

COMMERCIAL REIMBURSEMENT POLICY

Cellular and Gene Therapy Products

Active

Section: General Coding
Policy Number: 074
Effective Date: 05/01/24

Description

This policy addresses coding and reimbursement for Cellular and Gene Therapy Products.

This policy does not apply to FEP.

Definitions

Healthcare Common Procedure Coding System (HCPCS) codes include medical therapies and drugs that ordinarily cannot be self-administered, such as chemotherapy drugs, immunosuppressive drugs, inhalation solutions, and other miscellaneous drugs, solutions, and implants. Typically, cellular and gene therapy products are submitted with an unlisted HCPCS code. Refer to *Commercial Reimbursement Policy General Coding – 005 Unlisted Codes*.

Cellular Therapy: The transfer of cells into a person with the goal of improving a disease or to replace or repair damaged tissue. Gene modified cell therapy removes the cells from a person's body and alters the genetic material of the cell. The modified cells are then reintroduced into the body.

Gene Therapy: The introduction, removal, or change in the content of a person's genetic material with the goal of treating or curing a disease. It includes therapies such as gene transfer, gene modified cell therapy, and gene editing.

Policy Statement

Submit the HCPCS Level II code that best describes the injection given in terms of the drug and dosage. Codes for injections include the charge for the drug only. When the dosage given is greater than that listed, use the units field to specify the appropriate number of units according to code definition found in the HCPCS manual.

Reimbursement

Reimbursement will be determined on the following methodology:

- Wholesale Acquisition (WAC) reimbursement

Applicable Cellular and Gene Therapy Products:

The following table represents a subset of products and codes reimbursed with WAC payment methodology.

Name (Product Name)	HCPCS Codes
Atidarsagene Atotemcel (LENMELDY)	J3490, J3590, C9399
Axicabtagene Ciloleucel (YESCARTA)	Q2041
Beremeagene Geperpavec-svdt (VYJUVEK)	J3401
Betibeglogene Autotemcel (ZYNTEGLO)	J3490, J3590, C9399
Brexucabagene Autoleucel (TECARTUS)	Q2053
Ciltacabtagene Autoleucel (CARVYKTI)	Q2056
Delandistrogene Moxeparvovec (ELEVIDYS)	J1413
Donislecel (LANTIDRA)	J3490, C9399
Elivaldogene Autotemcel (SKYSONA)	J3590, C9399
Etranacogene Dezaparvovec (HEMGENIX)	J1411
Exagamglogene Autotemcel (CASGEVY)	J3590, C9399
Fidanacogene Eleparvovec (BEQVEZ)	J3490, J3590, C9399
Idecabtagene Vicleucel (ABECMA)	Q2055
Lifileucel (AMTAGVI)	J3490, J3590, C9399
Lisocabtagene Maraleucel (BREYANZI)	Q2054
Lovotibeglogene Autotemcel (LYFGENIA)	J3590, C9399
Lumasiran (OXLUMO)	J0224
Nadofaragene Firadenovec (ADSTILADRIN)	J9029
Nursinersen (SPINRAZA)	J2326
Omidubicel-only (OMISIRGE)	J3490, J3590, C9399
Onasemnogene Abeparvovec-xioi (ZOLGENSMA)	J3399
Patisiran (ONPATTRO)	J0222
Sipuleucel-T (PROVENGE)	Q2043
Talimogene Laherparepvec (IMLYGIC)	J9325
Tisagenlecleucel (KYMRIAH)	Q2042
Valoctocogene roxaparvovec-rvox (ROCTAVIAN)	J1412
Voretigene Neparvovec-rzyl (LUXTURNA)	J3398
Vutrisiran (AMVUTTRA)	J0225



Documentation Submission

Documentation must identify and describe the drug, dosage, and reason administered. Provide the National Drug Code (NDC) number, full description/name, strength, and dosage of the drug.

Coverage

Eligible services will be subject to the subscriber benefits, applicable fee schedule amount and any coding edits.

The following applies to all claim submissions.

All coding and reimbursement is subject to all terms of the Provider Service Agreement and subject to changes, updates, or other requirements of coding rules and guidelines. All codes are subject to federal HIPAA rules, and in the case of medical code sets (HCPCS, CPT, ICD), only codes valid for the date of service may be submitted or accepted. Reimbursement for all Health Services is subject to current Blue Cross Medical Policy criteria, policies found in the Provider Policy and Procedure Manual sections, Reimbursement Policies and all other provisions of the Provider Service Agreement (Agreement).

In the event that any new codes are developed during the course of Provider's Agreement, such new codes will be paid according to the standard or applicable Blue Cross fee schedule until such time as a new agreement is reached and supersedes the Provider's current Agreement.

All payment for codes based on Relative Value Units (RVU) will include a site of service differential and will be calculated using the appropriate facility or non-facility components, based on the site of service identified, as submitted by Provider.

Coding

The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply subscriber coverage or provider reimbursement.

CPT/HCPCS Modifier:	N/A						
ICD-10 Diagnosis:	N/A						
ICD-10 Procedure:	N/A						
CPT/HCPCS:	C9399						
	J0222	J0224	J0225	J1411	J1412	J1413	J2326
	J3398	J3399	J3401	J3490	J3590	J9029	J9325
	J9999						
	Q2041	Q2042	Q2043	Q2053	Q2054	Q2055	Q2056
Revenue Codes:	N/A						

Resources

Healthcare Common Procedure Coding System (HCPCS)

Policy History

11/18/2020	Initial Committee Approval
03/23/2021	Code update
06/29/2021	Code update
09/28/2021	Code update
12/28/2021	Code update



03/22/2022	Code update
06/28/2022	Code update
09/27/2022	Code update
10/25/2022	Code update
01/24/2023	Annual Policy Review and Code update
05/01/2023	Code update
07/05/2023	Code update
08/01/2023	Code update
01/01/2024	Code update
04/01/2024	Code update
05/01/2024	Code update

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