Cell and Gene Therapy

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Overview

Cell and gene therapies (CGTs) are a Medi-Cal benefit available to eligible members. CGTs involve collecting, processing and handling cells or other tissues, genetically modifying the cells or tissues and then administering the genetically modified cells or tissues to members to treat specific conditions.

All CGTs require an approved *Treatment Authorization Request* (TAR) or *Service Authorization Request* (SAR) establishing medical necessity for coverage and reimbursement under Medi-Cal.

Note: The Medi-Cal CGT policy does not apply to clinical trials. Refer to the *Clinical Trials Policy* section of the provider manual for the clinical trials policy.

Chimeric Antigen Receptor T Cell Therapy (CAR-T)

CAR-T therapy uses a member's own immune system to treat several types of cancer, including leukemia, lymphoma and multiple myeloma. Immune cells called T cells are collected from the member, genetically altered and then infused back into the same member.

‹‹Table of Procedure Codes for CAR-T Therapy››

CGT Name	Procedure Code	Code Description
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Table of Procedure Codes for CAR-T Therapy (continued)

CGT Name	Procedure Code	Code Description
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvykti	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Aucatzyl	Q2058	Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion

‹‹For additional policy on HCPCS codes Q2041, Q2042, Q2053, Q2054, Q2055 and Q2056, refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual.››

Billing Requirements

Billing for CAR-T drugs using their associated procedure codes is restricted to hospital outpatient services. CAR-T drugs must be administered at Certified Treatment Centers.

HCPCS codes Q2041 and Q2042 are separately payable services that are not reimbursed under the Diagnosis-Related Group (DRG) payment methodology. Refer to the *Diagnosis-Related Groups (DRG): Inpatient Services* section of the Provider Manual for additional details.

‹‹**Table of Procedure Codes for Administration of CAR-T Therapy**››

Procedure Code	Code Description
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

In accordance with American Medical Association (AMA) CPT® guidelines, the administration of CAR-T cell therapies includes monitoring and evaluation by a physician or other qualified healthcare professional immediately before, during and after the infusion. Components such as fluids used to administer the cells, incidental hydration and supportive medications given concurrently are generally considered part of the bundled service and should not be billed separately.

Note: CPT code 38228 must be billed with one of the CAR-T drug procedure codes.

Sickle Cell Disease

CGTs used to treat Medi-Cal members who have been diagnosed with sickle cell disease can be billed with the codes in the following table. ‹‹Billing for the following codes is restricted to Authorized Treatment Centers and Qualified Treatment Centers.››

Table of Procedure Codes for Sickle Cell Disease CGTs

CGT Name	Procedure Code	Code Description
Casgevy	J3392	Injection, exagamglogene autotemcel, per treatment
Lyfgenia	J3394	Injection, lovotibeglogene autotemcel, per treatment

Billing Requirements

Under the Centers for Medicare & Medicaid Services (CMS) CGT Access Model, J3392 (Casgevy) and J3394 (Lyfgenia) are carved out of the managed care delivery system when used for the treatment of sickle cell disease only. ‹‹Thus, Medi-Cal managed care plans (MCPs) will not be directly billed and will not be responsible for payment for these drugs when used for sickle cell disease. For all clinical indications other than treatment of sickle cell disease, including treatment of beta thalassemia, J3392 and J3394 remain the responsibility of Medi-Cal MCPs.›› Refer to the applicable Medi-Cal policies for billing requirements.

For information on how to bill CGT medications for sickle cell disease, refer to the *CMS Cell and Gene Therapy Access Model* section of the provider manual.

Hemophilia A and B

CGTs used to treat Medi-Cal members who have been diagnosed with hemophilia A or B can be billed with the codes in the following table. Billing for the following codes is restricted to hospital outpatient services and hemophilia treatment centers.

Table of Procedure Codes for Hemophilia A and B CGTs

CGT Name	Procedure Code	Code Description
Hemgenix	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
Roctavian	J1412	Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 1013 vector genomes

‹‹Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS codes J1411 and J1412.››

Duchenne Muscular Dystrophy

CGTs used to treat Medi-Cal members who have been diagnosed with Duchenne muscular dystrophy can be billed with the codes in the following table. Billing for the following codes is restricted to hospital outpatient services.

Table of Procedure Codes for Duchenne Muscular Dystrophy CGTs

CGT Name	Procedure Code	Code Description
Elevidys	J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

‹‹Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS code J1413.››

Spinal Muscular Atrophy

CGTs used to treat Medi-Cal members who have been diagnosed with spinal muscular atrophy can be billed with the codes in the following table. Billing for the following codes is restricted to hospital outpatient services.

Table of Procedure Codes for Spinal Muscular Atrophy CGTs

CGT Name	Procedure Code	Code Description
Itvisma	‹‹J3405››	Injection, onasemnogene abeparvovec-brve, per treatment
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10

Billing Requirements

J3399 is a separately payable service that is not reimbursed under the DRG payment methodology. Refer to the *Diagnosis-Related Groups (DRG): Inpatient Services* section of the provider manual for additional details. ‹‹Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS codes J3405 and J3399.››

Retinal Dystrophy

CGTs used to treat Medi-Cal members who have been diagnosed with retinal dystrophy can be billed with the following codes:

CGT Name	Procedure Code	Code Description
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes

Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS codes J3398.

Beta Thalassemia

CGTs used to treat Medi-Cal members who have been diagnosed with beta thalassemia can be billed with the codes in the following table. Billing for the following codes is restricted to hospital outpatient services and qualified treatment centers.

Table of Procedure Codes for Beta Thalassemia CGTs

CGT Name	Procedure Code	Code Description
Casgevy	J3392	Injection, exagamglogene autotemcel, per treatment
Zynteglo	J3393	Injection, betibeglogene autotemcel, per treatment

Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS codes J3392 and J3393.

Synovial Sarcoma

CGTs used to treat Medi-Cal members who have been diagnosed with synovial sarcoma can be billed with the codes in the following table. Billing for the following codes is restricted to hospital outpatient services.

CGT Name	Procedure Code	Code Description
Tecelra	Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose

Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS code Q2057.

‹‹Recurrent Respiratory Papillomatosis (RRP)

CGTs used to treat Medi-Cal members who have been diagnosed with RRP can be billed with the following codes:

Table of Procedure Codes for RRP CGTs

CGT Name	Procedure Code	Code Description
Papzimeos	J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose

Refer to the *List of Physician-Administered Drugs and HCPCS Codes* section in this manual for additional policy on HCPCS codes J3404.››

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.