (nusinersen)**	• I-157: Treatment of Spinal Muscular Atrophy	• I-239: Treatment of Spinal Muscular Atrophy

**May warrant multiple administrations based on recommended use, as outlined in the product prescribing information.

Place of service (inpatient/outpatient) may be variable based on patient-specific requirements, unique administration requirements, need for close monitoring, and specifications in treatment protocols by each qualified treatment center.

NOC (not otherwise classified) codes for unclassified biologic drugs consists of J3590 and C9399 (for hospital outpatient use only). When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

DEFINITIONS:

Term or Acronym	Definition
Gene Therapy	The use of genetic material in the treatment or prevention of disease. The transferred genetic material changes how cells produce disease modifying protein(s). The therapeutic impact can include gene addition, correction, silencing, reprogramming, or cell elimination.

Cell Therapy	The transfer of intact, live cells into a patient to help reduce or cure a disease. The cells may be autologous (originating from the patient) or allogeneic (originating from donor). The type of cells administered depends on the treatment and can be classified by their potential to transform into different cell types.
Chimeric Antigen Receptor (CAR)-T Cell Therapy	A method of modifying the patient's own immune cells (T-cells) to express a receptor on their surface that recognizes structures (antigens) on the surface of malignant cells. Once the receptor binds to a tumor antigen, the T-cell is stimulated to attack the malignant cells.
RNA therapy	The use of shorter sequences of genetic material in RNA format to treat or prevent a disease. These therapies typically require repeat dosing to maintain a therapeutic effect since the DNA is not being enhanced or modified.

MODIFIERS:

Modifier LU: Fractionated payment of CAR-T-Therapy

The Plan does not reimburse fractionate amounts for CAR-T therapy services. Providers should not report this modifier or bill fractionated CAR-T services on claims.

REFERENCES:

- National Uniform Billing Committee, UB-04 Data Specifications Manual 2024
[National Uniform Billing Committee | NUBC](#)
- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19024.pdf>

POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
1 / 2020	Added Medicare Statement, removed medical policy I-180, ref MLN article, ref. N-XXX-001
5 / 2020	Updated Inpatient guidelines for CPT codes Q2042 and Q2041
11 / 2020	Added new Revenue code under the Outpatient Section. Also added a new drug Tecartus
1 / 2021	Removed Medicare Statement, Added Code C9073 for Tecartus
7 / 2021	Added C9076 and C9399. Added new policy header with expanded regional checkboxes
10 / 2021	Added Q2054 in place of C9076, Q2053 in place of C9073, C9081 in place of C9399
1 / 2022	Replaced C9081 with new code Q2055 for the same drug
4 / 2022	Removed I-206 Onasemnogene Apeparvovec (Zolgensma)
5 / 2022	Removed Value Code 86 replaced with Value Code 90 under Outpatient Section
7 / 2022	Added code C9098
10 / 2022	Replaced C9098 with new code Q2056 for the same drug
1 / 2023	Added direction for modifier LU

1 / 2024	Added novel therapies, HCPCs codes, and corresponding medical policies since the last update. Administrative changes were also made for clarity and alignment with current contracts.
8 / 2024	Added novel therapies, HCPCs codes, and updated corresponding medical policies. Administrative changes were also made for clarity and alignment with current contracts.
2 / 2025	Added new cell and gene therapies Beqvez and Tecelra. Replaced NOC with updated HCPCs for Zynteglo (J3393) and Lyfgenia (J3394). Updated references for Lenmeldy and Beqvez.

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053

Subject: Advanced Gene and Cellular Therapies

Effective Date: October 1, 2019

End Date:

Issue Date: August 8, 2024

Revised Date: August 2024

Date Reviewed: May 2024

Source: Reimbursement Policy

Applicable Commercial Market

PA ☐ WV ☒ DE ☐ NY ☐

Applicable Medicare Advantage Market

PA ☐ WV ☒ DE ☐ NY ☐

Applicable Claim Type

UB ☐ 1500 ☒

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

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PURPOSE:

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Gene therapy is the use of genetic material in the treatment or prevention of disease. The transferred genetic material changes how cells produce disease modifying protein(s). The therapeutic impact can include gene addition, correction, silencing, reprogramming, or cell elimination.

Cell therapy is the transfer of intact, live cells into a patient to help reduce or cure a disease. The cells may be autologous (originating from the patient) or allogeneic (originating from donor). The type of cells administered depends on the treatment and can be classified by their potential to transform into different cell types. **Chimeric antigen receptor (CAR)-T cell therapy** is a way of modifying the patient's own immune cells (T-cells) to express a receptor on their surface that recognizes structures (antigens) on the surface of malignant cells. Once the receptor binds to a tumor antigen, the T-cell is stimulated to attack the malignant cells.

RNA therapy is the use of shorter sequences of genetic material in RNA format to treat or prevent a disease. These therapies typically require repeat dosing to maintain a therapeutic effect since the DNA is not being enhanced or modified.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on Centers for Medicare and Medicaid (CMS) coverage guidelines for commercial and Medicare Advantage claims.

APPLICABLE CELLULAR & GENE THERAPY PRODUCTS AND RELATED HIGHMARK POLICIES:

HCPCs	Product Name	Related Highmark Medical Policies	
	Cellular Therapies: CAR-T	Commercial	Medicare Advantage
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	Other Cellular Therapies	Commercial	Medicare Advantage
Q2043	<ul style="list-style-type: none"> Provenge (sipuleucel-T)** 	<ul style="list-style-type: none"> I-26: Autologous Cellular Immunotherapy for Prostate Cancer S-11: Pheresis Therapy 	<ul style="list-style-type: none"> I-106: sipuleucel-T (Provenge) N-256: Autologous Cellular Immunotherapy Treatment – NCD 110.22
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NOC	<ul style="list-style-type: none"> Lantidra (donislecel) 	<ul style="list-style-type: none"> S-144: Islet Cell Transplantation 	<ul style="list-style-type: none"> N/A
NOC	<ul style="list-style-type: none"> Amtagvi (Lifileucel) 	<ul style="list-style-type: none"> I-283: Lifileucel (Amtagvi) 	<ul style="list-style-type: none"> I-295: Lifileucel (Amtagvi)
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J3399	<ul style="list-style-type: none"> Zolgensma (onasemnogene abeparvovec-xioi) 	<ul style="list-style-type: none"> I-157: Treatment of Spinal Muscular Atrophy 	<ul style="list-style-type: none"> I-239: Treatment of Spinal Muscular Atrophy
J1411	<ul style="list-style-type: none"> Hemgenix (etranacogene dezaparvovec) 	<ul style="list-style-type: none"> I-259: Etranacogene dezaparvovec (Hemgenix) 	<ul style="list-style-type: none"> I-269: Etranacogene dezaparvovec (Hemgenix)
J1412	<ul style="list-style-type: none"> Roctavian (valoctocogene roxaparvovec-rvox) 	<ul style="list-style-type: none"> I-271: Valoctocogene Roxaparvovec-rvox (Roctavian) 	<ul style="list-style-type: none"> I-280: Valoctocogene Roxaparvovec-rvox (Roctavian)
J1413	<ul style="list-style-type: none"> Elevidys (delandistrogene moxeparvovec) 	<ul style="list-style-type: none"> I-269: Delandistrogene moxeparvovec (Elevidys) 	<ul style="list-style-type: none"> N/A
NOC	<ul style="list-style-type: none"> Zynteglo (betibeglogene autotemcel) 	<ul style="list-style-type: none"> I-253: Betibeglogene autotemcel (Zynteglo) 	<ul style="list-style-type: none"> N/A
NOC	<ul style="list-style-type: none"> Skysona (elivaldogene autotemcel) 	<ul style="list-style-type: none"> I-258: Elivaldogene autotemcel (Skysona) 	<ul style="list-style-type: none"> N/A
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NOC	<ul style="list-style-type: none"> Lenmeldy (atidarsagene autotemcel) 	<ul style="list-style-type: none"> TBD 	<ul style="list-style-type: none"> TBD
J9325	<ul style="list-style-type: none"> Imlygic (talimogene laherparepvec)** 	<ul style="list-style-type: none"> I-147: Talimogene Laherparepvec (Imlygic) 	<ul style="list-style-type: none"> I-147: Talimogene Laherparepvec (Imlygic)
J9029	<ul style="list-style-type: none"> Adstiladrin (nadofaragene firadenovec)** 	<ul style="list-style-type: none"> I-264: Nadofaragene firadenovec-vncg (Adstiladrin) 	<ul style="list-style-type: none"> I-274: Nadofaragene firadenovec-vncg (Adstiladrin)
J3401	<ul style="list-style-type: none"> Vyjuvek (beremeagene geperpavec-svdt)** 	<ul style="list-style-type: none"> G-49: Beremagene geperpavec-svdt (Vyjuvek) 	<ul style="list-style-type: none"> G-55: Beremagene geperpavec-svdt (Vyjuvek)
	RNA Therapies	Commercial	Medicare Advantage
J2326	<ul style="list-style-type: none"> Spinraza (nusinersen)** 	<ul style="list-style-type: none"> I-157: Treatment of Spinal Muscular Atrophy 	<ul style="list-style-type: none"> I-239: Treatment of Spinal Muscular Atrophy

**May warrant multiple administrations based on recommended use, as outlined in the product prescribing information.

Place of service (inpatient/outpatient) may be variable based on patient-specific requirements, unique administration requirements, need for close monitoring, and specifications in treatment protocols by each qualified treatment center.

NOC (not otherwise classified) codes for unclassified biologic drugs consists of J3590 and C9399 (for hospital outpatient use only). When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

REIMBURSEMENT GUIDELINES:

The scenarios outlined below are common examples that should be followed for all cell and gene therapies outlined in this policy, where applicable.

Professional (1500)

Professional reimbursement pricing methodology will be documented for applicability at a future date only at this time.

Professional claims will be reimbursed at 100% of the CMS established professional rate. If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC), or invoice cost.

Facility (UB)

Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018, to capture CAR-T services and products. The 087X revenue code series must be included for services related to the therapy. Specifically, revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. The Plan is requiring revenue code 891 be used to report the actual drug. Value Code 90 with the invoice/acquisition cost needs to also be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. This Revenue code is more appropriate to bill for gene therapies.

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC), or invoice cost.

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPI/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPI.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

For facilities that bill for inpatient services, the drug payment will be included in their negotiated case rate.

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

MODIFIERS:

Modifier LU: Fractionated payment of CAR-T-Therapy

The Plan does not reimburse fractionate amounts for CAR-T therapy services. Providers should not report this modifier or bill fractionated CAR-T services on claims.

REFERENCES:

- National Uniform Billing Committee, UB-04 Data Specifications Manual 2024
[National Uniform Billing Committee | NUBC](#)
- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
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POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
1 / 2020	Added Medicare Statement, removed medical policy I-180, ref MLN article, ref. N-XXX-001
5 / 2020	Updated Inpatient guidelines for CPT codes Q2042 and Q2041
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7 / 2022	Added code C9098
10 / 2022	Replaced C9098 with new code Q2056 for the same drug
1 / 2023	Added direction for modifier LU
8 / 2024	Added novel therapies, HCPCS codes, and updated corresponding medical policies. Administrative changes were also made for clarity and alignment with current contracts.

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053

Subject: Gene and Cellular Therapy (CAR-T)

Effective Date: October 1, 2019

End Date:

Issue Date: January 9, 2023

Revised Date: January 2023

Date Reviewed: December 2022

Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☒

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible. Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells. Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Professional claims will be reimbursed at 100% of the CMS established professional rate. If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018, to capture CAR-T services and products. The 087X revenue code series must be included for services related to the therapy. Specifically, revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. Value Code 90 with the invoice/acquisition cost needs to also be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. The FDA also approved a new gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

Applicable Codes:

Q2042* – Kymriah	J3399 – Zolgensma
Q2041* – Yescarta	Q2053 – Brexucabtagene Autoleucel (Tecartus)
J2326 – Spinraza	Q2054 – Lisocabtagene Maraleucel (Breyanzi)
J3398 – Luxturna	Q2055 – Idecabtagene Vicleucel (Abecma)
	Q2056 – Ciltacabtagene Autoleucel

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPI/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPI.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza	Q2053 - Brexucabtagene Autoleucel (Tecartus).
J3398 – Luxturna	Q2054 - Lisocabtagene Maraleucel (Breyanzi)
J3399 – Zolgensma	Q2055 - Idecabtagene Vicleucel (Abecma)
	Q2056 – Ciltacabtagene Autoleucel

Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

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MODIFIERS:

Modifier LU: Fractionated payment of CAR-T-Therapy

The Plan does not reimburse fractionate amounts for CAR-T therapy services. Providers should not report this modifier or bill fractionated CAR-T services on claims.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-157: Treatment of Spinal Muscular Atrophy
- I-183: Voretigene Neparvovec-rzyl (Luxturna)

Refer to the following Medicare Advantage Medical Policies for additional information:

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Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053

Subject: Gene and Cellular Therapy (CAR-T)

Effective Date: October 1, 2019

End Date:

Issue Date: October 1, 2022

Revised Date: October 2022

Date Reviewed: September 2022

Source: Reimbursement Policy

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PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

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Applicable Claim Type

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Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053

Subject: Gene and Cellular Therapy (CAR-T)

Effective Date: October 1, 2019

End Date:

Issue Date: July 1, 2022

Revised Date: June 2022

Date Reviewed: June 2022

Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☒

Applicable Claim Type

UB ☒ 1500 ☒

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Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP-053

Subject: Gene and Cellular Therapy (CAR-T)

Effective Date: October 1, 2019

End Date:

Issue Date: May 25, 2022

Revised Date: April 2022

Date Reviewed: April 2022

Source: Reimbursement Policy

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This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible. Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells. Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Professional claims will be reimbursed at 100% of the CMS established professional rate. If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018 to capture CAR-T services and products. The 087X revenue code series must be included for services related to the therapy. Specifically, revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. Value Code 90 with the invoice/acquisition cost needs to also be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. The FDA also approved a new gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

Applicable Codes:

Q2042* – Kymriah	J3399 – Zolgensma
Q2041* – Yescarta	Q2053 – Brexucabtagene Autoleucel (Tecartus)
J2326 – Spinraza	Q2054 – Lisocabtagene Maraleucel (Breyanzi)
J3398 – Luxturna	Q2055 – Idecabtagene Vicleucel (Abecma)

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPI/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPI.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza	Q2053 - Brexucabtagene Autoleucel (Tecartus).
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J3399 – Zolgensma	Q2055 - Idecabtagene Vicleucel (Abecma)

Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

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RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-157: Treatment of Spinal Muscular Atrophy
- I-183: Voretigene Neparvovec-rzyl (Luxturna)

Refer to the following Medicare Advantage Medical Policies for additional information:

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- I-157: Treatment of Spinal Muscular Atrophy
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REFERENCES:

This policy has been developed through consideration of the following:

- National Uniform Billing Committee, UB-04 Data Specifications Manual 2022
[National Uniform Billing Committee | NUBC](#)
- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
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POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
1 / 2020	Added Medicare Statement, removed Commercial I-180, ref MLN article, ref. N-XXX-001
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01 / 2022	Replaced C9081 with new code Q2055 for the same drug.
04 / 2022	Medical Policy I-206 Onasemnogene Apeparvovec (Zolgensma) was archived. I-157 policy name change
05 / 2022	Removed Value Code 86 replaced with Value Code 90 under Outpatient Section

Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019 **End Date:**
Issue Date: April 4, 2022 **Revised Date:** February 2022
Date Reviewed: February 2022
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☐

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☐

Applicable Claim Type

UB ☒ 1500 ☒

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible. Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells. Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

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Professional (1500):

Professional claims will be reimbursed at 100% of the CMS established professional rate. If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

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All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018 to capture CAR-T services and products. The 087X revenue code series must be included for services related to the therapy. Specifically, revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost needs to also be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. The FDA also approved a new gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

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***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

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Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

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In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

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Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

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This policy has been developed through consideration of the following:

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Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019 **End Date:**
Issue Date: December 1, 2021 **Revised Date:** November 2021
Date Reviewed: November 2021
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☐

Applicable Medicare Advantage Market

PA ☒ WV ☒ DE ☒ NY ☐

Applicable Claim Type

UB ☒ 1500 ☒

➔ A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible. Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells. Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

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In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

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Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP- RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019 **End Date:**
Issue Date: October 25, 2021 **Revised Date:** September 2021
Date Reviewed: September 2021
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒ NY ☐

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PA ☒ WV ☒ DE ☒ NY ☐

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Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza	Q2053 - Brexucabtagene Autoleucel (Tecartus).
J3398 – Luxturna	Q2054 - Lisocabtagene Maraleucel (Breyanzi)
J3399 – Zolgensma	C9081- Idecabtagene Vicleucel (Abecma)

Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

Q2042* – Kymriah	Q2054 - Lisocabtagene Maraleucel (Breyanzi)
Q2041* – Yescarta	C9081- Idecabtagene Vicleucel (Abecma)

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-157: Nusinersen (Spinraza)
- I-183: Voretigene Neparvovec-rzyl (Luxturna)
- I-206: Onasemnogene Abeparvovec (Zolgensma)

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-180: Chimeric Antigen Receptor T-Cell Therapy
- I-157: Nusinersen (Spinraza)
- I-183: Voretigene Neparvovec-rzyl (Luxturna)
- I-206: Onasemnogene Abeparvovec (Zolgensma)

REFERENCES:

This policy has been developed through consideration of the following:

- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
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POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
1 / 2020	Added Medicare Statement, removed Commercial I-180, ref MLN article, ref. N-XXX-001
5 / 2020	Updated Inpatient guidelines for CPT codes Q2042 and Q2041
11 / 2020	Added new Revenue code under the Outpatient Section. Also added a new drug Tecartus.
1 / 2021	Removed Medicare Statement, Added Code C9073 for Tecartus
7 / 2021	Added C9076 and C9399. Added new policy header with expanded regional checkboxes.
10 / 2021	Added Q2054 in place of C9076, Q2053 in place of C9073, C9081 in place of C9399

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019
Issue Date: July 29, 2021
Date Reviewed: July 2021
Source: Reimbursement Policy

End Date:

Revised Date: July 2019

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>	NY	<input type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input type="checkbox"/>	NY	<input type="checkbox"/>
UB	<input checked="" type="checkbox"/>	1500	<input checked="" type="checkbox"/>				

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible. Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells. Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Professional claims will be reimbursed at 100% of the CMS established professional rate. If no Medicare professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective January 1, 2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs" - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. There is now an FDA approved gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

Applicable Codes:

Q2042* – Kymriah	J3399– Zolgensma
Q2041* – Yescarta	C9073- Brexucabtagene Autoleucel (Tecartus)
J2326 – Spinraza	C9076 -Lisocabtagene Maraleucel (Breyanzi)
J3398 – Luxturna	C9399*-Idcabtagene Vicleucel (Abecma)

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPTS/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPTS.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza	C9073 - Brexucabtagene Autoleucel (Tecartus).
J3398 – Luxturna	C9076 - Lisocabtagene Maraleucel (Breyanzi)
J3399 – Zolgensma	C9399*- Idecabtagene Vicleucel (Abecma)

Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

Q2042* – Kymriah	C9076 - Lisocabtagene Maraleucel (Breyanzi)
Q2041* – Yescarta	C9399*- Idecabtagene Vicleucel (Abecma)

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Commercial Medical Policies for additional information:

- I-157: Nusinersen (Spinraza)

- I-183: Voretigene Neparvovec-rzyl (Luxturna)
- I-206: Onasemnogene Abeparvovec (Zolgensma)

Refer to the following Medicare Advantage Medical Policies for additional information:

- I-180: Chimeric Antigen Receptor T-Cell Therapy
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REFERENCES:

This policy has been developed through consideration of the following:

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1 / 2021	Removed Medicare Statement, Added Code C9073 for Tercartus
7 / 2021	Added C9076 and C9399. Added new policy header with expanded regional checkboxes.

Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019
End Date:
Issue Date: July 12, 2021
Revised Date: June 2021
Date Reviewed: June 2021
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒

Applicable Claim Type

UB ☒ 1500 ☒

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible.

Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells.

Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Reimbursement - Professional claims will be reimbursed at 100% of the CMS established Professional rate. If no Medicare Professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective 1/1/2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. There is now an FDA approved gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

Applicable Codes:

Q2042* – Kymriah
 Q2041* – Yescarta
 J2326 – Spinraza
 J3398 – Luxturna
 J3399 – Zolgensma
 C9073- Brexucabtagene Autoleucel (Tecartus).
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 C9399*-Idcabtagene Vicleucel (Abecma)

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPTS/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPTS.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza
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Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

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***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

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7 / 2021	Adding CPT codes C9076 -Lisocabtagene Maraleucel (Breyanzi) C9399*-Idcabtagene Vicleucel (Abecma)

HISTORY

Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019
End Date:
Issue Date: January 1, 2021
Revised Date: December 2020
Date Reviewed: November 2020
Source: Reimbursement Policy

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>		
UB	<input checked="" type="checkbox"/>	1500	<input checked="" type="checkbox"/>		

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

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Applicable Codes:

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Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

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Facilities that bill for inpatient services for the following drug payment will be included in their negotiated case rate.

Applicable codes:

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Highmark Reimbursement Policy Bulletin



HISTORY VERSION

Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019
End Date:
Issue Date: November 1, 2020
Revised Date: September 2020
Date Reviewed: September 2020
Source: Reimbursement Policy

Applicable Commercial Market

PA ☒ WV ☒ DE ☒

Applicable Medicare Advantage Market

PA ☒ WV ☒

Applicable Claim Type

UB ☒ 1500 ☒

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible.

Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells.

Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Effective August 7, 2019 and for calendar years 2019 and 2020, Fee For Service (FFS) Medicare will pay for CAR-T cell therapy for beneficiaries enrolled in a Medicare Advantage (MA) plan when the coverage criteria outlined in the decision memorandum is met.

(See references area below for the link)

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Reimbursement - Professional claims will be reimbursed at 100% of the CMS established Professional rate. If no Medicare Professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):

Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective 1/1/2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891. Revenue code 0892 - "Special Processed Drugs - FDA Approved Gene Therapy. This mirrors the existing code 0891 for cell therapy products. There is now an FDA approved gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA). This new Revenue code is more appropriate to bill for gene therapies.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department ("HOPD") Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPI/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPI.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT

codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza
J3398 – Luxturna
J3590* – Zolgensma

The following temporary codes are assigned for the following new drug therapy.
J3590*, J9999*, C9399* - Brexucabtagene Autoleucel (Tecartus).

Facilities that bill for inpatient services for the following drugs will be included in their negotiated case rate.

Applicable codes:

Q2042* – Kymriah
Q2041* – Yescarta

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

- Medicare Advantage Policy I-180: Chimeric Antigen Receptor T-Cell Therapy
- Commercial Policy I-157: Nusinersen (Spinraza)
- Medicare Advantage Policy I-157: Nusinersen (Spinraza)
- Commercial Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Medicare Advantage Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Commercial Policy I-206: Onasemnogene Apeparvovec (Zolgensma)
- Medicare Advantage Policy I-206: Onasemnogene Apeparvovec (Zolgensma)

REFERENCES:

This policy has been developed through consideration of the following:

- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19024.pdf>

POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
01 / 2020	Added Medicare Statement, removed Commercial I-180, ref MLN article, ref. N-XXX-001
05 / 2020	Updated Inpatient guidelines for CPT codes Q2042 and Q2041
11 / 2020	Added new Revenue code under the Outpatient Section. Also added a new drug Tecartus for services and associated procedure codes for billing of that drug.

Highmark Reimbursement Policy Bulletin

HISTORY VERSION



Bulletin Number: RP-053
Subject: Gene and Cellular Therapy (CAR-T)
Effective Date: October 1, 2019
End Date:
Issue Date: May 1, 2020
Revised Date: April 2020
Date Reviewed: December 2019
Source: Reimbursement Policy

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>		
UB	<input checked="" type="checkbox"/>	1500	<input checked="" type="checkbox"/>		

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible.

Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells.

Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Effective August 7, 2019 and for calendar years 2019 and 2020, Fee For Service (FFS) Medicare will pay for CAR-T cell therapy for beneficiaries enrolled in a Medicare Advantage (MA) plan when the coverage criteria outlined in the decision memorandum is met.

(See references area below for the link)

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Reimbursement - Professional claims will be reimbursed at 100% of the CMS established Professional rate. If no Medicare Professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):

Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective 1/1/2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department (“HOPD”) Setting:

When administering the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPSS/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPSS.

Report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

J2326 – Spinraza
J3398 – Luxturna
J3590* – Zolgensma

Facilities that bill for inpatient services for the following drugs will be included in their negotiated case rate.

Applicable codes:

Q2042* – Kymriah
Q2041* – Yescarta

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

- Medicare Advantage Policy I-180: Chimeric Antigen Receptor T-Cell Therapy
- Commercial Policy I-157: Nusinersen (Spinraza)
- Medicare Advantage Policy I-157: Nusinersen (Spinraza)
- Commercial Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Medicare Advantage Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Commercial Policy I-206: Onasemnogene Abeparvovec (Zolgensma)
- Medicare Advantage Policy I-206: Onasemnogene Abeparvovec (Zolgensma)

REFERENCES:

This policy has been developed through consideration of the following:

- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19024.pdf>

POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
01 / 2020	Added Medicare Statement, removed Commercial I-180, ref MLN article, ref. N-XXX-001
05 / 2020	Updated Inpatient guidelines for CPT codes Q2042 and Q2041

Highmark Reimbursement Policy Bulletin



[CLICK FOR HISTORY VERSION](#)

Bulletin Number: RP-053
Subject: Gene and Cellular Therapy
Effective Date: October 1, 2019
Issue Date: February 1, 2020
Date Reviewed: December 2019
Source: Reimbursement Policy

End Date:

Revised Date: January 2020

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>		
UB	<input checked="" type="checkbox"/>	1500	<input checked="" type="checkbox"/>		

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible.

Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells.

Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Effective August 7, 2019 and for calendar years 2019 and 2020, Fee For Service (FFS) Medicare will pay for CAR-T cell therapy for beneficiaries enrolled in a Medicare Advantage (MA) plan when the coverage criteria outlined in the decision memorandum is met.

(See references area below for the link)

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Reimbursement - Professional claims will be reimbursed at 100% of the CMS established Professional rate. If no Medicare Professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):

Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective 1/1/2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department (“HOPD”) Setting:

In instances when you administer the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPTS/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPTS.

However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

Q2042* – Kymriah
 Q2041* – Yescarta
 J2326 – Spinraza
 J3398 – Luxturna
 J3590* – Zolgensma

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

- Medicare Advantage Policy I-180: Chimeric Antigen Receptor T-Cell Therapy
- Commercial Policy I-157: Nusinersen (Spinraza)
- Medicare Advantage Policy I-157: Nusinersen (Spinraza)
- Commercial Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Medicare Advantage Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Commercial Policy I-206: Onasemnogene Abeparvovec (Zolgensma)
- Medicare Advantage Policy I-206: Onasemnogene Abeparvovec (Zolgensma)

REFERENCES:

This policy has been developed through consideration of the following:

- MLN Matters, SE19009, Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
- MLN Matters, SE19024, Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19024.pdf>

POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
01 / 2020	Added Medicare Statement, removed Commercial I-180, ref MLN article, ref. N-XXX-001

Highmark Reimbursement Policy Bulletin



Bulletin Number: RP-053
Subject: Gene and Cellular Therapy
Effective Date: October 1, 2019
Issue Date: September 9, 2019
Date Reviewed: July 2019
Source: Reimbursement Policy

End Date:

Revised Date:

Applicable Commercial Market

Applicable Medicare Advantage Market

Applicable Claim Type

PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>	DE	<input checked="" type="checkbox"/>
PA	<input checked="" type="checkbox"/>	WV	<input checked="" type="checkbox"/>		
UB	<input checked="" type="checkbox"/>	1500	<input checked="" type="checkbox"/>		

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

This policy is designed to provide direction on how the Gene & Cellular Therapy drugs specified on this policy are reimbursed by the Plan when eligible.

Gene therapy is an evolving technique that uses genes to treat or prevent disease. Gene therapy targets the cause of disease by delivering a fully functioning copy of the gene into motor neuron cells.

Cellular/Chimeric Antigen Receptor (CAR) T-cell Therapy is a process where the patient's T Cells are genetically modified in the laboratory to attack cancer cells. This type of immunotherapy uses a patient's own T Cells to locate and kill cancer cells.

This policy does not guarantee coverage or clinical approval for Commercial or Medicare Advantage. The Plan's determination of coverage will be based on CMS coverage guidelines for commercial and Medicare Advantage claims.

REIMBURSEMENT GUIDELINES:

Professional reimbursement pricing methodology is documented for applicability at a future date only at this time.

Professional (1500):

Reimbursement - Professional claims will be reimbursed at 100% of the CMS established Professional rate. If no Medicare Professional rate exists, then the drug(s) – referenced below – will pay at the wholesale acquisition cost (WAC).

Facility (UB):Outpatient

All claims must include revenue codes created by National Uniform Billing Committee (NUBC) effective 1/1/2018 to capture CAR-T services and products. 087X revenue code series must be included for services related to the therapy, specifically revenue codes 874 and 875 must be reported for the actual infusion or injection of the drug. Highmark is requiring revenue code 891 be used to report the actual drug. The new Value Code 86 with the invoice/acquisition cost also needs to be reported on any claim that reports revenue code 891.

Note: Outpatient claims will be reimbursed at 100% of the CMS established APC rate. If no APC rate exists, then the drug(s) – referenced below – will pay at the Wholesale Acquisition cost (WAC).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Department (“HOPD”) Setting:

In instances when you administer the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPS/ASC final rule (83 FR 58904), the procedures described by CPT codes 0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPS.

However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Highmark will reject them on the outpatient claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Highmark will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q-code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the hospital outpatient setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Inpatient

If the claim is billed as inpatient, the drug charge will not be included in the DRG cost outlier calculation. The drug will be reimbursed separately per the outpatient reimbursement guidelines outlined in this policy.

Applicable codes:

Q2042* – Kymriah
 Q2041* – Yescarta
 J2326 – Spinraza
 J3398 – Luxturna
 J3590* – Zolgensma

***Note:** When drugs with NOC or temporary codes are assigned a specific code, they will remain applicable to this Policy.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

- Commercial Policy I-180: Chimeric Antigen Receptor T-Cell Therapy
- Medicare Advantage Policy I-180: Chimeric Antigen Receptor T-Cell Therapy
- Commercial Policy I-157: Nusinersen (Spinraza)
- Medicare Advantage Policy I-157: Nusinersen (Spinraza)
- Commercial Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Medicare Advantage Policy I-183: Voretigene Neparvovec-rzyl (Luxturna)
- Commercial Policy I-206: Onasemnogene Abeparvovec (Zolgensma)
- Medicare Advantage Policy I-206: Onasemnogene Abeparvovec (Zolgensma)

REFERENCES:

This policy has been developed through consideration of the following:

- SE19009 - Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>

POLICY UPDATE HISTORY INFORMATION:

10 / 2019	Implementation
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HISTORICAL