# Physician-Administered Drugs (PADs) Special Billing

Page updated: March 2026

This section outlines policy related to billing and special billing instructions for physician-administered drugs (PADs) including injection, non-injectable drug, chemotherapy and ophthalmology services, listed in alphabetical order by generic drug name or drug type.

For general billing policy information regarding PADs, refer to the *Physician-Administered Drugs (PADs) Overview* section in this manual. Additional policy information for PADs can be found in the *List of Physician-Administered Drugs and HCPCS Codes* section of this manual.

## Acamprosate Calcium

### Billing

HCPCS code J8499 (prescription drug, oral, non-chemotherapeutic, NOS).

### Special Billing Instructions

To ensure appropriate reimbursement, providers must provide the following on each claim:

- Name and strength of drug administered
- National Drug Code (NDC)
- Amount given
- Actual acquisition cost
- Copy of the drug invoice or a manufacturer catalog page or price list with documentation of product cost

# Afamitresgene Autoleucel (TECELRA)

## Billing

HCPCS code Q2057 (injection, Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose)

Administration code: CPT® code 96413 (chemotherapy administration, intravenous infusion; up to 1 hour, single or initial substance/drug).

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting claims for TECELRA:

TAR/SAR Submission

1. Submit and receive back an approved *Treatment Authorization Request* (TAR) or approved product specific Service Authorization Request (SAR).
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line for eight (8) units on the TAR/SAR request and enter “8” in the Units box.

Claim Submission

1. Bill using HCPCS code Q2057 (injection, Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose).
2. Completion of Claim forms:
   - This billing methodology is restricted to hospital outpatient services.

     **Note:** Pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ Provider must submit eight (8) claim lines to represent one (1) service.
     - ❖ Each claim line to represent one unit.
     - ❖ Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the eight (8) claim lines is no more than provider submitted invoice paid price.
     - ❖ TECELRA must be billed on its own with no other drug or biologics.
3. Providers are advised to take the following steps in order to ensure that TECELRA claims are identified and processed expeditiously:
4. Paper claims may be identified by notation of “TECELRA” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

   Attention: Claims Manager
   Medi-Cal Fiscal Intermediary
   P.O. Box 526006
   Sacramento, CA 95852-6006
5. Electronic claims may be identified by notation of “TECELRA” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.

# Aflibercept

## Billing

HCPCS codes:

- J0177 (injection, aflibercept hd, 1 mg)
- J0178 (injection, aflibercept, 1 mg)
- Q5155 (injection, aflibercept-jbvf [yesafili], biosimilar, 1 mg)

## Special Billing Instructions

CTP code 67028 (Intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (left side)
- RT (right side)

# Aflibercept-ayyh (PAVBLU)

## Billing

HCPCS code Q5147 (injection, aflibercept-ayyh [pavblu], biosimilar, 1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Aflibercept-abzv (ENZEEVU)

## Billing

HCPCS code Q5149 (injection, aflibercept-abzv [enzeevu], biosimilar, 1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Aflibercept-mrbb (AHZANTIVE)

## Billing

HCPCS code Q5150 (injection, aflibercept-mrbb [ahzantive], biosimilar, 1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Aflibercept-yszy (Opuviz)

## Billing

HCPCS code Q5153 (injection, aflibercept-yszy [opuviz], biosimilar, 1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Atidarsagene autotemcel (LENMELDY)

## Billing

HCPCS code J3391 (injection, atidarsagene autotemcel, per treatment).

Administration code: CPT code 96413 (chemotherapy administration, intravenous infusion; up to 1 hour, single or initial substance/drug).

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting claims for LENMELDY:

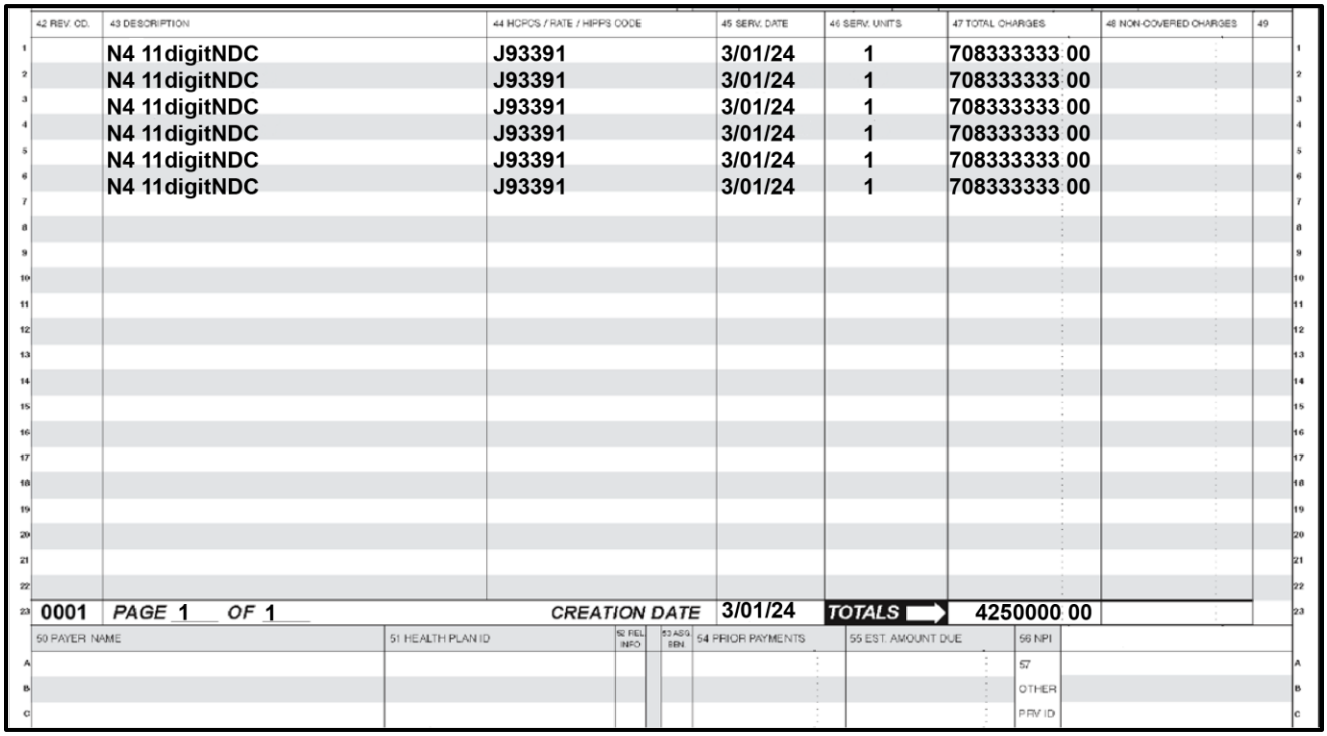
TAR/SAR Submission:

1. Submit and receive back an approved TAR or approved product-specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line for six (6) units on the TAR/SAR request and enter “6” in the Units box.

Claim Submission:

1. Bill using HCPCS code J3391 (injection, atidarsagene autotemcel, per treatment).
2. Completion of Claim forms:
   - This billing methodology is restricted to hospital outpatient services. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ Provider must submit six (6) claim lines to represent one (1) service.
     - ❖ Each claim line to represent one unit.
     - ❖ Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the six (6) claim lines is no more than provider submitted invoice paid price.
     - ❖ LENMELDY must be billed on its own with no other drug or biologics.
3. Providers are advised to take the following steps in order to ensure that LENMELDY claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “LENMELDY” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “LENMELDY” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for LENMELDY shall be a once in a lifetime reimbursement under J3391 or any other code (HCPCS, CPT, or by NDC).
6. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04* claim forms.



| 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | 49 |
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| | N4 11digitNDC | J93391 | 3/01/24 | 1 | 708333333 00 | | |
| | N4 11digitNDC | J93391 | 3/01/24 | 1 | 708333333 00 | | |
| | N4 11digitNDC | J93391 | 3/01/24 | 1 | 708333333 00 | | |
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| 0001 | PAGE 1 OF 1 | CREATION DATE | 3/01/24 | TOTALS | 4250000 00 | | |

| 50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL INFO | 53 ASG BEN | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | |
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**Figure:** Atidarsagene autotemcel (LENMELDY) *UB-04* Billing Example.

- The total invoice cost of LENMELDY is $4,250,000.
- Note that each provider's invoice cost may be different.
- This is split evenly between the six lines.
- The sum of the six claim lines must equal the paid price on the invoice.

**Note:** It is not necessary to include the unit of measure qualifier and numeric quantity.

# Avacincaptad-pegol (IZERVAY)

## Billing

HCPCS code J2782 (injection, avacincaptad pegol, 0.1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Axicabtagene ciloleucel (Yescarta®)

## Billing

HCPCS code Q2041 (Axicabtagene ciloleucel, up to 200 million autologus anti-CD19 CAR T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting claims for Yescarta:

TAR/SAR Submission

1. Submit and receive back an approved TAR/SAR.
2. Providers must submit one service line on the TAR/SAR request and enter “6” in the *Units* box.

Claim Submission

- Bill using Q2041 (Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 car-positive viable T cells, including leukapheresis and dose preparation procedures per therapeutic dose).
- Completion of claim forms:
  - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied.
  - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I.
  - On the 837I or *UB-04* claim form, providers must submit one claim line to represent one service or six (6) units.
    - ❖ Claims submitted with more than one claim line will be denied.
  - Providers must submit an invoice for reimbursement.
  - This process will ensure that the total reimbursement paid for the quantity of six is no more than the paid price on the provider submitted invoice.
  - Yescarta must be billed on its own with no other drug or biological.

  - For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website for completion of 837I and *UB-04* claim forms.
- Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Bedaquiline (SIRTURO®)

## Billing

Drug code:

Bill the following miscellaneous HCPCS code for drug reimbursement:

- S5000 (prescription drug, generic)
- S5001 (prescription drug, brand name)

## Special Billing Instructions

Provide the following on each claim:

- Name and strength of drug administered
- NDC Amount given
- Actual acquisition cost
- Copy of the drug invoice

Administration code:

Directly Observed Therapy (DOT) billed using HCPCS code H0033 (oral medication administration, direct observation), in the setting determined appropriate by the public health department and may be in the community.

# Betibeglogene autotemcel (ZYNTEGLO)

## Billing

HCPCS code: J3393 (injection, betibeglogene autotemcel, per treatment).

Administration Code

CPT code 96413 (chemotherapy administration, intravenous infusion; up to one hour, single or initial substance/drug).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims for Zynteglo:

TAR/SAR Submission Requirements

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter "3" in the Units box.

Claim Submission

1. Bill using J3393 (injection, betibeglogene autotemcel, per treatment).
2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and Qualified Treatment Centers (QTCs). Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or *UB-04* claim form, provider must submit three (3) claim lines to represent one (1) service.
       - Each claim line to represent one unit.
       - Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the three claim lines is no more than provider submitted invoice paid price.
     - ❖ Zynteglo must be billed on its own with no other drug or biologics.
3. Providers are advised to take the following steps in order to ensure that Zynteglo claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of "Zynteglo "on the "Remarks" section of the *UB-04* claim form (Field 80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006

- Electronic claims may be identified by notation of ‘Zynteglo’ on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.

4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for Zynteglo shall be one dose (three units) in a lifetime reimbursement under J3393 or any other code (HCPCS, CPT or by NDC).
6. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04* claim forms.

| 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | 49 |
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| | N4 11digitNDC | J3393 | 07/01/2024 | 1 | 933,333 33 | | |
| | N4 11digitNDC | J3393 | 07/01/2024 | 1 | 933,333 33 | | |
| | N4 11digitNDC | J3393 | 07/01/2024 | 1 | 933,333 34 | | |
| 0001 | PAGE 1 OF 1 | CREATION DATE | 07/01/2024 | TOTALS | 2,800,000 00 | | |

**Figure:** Betibeglogene autotemcel *UB-04* Billing Example.

- The total invoice cost of Zynteglo is $2,800,000.
- Note that each provider’s invoice cost may be different.
- If this is split evenly between the three lines, each claim line will have a total of $933,333.33.
- The sum of the three claim lines must equal the paid price on the invoice.

**Note:** It is not necessary to include the unit of measure qualifier and numeric quantity.

# Bevacizumab

## Billing

HCPCS code: J9035 (injection, bevacizumab, 10 mg).

## Special Billing Instructions

CPT code 67028 (Intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (left side)
- RT (right side)
- 50 (bilateral)

Providers may bill for the quantity that is equal to the amount given to the patient plus the amount wasted up to a total dose of 10 mg (one unit). Maximum reimbursement will not exceed 10 mg (one unit), per patient, per date of service when bevacizumab is used as an intravitreal injection. This limitation applies only to the intravitreal use of bevacizumab.

# Casimersen (Amondys 45)

## Billing

HCPCS code J1426 (injection, casimersen, 10 mg).

## Special Billing Instructions for CCS Patients

- Submissions of authorization requests for eteplirsen, golodirsen, viltolarsen, or casimersen are not included in Service Code Groupings. Providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, and clinical progress notes from a visit within the past six months.
  - For patients residing in an independent county, SARs should be submitted to the California Children's Services (CCS) independent county office.

  - For patients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) Integrated Systems of Care Division (ISCD) Special Populations Authorization Unit e-mail at *CCSExpeditedReview@dhcs.ca.gov* or via secure RightFax (916) 440-5306.
- All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding the policy for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

# Brexucabtagene autoleucel (Tecartus™)

## Billing

HCPCS code Q2053 (brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims.

For Tecartus:

- Submit and receive back an approved TAR.

Bill using Q2053 (Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

- Completion of claim forms:
  - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied.
  - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I.
  - Providers must submit one service line on the TAR request and enter “5” in the Units box.
  - On the 837I or *UB-04* claim form, provider must submit one claim line to represent one service:
    - ❖ Claims submitted with more than one claim line will be denied:
      - Provider must submit an invoice for reimbursement.
      - This process will ensure that the total reimbursement paid for the quantity of five is no more than the paid price on the provider submitted invoice.
      - Tecartus must be billed on its own with no other drug or biological.
- For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04* claim forms.
- Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Cefiderocol (Fetroja®)

## Billing

HCPCS code J0699 (injection, cefiderocol, 10 mg).

## Special Billing Instructions

Since the same injection will be administered more than once on the same day, each injection must be listed on a separate claim line. For additional details, refer to the *Physician-Administered Drugs (PADs): Overview* section of the appropriate Part 2 provider manual.

Providers must use modifier XE (separate encounter) for each subsequent claim line to ensure appropriate reimbursement.

# Ciltacabtagene autoleucel; cilta-cel (Carvykti™)

## Billing

HCPCS code 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).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims for Carvykti:

- Submit and receive back an approved TAR/SAR.
- Bill using Q2056.
- Completion of claim forms:
  - Claims are restricted to hospital outpatient services. Note that claims from pharmacies and clinics will be denied.
  - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I.
  - Providers must submit one (1) service line on the TAR/SAR request and enter "6" in the *Units* box.
  - On the 837I or *UB-04* claim form, providers must submit one claim line to represent one (1) service.
    - ❖ Claims submitted with more than one claim line will be denied.
  - Providers must submit an invoice for reimbursement.
  - This process will ensure that the total reimbursement paid for the quantity of six is no more than the paid price on the provider submitted invoice.
  - Carvykti must be billed on its own with no other drug or biological.
- For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04* claim forms.
- Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Darbepoetin Alfa

## Billing

HCPCS code J0881 (Injection, darbepoetin alfa, 1 mcg [non-ESRD use]).

HCPCS code J0882 (Injection, darbepoetin alfa, 1 mcg [for ESRD on dialysis]).

## Billing Instructions

If darbepoetin alfa is self-administered, the provider must submit the following information:

- A statement that the drug was provided to the patient for self-administration.
- The date and quantity of drug given to the patient, darbepoetin alfa doses, patient weight in kilograms and Hbg levels for the previous three months.

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

# Delandistrogene Moxeparvovec (ELEVIDYS™)

## Billing

HCPCS code J1413 (injection, delandistrogene moxeparvovec-rokl, per therapeutic dose).

One billed unit equals the total dose administered to the patient.

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Elevidys:

TAR/SAR Submission

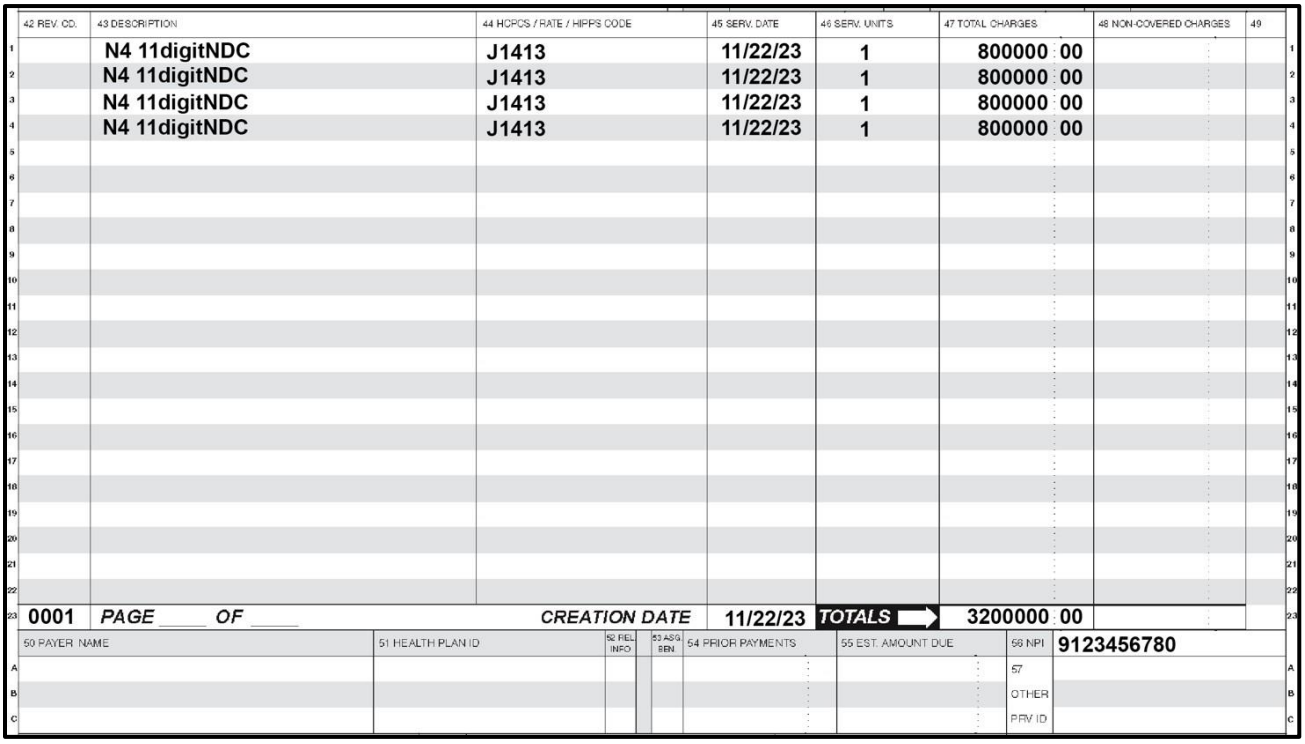
1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “4” in the Units box.

Claim Submission

1. Bill using HCPCS code J1413.
2. Completion of Claim forms:
   - This billing methodology is restricted to hospital outpatient services. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:
     - ❖ Provider must submit one (1) service line for four (4) units on the TAR/SAR request and will submit four (4) claim lines.
     - ❖ Each claim line to represent one unit.
     - ❖ Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the four claim lines is no more than provider submitted invoice paid price.
     - ❖ Elevidys must be billed on its own with no other drug or biologics.
3. Providers are advised to take the following steps in order to ensure that Elevidys claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Elevidys” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Elevidys” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for Elevidys shall be a once-in-a-lifetime reimbursement under J1413 or any other code (HCPCS, CPT, or by NDC).

For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04* claim forms.



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| 1 | | N4 11digitNDC | J1413 | 11/22/23 | 1 | 800000 00 | | | 1 |
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| 3 | | N4 11digitNDC | J1413 | 11/22/23 | 1 | 800000 00 | | | 3 |
| 4 | | N4 11digitNDC | J1413 | 11/22/23 | 1 | 800000 00 | | | 4 |
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| | 50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL INFO | 53 ASG BEN | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 9123456780 | |
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| B | | | | | | | OTHER | | B |
| C | | | | | | | PRV ID | | C |

**Figure:** Delandistrogene Moxeparvovec Gene Therapy UB-04 Billing Example.

- The total invoice cost of Elevidys is $3,200,000.
- Note that each provider's invoice cost may be different.
- If this is split evenly between the four lines, each claim line will have a total of $800,000.
- The sum of the four claim lines must equal the paid price on the invoice.
- Note that it is not necessary to include the unit of measure qualifier and numeric quantity.

# Disulfiram

## Billing

HCPCS code J8499 (prescription drug, oral, non chemotherapeutic, NOS).

## Special Billing Instructions

To ensure appropriate reimbursement, providers must provide the following on each claim:

- Name and strength of drug administered
- National Drug Code (NDC)
- Amount given
- Actual acquisition cost
- Copy of the drug invoice or a manufacturer catalog page or price list with documentation of product cost

# Dexamethasone 9% Intraocular

## Billing

HCPCS code J1095 (injection, dexamethasone 9% intraocular, 1 mcg).

## Special Billing Instructions

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Dexamethasone Intravitreal Implant

## Billing

HCPCS code J7312 (injection, dexamethasone intravitreal implant, 0.1 mg).

## Special Billing Instructions

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Elivaldogene Autotemcel (Skysona)

## Billing

HCPCS code J3387 (injection, elivaldogene autotemcel, per treatment).

## Special Billing Instructions

Due to system limitations, providers must take the following steps when submitting a TAR/SAR and claims for Skysona:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product-specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter "4" in the "Units" box.

Claim Submission

1. Bill using J3387.
2. Complete claim forms:
   a. This billing methodology is restricted to hospital outpatient services and Hemophilia Treatment Centers (HTCS). Pharmacies and clinics cannot bill using this methodology.
   b. Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
      i. On the 837I or *UB-04* claim form, provider must submit four (4) claim lines to represent one (1) service.
      ii. Each claim line represents one unit.
3. Claims submitted with one or two claim lines will be denied.
   a. Provider must submit an invoice for reimbursement.
   b. This process will ensure that the total reimbursement paid for the four (4) claim lines is no more than the price paid on the provider's submitted invoice.
   c. Skysona must be billed on its own with no other drug or biological.

4. Providers are advised to take the following steps to ensure that Skysona claims are identified and processed expeditiously:

   Paper claims may be identified by notation of “Skysona” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

   Attention: Claims Manager
   Medi-Cal Fiscal Intermediary
   P.O. Box 526006
   Sacramento, CA 95852-6006

5. Electronic claims may be identified by notation of “Skysona” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
6. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
7. Payment for Skysona shall be once-in-a-lifetime reimbursement under J3387 or any other code (HCPCS, CPT or by NDC).
8. For instructions regarding physical claim form completion, refer to the Forms page on the Medi-Cal Providers website and forms section *UB-04 Completion: Outpatient Services* for completion of 837I and *UB-04* claim forms.

# Epoetin Alfa

## Billing

HCPCS code J0885 (injection, epoetin alfa, [for non-ESRD use], 1000 units).

HCPCS code Q4081 (injection, epoetin alfa, 100 units [for ESRD on dialysis]).

## Special Billing Instructions

If Epoetin Alfa (EA) is administered by the provider, the claim must include current and previous:

- EA dose
- Patient weight in kilograms
- Hemoglobin levels

If EA is self-administered by the patient, the claim must include:

- A statement that the drug was provided to the patient for self-administration
- The date and quantity of drug given to the patient
- EA doses, hemoglobin levels and patient weight in kilograms for the previous three months

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

If EA is administered outside of the general guidelines above or dosage is more than 90,000 units per week, documentation must be submitted in order to establish medical necessity.

# Eteplirsen (Exondys 51)

## Billing

HCPCS code J1428 (injection, eteplirsen, 10 mg).

## Special Billing Instructions for CCS Patients

Submission of authorization requests for eteplirsen is not included in Service Code Groupings (SCGs).

- For patients residing in an independent county, SARs should be submitted to the CCS independent county office.
- For patients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documents to the DHCS ISCD Special Populations Authorization Unit e-mail at CCSOperations@dhcs.ca.gov or via secure RightFax at (916) 440-5768.

All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding benefit for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

# Etranacogene Dezaparvovec-drlb (Hemgenix)

## Billing

HCPCS code J1411 (injection, etranacogene dezaparvovec-drlb, per therapeutic dose).

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Hemgenix:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “4” in the Units box.

Claim Submission

1. Bill using J1411 (Injection, etranacogene dezaparvovec-drlb, per therapeutic dose).
2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and HTCS. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or UB-04 claim form, provider must submit four (4) claim lines to represent one (1) service.
       - Each claim line to represent one unit.
       - Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the four (4) claim lines is no more than the paid price on the provider submitted invoice.
     - ❖ Hemgenix must be billed on its own with no other drug or biological.
3. Providers are advised to take the following steps to ensure that Hemgenix claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Hemgenix” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Hemgenix” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for Hemgenix shall be once in a lifetime reimbursement under J1411 or any other code (HCPCS, CPT or by NDC).
6. For instructions regarding physical claim form completion, refer to the Forms page on the Medi-Cal Providers website and forms section *UB-04 Completion: Outpatient Services* for completion of 837I and *UB-04* claim forms.

# Fidanacogene elaparvovec-dzkt (BEQVEZ™)

## Billing

HCPCS code J1414 (injection, fidanacogene elaparavovec-dzkt, per therapeutic dose).

## Special Billing Instructions

When submitting a TAR or SAR and claims for Beqvez™, providers are instructed to follow these steps:

TAR and SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one service line on the TAR/SAR request, and enter “4” in the Units box.

Claim Submission

National Standards and system limitations do not allow for accurate claims adjudication when billing a single claim line. National Council for Prescription Drug Programs (NCPDP) standards and the *UB-04* or other standard claim forms do not accommodate the large dollar amount of the claim, which is in excess of three million dollars.

1. Bill using appropriate HCPCS codes:
   - J3590 (unclassified biologics) per therapeutic dose for services prior to October 1, 2024.
   - C9172 (injection, fidanacogene elaparvovec-dzkt, per therapeutic dose) for services provided on or after October 1, 2024, until December 31, 2024.
   - J1414 (injection, fidanacogene elaparvovec-dzkt, per therapeutic dose) for services provided on or after January 1, 2025.

2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and hemophilia treatment centers. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or *UB-04* claim form, provider must submit four claim lines to represent one service.
       - Each claim line to represent one unit.
       - Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the four claim lines is no more than the paid price on the provider submitted invoice.
     - ❖ Beqvez™ must be billed on its own with no other drug or biological.
3. Providers are advised to take the following steps to ensure BeqvezTM claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Beqvez“on the “Remarks” section of the *UB-04* claim form (Field 80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary/Gainwell Technologies
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of ‘Beqvez’ on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for BeqvezTM shall be a once-in-a-lifetime reimbursement under C9172, J1414 or J3590 or any other code (HCPCS, CPT, or by NDC).

For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, forms section for completion of 837I and *UB-04 Completion: Outpatient Services* for completion of the *UB-04* form.

| | 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | 49 |
|---|---|---|---|---|---|---|---|---|
| 1 | | N4 11digitNDC | J1414 | 04/01/24 | 1 | 875,000 00 | | |
| 2 | | N4 11digitNDC | J1414 | 04/01/24 | 1 | 875,000 00 | | |
| 3 | | N4 11digitNDC | J1414 | 04/01/24 | 1 | 875,000 00 | | |
| 4 | | N4 11digitNDC | J1414 | 04/01/24 | 1 | 875,000 00 | | |
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| 23 | 0001 | PAGE 1 OF 1 | CREATION DATE | 04/01/24 | TOTALS | 3,500,000 00 | | |

| 50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL INFO | 53 ASG BEN | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | XXXXXXXXXX |
|---|---|---|---|---|---|---|---|

**Figure:** BEQVEZ™ UB-04 Billing Example.

- The total invoice cost of J3590, C9172 or J1414 is $3,500,000.00.
- Note that each provider's invoice cost may be different.
- If this is split evenly between the four lines, each claim line will have a total of $875,000.00.
- The sum of the four claim lines must equal the paid price on the invoice.

# Fluocinolone Acetonide Intravitreal Implant (Iluvien)

## Billing

HCPCS code J7313 (injection, fluocinolone acetonide, intravitreal implant [Iluvien], 0.01 mg).

## Special Billing Instructions

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Fluocinolone Acetonide, Intravitreal Implant (Retisert)

## Billing

HCPCS code J7311 (injection, fluocinolone acetonide, intravitreal implant [Retisert], 0.01 mg).

## Special Billing Instructions

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Fluocinolone Acetonide Intravitreal Implant (Yutiq)

## Billing

HCPCS code J7314 (injection, fluocinolone acetonide, intravitreal implant [Yutiq], 0.01 mg).

## Special Billing Instructions

One of the following modifiers is required for reimbursement:

- LT (Left side)
- RT (Right side)

# Golodirsen (Vyondys 53™)

## Billing

HCPCS code J1429 (injection, golodirsen, 10 mg).

## Special Billing Instructions for CCS Patients

- Submission of authorization requests for golodirsen are not included in Service Code Groupings (SCGs).
  - For patients residing in an independent county, SARs should be submitted to the CCS independent county office.
  - For patients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documents to the DHCS ISCD Special Populations Authorization Unit e-mail at CCSOperations@dhcs.ca.gov or via secure RightFax at (916) 440-5768.
- All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding benefit for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

# Idecabtagene Vicleucel (Abecma®)

## Billing

HCPCS code 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).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims for Abecma:

1. Submit and receive back an approved TAR/SAR.
2. Bill using 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).
3. Completion of claim forms:
   - Claims are restricted to Hospital Outpatient Services. Note that claims from pharmacies and clinics will be denied.
   - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I.
   - Providers must submit one (1) service line on the TAR/SAR request and enter “6” in the Units box.
   - On the 837I or *UB-04* claim form, providers must submit one claim line to represent one (1) service.
   - Claims submitted with more than one claim line will be denied.
   - Providers must submit an invoice for reimbursement.
   - This process will ensure that the total reimbursement paid for the quantity of six (6) is no more than the paid price on the provider submitted invoice.
   - Abecma must be billed on its own with no other drug or biological.
4. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, for completion of 837I and *UB-04* claim forms. Providers may also refer to the *UB-04 Completion: Outpatient Services* section of the provider manual.
5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Linezolid (Zyvox®) (Injection or Oral Drug)

## Billing

HCPCS codes:

- S5000 (prescription drug, generic)
- S5001 (prescription drug, brand name)
- J2020 (injection, linezolid, 200 mg)

## Special Billing Instructions

Provide the following on each claim:

- Name and strength of drug administered
- NDC
- Amount given
- Actual acquisition cost
- Copy of the drug invoice

Oral Drug Administration Code:

Directly Observed Therapy (DOT) billed using HCPCS code H0033 (oral medication administration, direct observation), in the setting determined appropriate by the public health department and may be in the community.

# Lisocabtagene Maraleucel (Breyanzi®)

## Billing

HCPCS code Q2054 (lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims for Breyanzi:

1. Submit and receive back an approved TAR/SAR.
2. Bill using Q2054 (lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).
3. Completion of claim forms:
   - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I.
   - Providers must submit one (1) service line on the TAR/SAR request and enter “6” in the *Units* box.
   - On the 837I or *UB-04* claim form, provider must submit one claim line to represent one (1) service.
     - ❖ Claims submitted with more than one claim line will be denied.
   - Providers must submit an invoice for reimbursement.
   - This process will ensure that the total reimbursement paid for the quantity of six (6) is no more than the paid price on the provider submitted invoice.
   - Breyanzi must be billed on its own with no other drug or biological.
4. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, for completion of 837I and *UB-04* claim forms. Providers may also refer to the *UB-04 Completion: Outpatient Services* section of the provider manual.
5. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Methoxy polyethylene glycol-epoetin beta (Mircera®)

## Billing

HCPCS codes:

- J0887 (injection, epoetin beta, 1 mcg, [for ESRD on dialysis])
- J0888 (injection, epoetin beta, 1 mcg, [for non-ESRD use])

## Billing Notes

- Providers must bill with the appropriate code for the patient's diagnosis for approval.
- Claims billed for the treatment of anemia due to cancer chemotherapy or for use as a substitute for RBC transfusions in patients who require immediate correction of anemia, which can be billed with J0888, are not a covered benefit and will be denied.
- There are other codes for non-ESRD use that may be more appropriate for the patient's condition (for example, J0885 [Injection, epoetin alfa, (for non-esrd use), 1000 units]).

# Nusinersen (SPINRAZA®)

## Billing

HCPCS code J2326 (injection, nusinersen, 0.1 mg).

## Special Billing Instructions for CCS Patients

Nusinersen (Spinraza)

1. Nusinersen is not covered by a Service Code Grouping (SCG) authorization. Special Care Centers (SCCs) or pharmacies should submit a separate SAR and supporting documentation in the following manner:
   - For nusinersen outpatient administration, as a hospital or physician-administered drug (PAD):
     - ❖ Dates of service beginning January 1, 2018, use HCPCS code J2326. One unit of J2326 is equal to injection, nusinersen, 0.1mg.
     - ❖ SCG02 or SCG01 with additional codes needed for procedures and equipment related to nusinersen administration.

- For pharmacy dispensing nusinersen, when the drug is dispensed by a pharmacy provider and delivered to the provider administering the drug:
  - ❖ Authorize its National Drug Code (NDC) to pharmacy.

2. Requesting CCS Program providers must submit the following items to their patients' local CCS Program county office for patients who live in independent counties, or directly to the ISCD Special Populations Authorization Unit for patients who live in dependent CCS counties:
   - CCS Program SAR
   - Medical documentation from the CCS Program approved SCC, with neuromotor assessment scores every 12 months and summary of changes in neuromotor status every six months.
   - Supporting documentation
3. When the County CCS Program determines that the request and documentation submitted by the SCC is complete, the county will pend a SAR and forward the request) and supporting documentation to:
   - CCSExpeditedReview@dhcs.ca.gov or via secure Right fax number: (916) 440-5306.
   - The State CCS Program office will issue the authorization.
   - The State CCS Program office will issue initial authorization for a period of 12 months or until the end of program eligibility period.
   - Reauthorization shall be granted every twelve months following review of documentation described above unless there are significant adverse effects or change in eligibility.

Reauthorizations will be done by the independent county CCS Program or ISCD Special Populations Authorization Unit for dependent counties.

# Obecabtagene autoleucel (AUCATZYL®)

## Billing

HCPCS code Q2058 (Obecabtagene autoleucel, 10 up to 400 million CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to system limitations, providers are to take the following steps when submitting a TAR/SAR and claims for Aucatzyl:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “6” in the Units box.

Claim Submission

1. Bill using Becabtagene autoleucel, 10 up to 400 million CD19 car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion.
2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and Hemophilia Treatment Centers (HTCs). Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or *UB-04* claim form, provider must submit six (6) claim lines to represent one (1) service.
     - ❖ Each claim line represents one unit.
   - Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the six (6) claim lines is no more than the paid price on the provider submitted invoice.
     - ❖ Aucatzyl must be billed on its own with no other drug or biological.

3. Providers are advised to take the following steps to ensure that Aucatzyl claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Aucatzyl” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006 Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Aucatzyl” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Providers note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. For instructions regarding physical claim form completion, refer to the Forms page on the Medi-Cal Providers website and forms section *UB-04 Completion: Outpatient Services* for completion of 837I and *UB-04* claim forms.
6. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Onasemnogene abeparvovec-xioi (Zolgensma)

## Billing

HCPCS code J3399 (injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes).

## Special Billing instruction for CCS Patients

1. Onasemnogene abeparvovec is not covered by a Service Code Grouping (SCG) authorization and a separate authorization is needed for outpatient administration.
2. Requesting CCS Program providers must submit the following items to their patients' local CCS Program county office or ISCD Special Populations Authorization Unit:
   - CCS Program SAR with Outpatient National Provider Identifier number for:
     - ❖ HCPCS code J3399, Injectiononasemnogene abeparvovec-xioi, per treatment up to 5x10^15 vector genomes
     - ❖ Supporting clinical documentation should justify medical necessity and that the service is the least costly to meet the patient's needs
     - ❖ SCG02 or SCG01 with additional codes needed for procedures and equipment related to onasemnogene abeparvovec-xioi administration
3. When the County CCS Program determines that the request and documentation submitted by the SCC is complete, the county will pend a SAR and forward the request and supporting documentation to CCS_Operations@dhcs.ca.gov or via secure Right fax number: (916) 440-5768.
4. The State CCS Program office will issue the authorization.
5. Each CCS patient is eligible to receive only one treatment of onasemnogene abeparvovec, under J3399, or any other code (HCPCS, CPT or by NDC).
6. Requesting providers must adhere to the following special instructions when filing a claim:
   - Provider must submit one (1) service line for three (3) units on the TAR/SAR request, and enter "3" in the Units box.
   - On the *837I* (institutional) electronic form *or UB-04* form, provider must submit three (3) claim lines to represent one (1) service.
     - ❖ Each claim line to represent one unit.
     - ❖ Claims submitted with one or two claim lines will be denied.
   - Provider must submit an invoice for reimbursement.

- This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than the paid price on the provider submitted invoice paid price.
- Zolgensma must be billed on its own with no other drug or biological.
- Providers must identify Zolgensma paper claims by notation as such in the remarks section of the paper claim. For electronic claims, provider shall indicate claim is for Zolgensma on a coversheet, to ensure that these are processed expeditiously.
- Providers should note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
- Payment for Zolgensma shall be a once-in-a-lifetime reimbursement under J3399, (or by specific CPT code or NDC).

**Notice to providers regarding the special billing of Zolgensma™ claims effective July 1, 2020**

The Department of Health Care Services (DHCS) would like to notify providers of the special billing and claims processing requirements for Zolgensma™ (onasemnogene abeparvovec-xioi) suspension for intravenous infusion, when billed under HCPCS code, J3399.This communication supersedes the department's related communication, dated April 22, 2020.

Under the Healthcare Common Procedural Coding System (HCPCS), and effective July 1, 2020, Zolgensma™ was assigned the unique code, J3399 (injection, onasemnogene abeparvovec-xioi, per treatment, up to 5 $x10^{15}$ vector genomes.). A non-specific HCPCS code, J3590, was used previously.

Coverage and policy details for Zolgensma™ under the Medi-Cal and California Children's Service (CCS) Programs are covered elsewhere.

National Standards and system limitations for J3399 do not allow for accurate claims adjudication when billing a single claim line. National Council for Prescription Drug Programs (NCPDP) standards and the *UB-04* or other standard claim forms do not accommodate the large dollar amount of the claim, which is in excess of $2 million.

## Special Billing Instructions

When submitting claims for Zolgensma™, providers are instructed to do the following:

1. Submit and receive back an approved TAR or approved product specific SAR.
2. Bill using J3399, injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes.
3. Completion of claim forms:
   - Zolgensma™ may be administered during a Diagnosis Related Group (DRG) inpatient hospital stay as carve-out service and must be billed and submitted separately as a hospital outpatient service.
   - This billing methodology is restricted to hospital outpatient services. Note that pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ The TAR/SAR is not negotiated.
     - ❖ Provider must submit one (1) service line on the TAR/SAR request, and enter “3” in the Units box.
     - ❖ On the 837I or *UB-04* claim form, provider must submit three (3) claim lines to represent one (1) service.
       - Each claim line to represent one unit.
       - Claims submitted with one or two claim lines will be denied.
     - ❖ Provider must submit an invoice for reimbursement.
     - ❖ This process will ensure that the total reimbursement paid for the three (3) claim lines is no more than the paid price on the provider submitted invoice.
     - ❖ Zolgensma must be billed on its own with no other drug or biological.

4. Providers are advised to take the following steps in order to ensure that Zolgensma claims are identified and processed expeditiously.
   - Paper claims may be identified by notation of “Zolgensma” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary/Gainwell Technologies
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Zolgensma” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
5. Providers to note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
6. Payment for Zolgensma shall be a once-in-a-lifetime reimbursement under J3399 or any other code (HCPCS, CPT or by NDC).
7. For instructions regarding physician claim form completion, refer to the Med-Cal website, forms section for completion of 837I form and *UB-04* form.

Below is a Zolgensma billing example using *UB-04* form and with 3 claim lines:

- In this example, the total invoice cost of J3399 is $2,125,002.00.
- Note that each provider’s invoice cost may be different.
- If this is split evenly between the three lines, each claim line will have a total of $708,334.00.
- The sum of the three claim lines must equal the paid price on the invoice.
- Note that it is not necessary to include the unit of measure qualifier and numeric quantity.

| 38 | | | a b c d | 39 CODE | VALUE CODES AMOUNT | VALUE CODES AMOUNT | 41 CODE | VALUE CO AM T | |
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| 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | | 46 SERV. UNITS | | 47 TOTAL CHARGES | | 48 NON-COVERED CHARGES |
| | **N4 11digitNDC** | **J3399** | 070120 | | **1** | | **708,334** | **00** | |
| | **N4 11digitNDC** | **J3399** | 070120 | | **1** | | **708,334** | **00** | |
| | **N4 11digitNDC** | **J3399** | 070120 | | **1** | | **708,334** | **00** | |
| 0001 | ***PAGE 1 OF 1*** | CREATION DATE | 070220 | | ***TOTAL*** | | **2,125,002** | **.00** | |
| 50 PAYER NAME | | 51 HEALTH PLAN ID | 52 REL INF D. | 53 ASG. BEN. | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | XXXXXXXXXX | |

**Figure:** Zolgensma Billing Example using a UB-04 form

**Note:** To complete a request, refer to the *Onasemnogene Abeparvovec (Zolgensma) Request* Form.

# Prademagene Zamikeracel (ZEVASKYN™)

## Billing

HCPCS code J3389 (topical administration, prademagene zamikeracel, per treatment). Administration code CPT codes:

- 11104 (punch biopsy of skin [including simple closure, when performed]; single lesion)
- 11105 (punch biopsy of skin [including simple closure, when performed]; each separate/additional lesion)
- 15040 (harvest of skin for tissue cultured skin autograft, 100 sq cm or less).

## Special Billing Instructions

There are two billable steps for ZEVASKYN:

- Biopsy Cell Collection
- Surgical Application

Due to system limitations, providers are to take the following steps when submitting claims for ZEVASKYN for surgical application:

TAR/SAR Submission:

1. Submit and receive back an approved TAR or approved product-specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line for four (4) units on the TAR/SAR request and enter “4” in the Units box.

Claim Submission:

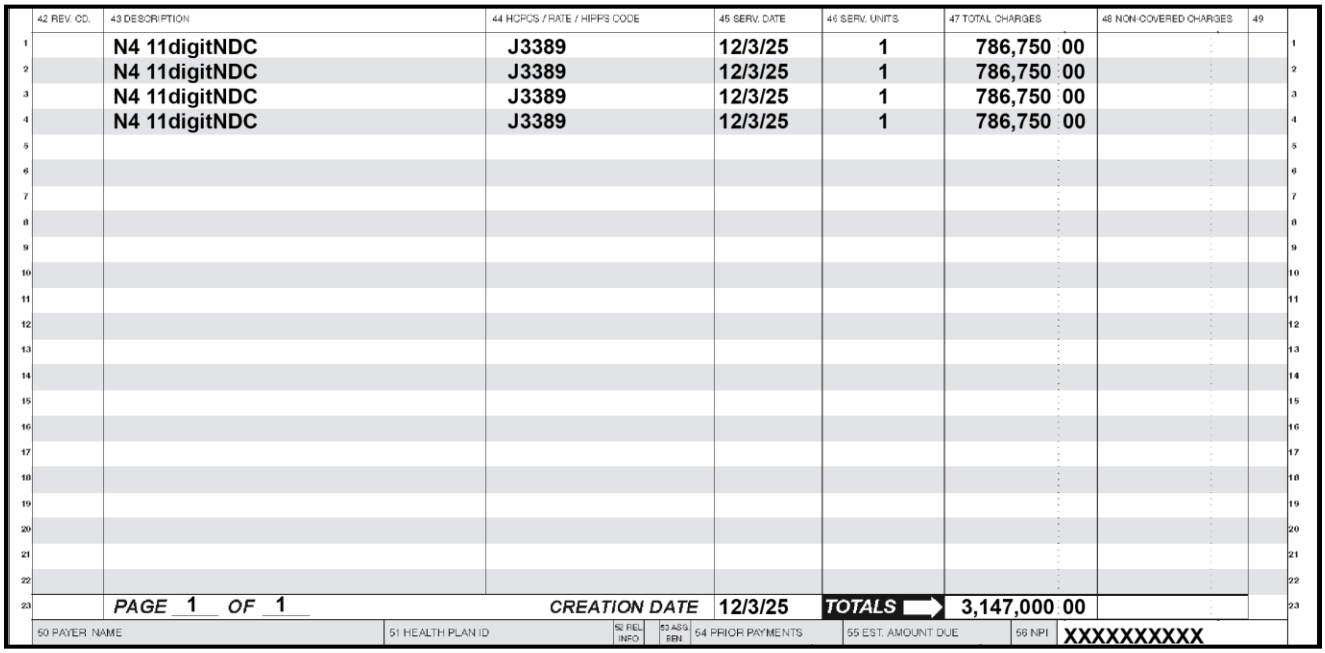
1. Bill using J3389 (topical administration, prademagene zamikeracel, per treatment).
2. Complete claim forms:
   - This billing methodology is restricted to hospital outpatient services (Qualified Treatment Centers). Pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ Provider must submit four (4) claim lines to represent one (1) service.
     - ❖ Each claim line represents one unit.
     - ❖ Provider must submit an invoice for reimbursement.

- ❖ This process will ensure that the total reimbursement paid for the four (4) claim lines is no more than the paid price on the provider-submitted invoice.
- ❖ ZEVASKYN must be billed on its own with no other drug or biologics.

3. Providers are advised to take the following steps in order to ensure that ZEVASKYN claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “ZEVASKYN” on the “Remarks” section of the *UB-04* claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “ZEVASKYN” on the cover sheet, addressed to Attention: Claims Manager and submitted with the 837I claim form.
4. Except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
5. Payment for ZEVASKYN shall be a once-in-a-lifetime reimbursement under J3389 or any other code (HCPCS, CPT or by NDC).

6. For instructions regarding physician claim form completion of 837I and *UB-04* claim forms, refer to the Forms page of the Medi-Cal Providers website.



| | 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | 49 |
|---|---|---|---|---|---|---|---|---|
| 1 | | N4 11digitNDC | J3389 | 12/3/25 | 1 | 786,750 00 | | |
| 2 | | N4 11digitNDC | J3389 | 12/3/25 | 1 | 786,750 00 | | |
| 3 | | N4 11digitNDC | J3389 | 12/3/25 | 1 | 786,750 00 | | |
| 4 | | N4 11digitNDC | J3389 | 12/3/25 | 1 | 786,750 00 | | |
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| 23 | | PAGE 1 OF 1 | CREATION DATE | 12/3/25 | TOTALS | 3,147,000 00 | | |

| 50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL INFO | 53 ASG BEN | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | XXXXXXXXX |
|---|---|---|---|---|---|---|---|

**Figure:** Prademagene zamikeracel (ZEVASKYN) UB-04 Billing Example.

- The total invoice cost of ZEVASKYN is $3,147,000.
- Note that each provider's invoice cost may be different.
- This is split between the four lines.
- The sum of the four claim lines must equal the paid price on the invoice.

**Note**: It is not necessary to include the unit of measure qualifier and numeric quantity.

# Pretomanid

## Billing

Drug code:

Bill the following miscellaneous HCPCS code for drug reimbursement:

- S5000 (prescription drug, generic)
- S5001 (prescription drug, brand name)

## Special Billing Instructions

Provide the following on each claim:

- Name and strength of drug administered
- NDC
- Amount given
- Actual acquisition cost
- Copy of the drug invoice

Administration code:

Directly Observed Therapy (DOT) billed using HCPCS code H0033 (oral medication administration, direct observation) DOT will be administered in the setting determined appropriate by the public health department and may be in the community.

# Ranibizumab

## Billing

HCPCS code: J2778 (injection, ranibizumab, 0.1 mg).

## Special Billing Instructions

CPT code 67028 (intravitreal injection of a pharmacologic agent [separate procedure]) must be billed on the same claim form.

One of the following modifiers is required for reimbursement:

- LT (left side)
- RT (right side)

# Remestemcel-L-rknd (RYONCIL)

## Billing

HCPCS code J3402 (injection, remestemcel-l-rknd, per therapeutic dose).

## Special Billing Instructions

Due to systems limitations, providers must take the following steps when billing J3402 for appropriate reimbursement:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “3” in the Units box.

Claim Submission

1. Bill using J3402 (injection, remestemcel-l-rknd, per therapeutic dose).
2. Completion of claim forms:
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or UB-04 Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I or UB-04 claim form, the provider must submit up to three (3) claim lines to represent a total of one (1) service (for example, one therapeutic dose).
     - ❖ Each claim line represents one unit with a charge amount up to $99,999.99.
     - ❖ The sum of the three claim lines (3 units) shall equal the total amount billed “per therapeutic dose.”
   - Providers must submit an invoice for reimbursement.
   - This process will ensure that the total reimbursement paid for the submitted claim lines is no more than provider submitted invoice paid price.
   - Ryoncil must be billed on its own with no other drug or biologics.

3. Providers are advised to take the following steps in order to ensure that Ryoncil claims are identified and processed expeditiously:
   - Paper claims may be identified by notation of “Ryoncil” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims may be identified by notation of “Ryoncil” on the cover sheet, addressed to “Attention: Claims Manager” and submitted with the 837I claim form.

# Revakinagene taroretcel-lwey (ENCELTO)

## Billing

HCPCS code J3403 (revakinagene taroretcel-lwey, per implant).

## Special Billing Instructions

Due to systems limitations, providers must take the following steps when billing J3403 for appropriate reimbursement:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter “3” in the Units box.

Claim Submission

1. Bill using J3403 (revakinagene taroretcel-lwey, per implant).
2. Completion of claim forms:
   - Outpatient claims may be billed electronically or by paper claim using the 837I/*UB04* (Institutional) or 837P/*CMS1500* (Professional) Medi-Cal claim forms with the following conditions:
     - ❖ On the 837I/*UB-04* claim form, the provider may submit up to three (3) units on one claim line to represent a total of one (1) service (for example, one implant).

- ❖ Each claim line represents 3 units with a charge amount up to $999,999.99.

- On the 837P*/CMS 1500* claim form, the provider may submit one unit each on up to three (3) claim lines to represent a total of one (1) service (for example, one implant).
  - ❖ Each claim line represents 1 unit with a charge amount up to $99,999.99.
  - ❖ The sum of the three claim lines (3 units) shall equal the total amount billed "*per implant*."
- Providers must submit an invoice for reimbursement.
- This process will ensure that the total reimbursement paid for the submitted claim lines is no more than provider submitted invoice paid price.
- Encelto must be billed on its own with no other drug or biologics.

3. Providers are advised to take the following steps to ensure that Encelto claims are identified and processed expeditiously:
   - Paper claims: drug product may be identified by the notation of "Encelto" in Box 80 (Remarks) of the *UB-04* claim form or Box 19 (Additional Claim Information) on the *CMS 1500* claim form and submitted to:

     Attention: Claims Manager
     Medi-Cal Fiscal Intermediary
     P.O. Box 526006
     Sacramento, CA 95852-6006
   - Electronic claims: drug product may be identified by the notation of "Encelto" on the cover sheet, submitted with the 837I/837P claim form, addressed to "Attention: Claims Manager."

# Tisagenlecleucel (Kymriah™)

## Billing

HCPCS code Q2042 (Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).

Administration code: CPT code 38228 (chimeric antigen receptor T-cell [CAR-T] therapy; CAR-T cell administration, autologous).

## Special Billing Instructions

Due to systems limitations, providers are to take the following steps when submitting claims for Kymriah:

TAR/SAR Submission

1. Submit and receive back an approved TAR/SAR.
2. Providers must submit one service line on the TAR/SAR request and enter “6” in the *Units* box.

Claim Submission

1. Bill using Q2042 (tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).
2. Completion of claim forms:
   - Outpatient claims may be billed by paper claim using *UB-04* or electronically using 837I
   - On the 837I or *UB-04* claim form, provider must submit one claim line to represent one service or six (6) units.
     - ❖ Claims submitted with more than one claim line will be denied.
   - Providers must submit an invoice for reimbursement.
   - This process will ensure that the total reimbursement paid for the quantity of six (6) is no more than the paid price on the provider submitted invoice.
   - Kymriah must be billed on its own with no other drug or biological.
3. For instructions regarding physician claim form completion, refer to the Forms page on the Medi-Cal Providers website, for completion of 837I and UB-04 claim forms. Providers may also refer to the *UB-04 Completion: Outpatient Services* section of the provider manual.
4. Providers may bill separately for the administration (infusion) of the CAR-T cell using CPT code 38228.

# Valoctocogene Roxaparvovec-rvox (ROCTAVIAN™)

## Billing

HCPCS code J1412 (injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes).

**Note:** Reimbursement for Roctavian shall be one dose in a lifetime reimbursement under J1412 or any other code (HCPCS, CPT or by NDC).

## Special Billing Instructions

Due to systems limitations, providers must take the following steps when billing J1412 for appropriate reimbursement:

TAR/SAR Submission

1. Submit and receive back an approved TAR or approved product specific SAR.
2. The TAR/SAR is not negotiated.
3. Provider must submit one (1) service line on the TAR/SAR request and enter the total dose in milliliters (mls) in the Units box.

Claim Submission

1. Bill using HCPCS code, J1412 (injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes).
2. Completion of claim forms:
   - This billing methodology is restricted to hospital outpatient services and Hemophilia Treatment Centers (HTCs). Pharmacies and clinics cannot bill using this methodology.
   - Outpatient claims may be billed electronically or by paper claim using 837I (Institutional) or *UB-04* Medi-Cal claim forms with the following conditions:
     - ❖ Billing is based on total mL administered, which is determined by the patient's weight and the prescribed dose (in mL/kg).
     - ❖ Roctavian must be billed in whole HCPCS units.

Step-by-Step Billing Calculation Example

- Patient weight: 70kg
- Dose: three mL/kg
- Total dose in mL:
  - 70 kg multiplied by three mL/kg equals 210 mL

This means 210 HCPCS units (since one unit equals one mL for J1412).

Step 1: Determine Total HCPCS Units

Use the following formula:

Total HCPCS Units equals patient weight (kg) multiplied by dose (mL/kg)

For this example: 70 multiplied by three equals 210 units.

Step 2: Determine Number of Claim Lines

Due to system billing limits, no more than 99 units can be billed per claim line.

To find the number of required claim lines:

Number of claim lines equals total units divided by 99

For this example: 210 divided by 99 equates to 2.12. Round up to three claim lines.

Step 3: Distribute Units Across Claim Lines

Next, distribute the total units evenly across the calculated number of claim lines (or as evenly as possible), keeping each line less than or equal to 99 units.

For 210 units over three claim lines:

- Line one: 70 units
- Line two: 70 units
- Line three: 70 units

Total equals 70 plus 70 plus 70 equals 210 units.

Billing Requirements

- All claim lines are less than or equal to 99 units. The unit split may be adjusted slightly (for example, 99/99/12) if needed, as long as each line is less than or equal to 99 and the total adds up to the full dose.
- Ensure the total units on the TAR match the total units billed on the 8371 or UB-04 claim form. Any mismatch may result in denial or delay of authorization or payment.
- The provider must submit an invoice for reimbursement. The total reimbursement paid for the submitted claim lines is no more than the provider submitted invoice paid price.

- Roctavian must be billed on its own with no other drug or biologics.
- Providers are advised to take the following steps in order to ensure that Roctavian claims are identified and processed expeditiously:
  - Paper claims may be identified by notation of “Roctavian” on the “Remarks” section of the UB-04 claim form (Field #80) and submitted to:

    Attention: Claims Manager
    Medi-Cal Fiscal Intermediary
    P.O. Box 526006
    Sacramento, CA 95852-6006
  - Electronic claims may be identified by notation of “Roctavian” on the cover sheet, addressed to “Attention: Claims Manager” and submitted with the 837I claim form.
- Providers should note that except for the first claim line, payment for any additional line will be delayed for two to three additional weeks due to systems constraints.
- For instructions regarding physician claim form completion for 837I and UB-04 claim forms, refer to the Forms page on the Medi-Cal Providers website and the *UB-04 Completion: Outpatient Services* section of the appropriate Part 2 manual.

| | 42 REV. CD. | 43 DESCRIPTION | 44 HCPCS / RATE / HIPPS CODE | 45 SERV. DATE | 46 SERV. UNITS | 47 TOTAL CHARGES | 48 NON-COVERED CHARGES | 49 | |
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| 1 | | N4 11digitNDC | J1412 | 6/30/25 | 70 | 800000 00 | | | 1 |
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| 23 | 0001 | PAGE ____ OF ____ | CREATION DATE | 6/30/25 | TOTALS | 2400000 00 | | | 23 |

| 50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL INFO | 53 ASG BEN | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 9123456780 |
|---|---|---|---|---|---|---|---|

**Figure:** Valoctocogene Roxaparvovec-rvox Gene Therapy UB-04 Billing Example.

# Viltolarsen (Viltepso™)

## Billing

HCPCS code J1427 (Injection, viltolarsen, 10mg).

## Special Billing Instructions for CCS Patients

- Submissions of authorization requests for eteplirsen, golodirsen, or viltolarsen are not included in Service Code Groupings.
  - For clients residing in an independent county, SARs should be submitted to the CCS independent county office.
  - For clients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at CCSExpeditedReview@dhcs.ca.gov or via secure RightFax (916) 440-5306.
- All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

Any questions regarding the policy for CCS patients can be directed to the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

After the transition of pharmacy benefit to Medi-Cal RX in 2021, all requests for prior authorization of medications billed by National Drug Code and dispensed by a Medi-Cal enrolled pharmacy provider, shall be sent from the pharmacy provider to the Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (Magellan). The Medi-Cal RX website provides guidance.

## Legend

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

| Symbol | Description |
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| ‹‹ | 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. |