

VYKOURA™

(leucovorin calcium) injection

BILLING AND CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.



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The contents herein provide general coverage, coding, and payment information about VYKOURA. The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA™ does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

VYKOURA™ (leucovorin calcium) injection is indicated for:

- Rescue after high-dose methotrexate (MTX) therapy in adult and pediatric patients.
- Reducing the toxicity of:
 - Methotrexate in adult and pediatric patients with impaired methotrexate elimination
or
 - Folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose in adult and pediatric patients.
- Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients when oral therapy is not feasible.
- Treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

Limitations of Use

VYKOURA is not indicated for pernicious anemia and megaloblastic anemia secondary to the lack of vitamin B₁₂, because of the risk of progression of neurologic manifestations despite hematologic remission.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYKOURA is contraindicated in patients who have had a severe hypersensitivity reaction to leucovorin (folinic acid), levoleucovorin, or folic acid. Reactions have included anaphylactic reactions.

WARNINGS AND PRECAUTIONS

Hypersensitivity

Hypersensitivity reactions, including anaphylactic reactions and urticaria, have been reported following the administration of leucovorin. VYKOURA is contraindicated in patients who have had a severe hypersensitivity reaction to leucovorin, levoleucovorin, or folic acid. Withhold or permanently discontinue VYKOURA based on the severity of hypersensitivity.

Hypercalcemia

Because of the calcium content of the VYKOURA, do not administer more than 160 mg of VYKOURA intravenously per minute.

Risk of Administration Errors

In the treatment of accidental overdoses of intrathecally administered folic acid antagonists, do not administer VYKOURA intrathecally. VYKOURA MAY BE HARMFUL OR FATAL IF GIVEN INTRATHECALLY.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in patients receiving high-dose methotrexate therapy with leucovorin rescue are stomatitis and vomiting.

The most common adverse reactions (>50%) in patients receiving leucovorin in combination with fluorouracil for metastatic colorectal cancer are stomatitis, diarrhea, and nausea.

VYKOURA™

(leucovorin calcium) injection

Ordering Information

To order VYKOURA (leucovorin calcium) injection, please contact one of the authorized specialty distributors below:



50 mg/5 mL
NDC: 83831-0147-05



350 mg/35 mL
NDC: 83831-0148-35



500 mg/50 mL
NDC: 83831-0149-50



Highlights¹

- Aqueous formulation with enhanced solubility to avoid crystallization
 - Indicated for both intravenous (IV) and intramuscular (IM) administration
 - No reconstitution required prior to administration
 - Ready-to-use liquid formulation



Unique J-Code Expected
October 2026

AVYXASSIST™

Simplifying patient access, providing comprehensive support

AVYXASSIST can offer support to qualifying patients in need. The program provides the following services.*

- Benefit verification
- Prior authorization assistance
- Appeals support
- Claims support
- Referrals to 501(c)(3) foundations
- Free product assistance
- Bridge supply
- Product replacement
- Copay assistance

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

To enroll, please choose one of the following options.

Call 866-939-8927
Monday through Friday
8 AM to 8 PM ET



CALL NOW

Click on the link
below to begin
online enrollment



ENROLL
NOW

Download, print, and fax
a completed enrollment
form to 833-852-3420



DOWNLOAD
NOW

Eligible patients prescribed
an AVYXA product may
pay as little as

\$0 per dose*

AVYXASSIST™

ELIGIBLE PATIENTS
MAY PAY AS
LITTLE AS \$0

BIN 025706
PCN IFX
GROUP # 00000000
MEMBER # 0000000000



Patients with questions, please call 866-939-8927

Our dedicated AVYXASSIST Patient Access Specialists work collaboratively with you to explore tailored affordability solutions. AVYXA aims to facilitate financial accessibility for eligible patients in need.



ENROLL
NOW

Copay Program Details for Eligible Patients

In some cases, the patient out-of-pocket cost for their AVYXA product could be as low as \$0.*

- Up to \$25,000 per product in annual benefits

*Please visit avyxassist.com/copay-assistance-program to see full Terms and Conditions.

Additional Assistance

Patients without insurance or who do not qualify for copay assistance through AVYXASSIST may qualify for free product assistance. Call an AVYXASSIST Patient Access Specialist to learn more.

Call 866-939-8927 or Fax 833-852-3420 | Monday through Friday, 8:00 AM to 8:00 PM ET

Please see Important Safety Information on pages 3 and 17-18 and full [Prescribing Information for VYKOURA™](#).

VYKOURA™ Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA does not recommend using any particular diagnosis code in billing situations for VYKOURA (leucovorin calcium) injection. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs for VYKOURA Injection

National Drug Codes (NDC) are unique product identifiers used for drugs and biologicals. The Centers for Medicare & Medicaid Services (CMS) and private payers often require an NDC as part of the billing claim form. If the NDC Package code is less than 11 digits, the code must be padded with leading zeros, as shown below.²

NDC ¹	Strength	Vial Size	NDC Unit
83831-0147-05	50 mg/5 mL (10 mg/mL)	Single-dose vial	mL
83831-0148-35	350 mg/35 mL (10 mg/mL)	Single-dose vial	mL
83831-0149-50	500 mg/50 mL (10 mg/mL)	Single-dose vial	mL

Note: NDC Unit = mL to maintain consistency with Avyxa's standardized quick-reference tables for liquid dosage forms.

HCPCS Code³

HCPCS Level II codes are used to identify most drugs and biologics administered in an office setting. Correct coding requires reporting the most specific code to describe the service accurately. Not otherwise classified (NOC) and unclassified codes are used only when a more specific HCPCS code is not available or assigned.

VYKOURA Injection J-Code	Description
J3490	Unclassified drugs
J9999	Not otherwise classified, antineoplastic drugs

Note: Some payers might accept NOC code J9999 for this product, although code J3490 is considered correct coding. Check with individual payers for their guidelines.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

Related Service J-Codes ³	Description
J8610	Methotrexate; oral, 2.5mg
J8611	Methotrexate (iylamvo), oral, 2.5mg
J8612	Methotrexate (xatmep), oral, 2.5mg
J9190	Injection, fluorouracil, 500mg
J9255	Injection, methotrexate (Accord) not therapeutically equivalent to J9260, 50mg
J9260	Injection, methotrexate sodium, 50mg

For Medicare to properly reimburse unclassified or NOC drugs, providers must include the following supplemental information in the 2400/SV101-7 data element or Item 19 of the CMS-1500 form:

- The name of the drug,
- The total dosage (plus the strength of the dosage, if appropriate), and
- The method of administration.³⁻⁶

Some payers may require entering the NDC in item 19 of the CMS-1500 form. Medicare determines the proper payment for unclassified drugs and biologicals based on the narrative information listed above, not the number of units billed.^{5,6}

Service Units:

Until a permanent J-Code is assigned, VYKOURA™ injection is often billed using one (1) unit of service.⁵

Important: List one unit of service in the 2400/SV1-04 data element or item 24G of the CMS 1500 form. Do not quantity-bill unclassified drugs and biologicals even if multiple units of the drug are provided. Claims for unclassified drugs and biologicals may be rejected if any of the information listed above is missing or if the unclassified code is billed with more than one unit of service.⁵ This billing is used in traditional Medicare billing. Check with your payers for their unit requirements if you are unsure.

Modifiers

A medical coding modifier is two characters (letters or numbers) appended to a CPT or HCPCS Level II code. Modifiers provide additional information about the medical procedure or service without changing the definition of the code. Using modifiers allows healthcare providers to specify specific circumstances, such as the route of administration, wasted product, and other relevant details.⁷

Drug Waste Modifiers ⁸	
Modifier	Description
JW	Drug amount discarded/not administered to patient
JZ	Zero drug amount discarded/not administered to patient

VYKOURA injection is packaged as a single-dose vial.¹ Medicare will pay for drug waste on single-use items that are medically necessary and appropriately documented in the patient's medical record. Medicare requires discarded drugs to be reported with the -JW modifier on a separate line; if there is no waste, VYKOURA injection must be billed on one line with the modifier -JZ.⁸

Because VYKOURA does not currently have a permanent J-Code, it is billed with one service unit.⁵ There is no way to record waste, so one would attach Modifier -JZ to the claim line. Medicare requires this; please ascertain if other payers require -JZ and -JW modifiers.

340B Drug Pricing Modifier ⁹	
Modifier	Description
TB	Drug or biological acquired with 340b drug pricing program discount, reported for informational purpose

The "TB" modifier is used for informational purposes to identify drugs purchased through the 340B program. This enables CMS to accurately implement the Part B inflation rebate program established by the Inflation Reduction Act of 2022, as 340B drugs are excluded from the inflation rebate calculation.⁹

CPT Drug Administration Codes

CPT codes bill for drug administration services in the physician's office and other outpatient settings. Administration of VYKOURA™ varies by indication and usage. Please code based on the start and stop times listed in the patient's medical chart.¹⁰

CPT Code ¹¹	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump

CPT codes, descriptions, and other data are copyright 2025 American Medical Association. All Rights Reserved. Applicable FARS/ HHSARS apply. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Most Commonly Used Codes: CPT **96365** (initial IV infusion, up to 1 hour) and **96367** (additional sequential infusion of a new drug/substance, up to 1 hour) are most frequently used for **VYKOURA intravenous administration** based on treatment protocols.

Revenue Codes¹²

Claim Item	Revenue Code	Description
VYKOURA Injection	0636	Drugs requiring detailed coding
Drug Administration	0260	IV Therapy – General
	0261	IV Therapy – Infusion Pump
Pharmacy Services	0250	Pharmacy - General

Place of Service (POS) Codes¹³

Place of service (POS) Codes are used on professional claims to specify the entity where service(s) are rendered.

Place of Service	Code	Description
Physician Office	11	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
Off-Campus Outpatient Hospital	19	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
On-Campus Outpatient Hospital	22	A portion of a hospital's main campus, which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

ICD-10-CM Diagnosis Coding

VYKOURA™ (leucovorin calcium) injection is indicated for¹:

- Rescue after high-dose methotrexate (MTX) therapy in adult and pediatric patients.
- Reducing the toxicity of:
 - Methotrexate in adult and pediatric patients with impaired methotrexate elimination or
 - Folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose in adult and pediatric patients.
- Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients when oral therapy is not feasible.
- Treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

International Classification of Disease, 10th Edition, Clinical Modification Codes for VYKOURA Injection¹⁴

Indication	ICD-10-CM Codes
Colorectal Cancer	C18.0; C18.1; C18.2; C18.3; C18.4; C18.5; C18.6; C18.7; C18.8; C18.9; C19; C20; C21.8
Osteosarcoma	C40.00; C40.01; C40.02; C40.10; C40.11; C40.12; C40.20; C40.21; C40.22; C40.30; C40.31; C40.32; C40.80; C40.81; C40.82; C40.90; C40.91; C40.92; C41.0; C41.1; C41.2; C41.3; C41.4; C41.9
Folate Deficiency Anemia	D52.0; D52.1; D52.8; D52.9
Poisoning by Antineoplastic and Immunosuppressive Drugs	T45.1X1A; T45.1X1D; T45.1X1S
Adverse Effect of Antineoplastic and Immunosuppressive Drugs	T45.1X5A; T45.1X5D; T45.1X5S
Encounter for Antineoplastic Chemotherapy	Z51.11
Long Term Use of Antimetabolites (includes 5-fluorouracil and methotrexate)	Z79.631

VYKOURA™ injection Billing and Coding Information: ICD Diagnosis Codes by Indication

ICD-10-CM coding for VYKOURA injection varies by payer. Please check with each payer to ascertain the best coding for VYKOURA injection according to their policy.

Colorectal Cancer: ICD-10-CM Diagnosis Coding ¹⁴	
ICD-10 Code	Descriptor
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal

Osteosarcoma: ICD-10-CM Diagnosis Coding ¹⁴	
ICD-10 Code	Descriptor
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb

C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum, and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum, and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified

Folate Deficiency Anemia: ICD-10-CM Diagnosis Coding¹⁴

ICD-10 Code	Descriptor
D52.0	Dietary folate deficiency anemia
D52.1	Drug-induced folate deficiency anemia
D52.8	Other folate deficiency anemias
D52.9	Folate deficiency anemia, unspecified

Poisoning by Antineoplastic and Immunosuppressive Drugs (Unintentional): ICD-10-CM Diagnosis Coding¹⁴

ICD-10 Code	Descriptor
T45.1X1A	Poisoning by antineoplastic and immunosuppressive drugs, accidental (unintentional), initial encounter
T45.1X1D	Poisoning by antineoplastic and immunosuppressive drugs, accidental (unintentional), subsequent encounter
T45.1X1S	Poisoning by antineoplastic and immunosuppressive drugs, accidental (unintentional), sequela

Adverse Effect of Antineoplastic and Immunosuppressive Drugs: ICD-10-CM Diagnosis Coding¹⁴

ICD-10 Code	Descriptor
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding¹⁴

ICD-10 Code	Descriptor
Z51.11	Encounter for antineoplastic chemotherapy

Long Term Use of Anti-Metabolites (includes 5-fluorouracil and methotrexate): ICD-10-CM Diagnosis Coding¹⁴

ICD-10 Code	Descriptor
Z79.631	Long term (current) use of antimetabolite agent

Sample UB-04 / CMS 1450 Claim Form^{3,11,12,14,15}

Form Locator (FL) 42

(Electronic Claim Form = Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for VYKOURA™ injection to your revenue code, 0636.

Additionally, enter an appropriate revenue code for the administration service, such as 0260, IV Therapy - General or others based on the cost center where the service was performed.

FL 43

(NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed.

If required, submit the N4 indicator first, followed by the 11-digit NDC code. Then, report the NDC unit measurement code followed by the quantity.

The NDC unit measurement code for VYKOURA is ML for milliliters.

FL 44

(Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP)

Enter the appropriate HCPCS code: J3490, Unclassified drugs.

For administration, enter the appropriate code or codes for intravenous administration. As an example, CPT Code 96367* is used for intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion. List in addition to the primary procedure, unless drug is used alone.

*CPT Code 96367 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure).

FL 45

(Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46

(Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed.

Enter the number of service units for each item. For Medicare, when using miscellaneous codes, the service unit should be 1.

FL 63

(Electronic Claim Form = Loop 2300, REF/G1/02):

Enter treatment authorization code.

FL 67A-Q

(Electronic Claim Form Loop 2300, H101-2 (H101-1=BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible.

An example is: C40.02, Malignant neoplasm of scapula and long bones of left upper limb; and T45.1X5A, Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter.

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba. Com. Palmetto GBA, Accessed September 16, 2025. [https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/\\$FILE/EDI_837I_v5010A2_crosswalk.pdf](https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$FILE/EDI_837I_v5010A2_crosswalk.pdf)

CPT Codes are a registered trademark of the American Medical Association (AMA), All Rights Reserved.

THIS INFORMATION IS PROVIDED FOR EDUCATIONAL PURPOSES ONLY AND IS NOT A GUARANTEE OF COVERAGE. IT IS THE SOLE RESPONSIBILITY OF THE HEALTH CARE PROVIDER TO SELECT THE PROPER CODES AND ENSURE THE ACCURACY OF ALL STATEMENTS USED IN SEEKING COVERAGE AND REIMBURSEMENT FOR AN INDIVIDUAL PATIENT.

Sample CMS 1500 Claim Form^{3,5,6,11,13,14}

Item 19

(Electronic Claim Form = Loop 2400, Segment SV101-2) Additional claim information

When billing a Not Otherwise Classified code, providers must indicate the following: The name of the drug, total dosage (plus strength of dosage, if appropriate), method of administration, and wastage. Some payers may require NDC number.

Item 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record.

An example for this drug is: C40.02, Malignant neoplasm of scapula and long bones of left upper limb; and T45.1X5A, Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter.

Use Item 21 C-L fields for other secondary diagnoses.

Item 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Item 24A-B

(Electronic Claim Form: Item 24A (Electronic Claims = Loop 2400, DTP02; Item 24 B (Loop 2300/2400, Segment CLM05-1/SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Physician Office = 11.

If required, in the red shaded portion, submit the N4 indicator first, followed by the 11-digit NDC code. Then, report the NDC unit measurement code followed by the quantity in the same red shaded portion.

The NDC unit measurement code for VYKOURA™ is ML for milliliters.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare#) MEDICAID (Medical#) TRICARE (DMO#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BOX (LUNG) (ID#) OTHER (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM DD YY) SEX (M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.)

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) (MM DD YY) QUAL

15. OTHER DATE (MM DD YY) QUAL

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (I7a NPI 17b NPI)

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM DD YY TO MM DD YY)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? (YES NO \$ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24B)) (ICD Ind: A L E J K L)

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From DD YY To MM DD YY) B. PLACE OF SERVICE (EMG) C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (MODIFIER) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. UNIT (RPM) I. ID. QUAL J. RENDERING PROVIDER ID. #

25. FEDERAL TAX I.D. NUMBER SSN/EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (No part class. or back) (YES NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH# ()

SIGNED DATE a. NPI b. NPI a. NPI b. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Item 24D

(Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code: J3490, Unclassified drugs.

For administration, enter the appropriate code or codes for intravenous administration. As an example, CPT Code 96367* is used for intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion. List in addition to the primary procedure, unless drug is used alone.

Item 24E

(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Item 21.

Item 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of J-Code service units for each item.

For Medicare, when using miscellaneous codes, the service unit should be 1.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

Item 24D (Loop 2400, Segment SV101) is located in the top section of the form, corresponding to the PICA (Patient Information) area.

Item 24E (Loop 2400, Segment SV107) is located in the middle section of the form, corresponding to the diagnosis and provider information area.

Item 24G (Loop 2400, SV104) is located in the bottom section of the form, corresponding to the J-Code service units table.

The form includes sections for: 1. PICA, 2. PATIENT'S NAME, 3. PATIENT'S BIRTH DATE, 4. INSURED'S NAME, 5. PATIENT'S ADDRESS, 6. PATIENT RELATIONSHIP TO INSURED, 7. INSURED'S ADDRESS, 8. RESERVED FOR NUCC USE, 9. OTHER INSURED'S NAME, 10. IS PATIENT'S CONDITION RELATED TO, 11. INSURED'S POLICY GROUP OR FECA NUMBER, 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE, 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE, 14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (GMP), 15. OTHER DATE, 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION, 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE, 17a. NPI, 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES, 19. ADDITIONAL CLAIM INFORMATION, 20. OUTSIDE LAB?, 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY, 22. RE submission CODE, 23. PRIOR AUTHORIZATION NUMBER, 24. A. DATES OF SERVICE, B. PROCEDURES, SERVICES, OR SUPPLIES, C. DIAGNOSIS, D. CHARGES, E. DIAGNOSIS POINTER, F. \$ CHARGES, G. DATES (INTS), H. \$/UNIT, I. ID, J. RENDERING PROVIDER ID, 25. FEDERAL TAX I.D. NUMBER, 26. PATIENT'S ACCOUNT NO., 27. ACCEPT ASSIGNMENT?, 28. TOTAL CHARGE, 29. AMOUNT PAID, 30. Pts. for NUCC Use, 31. SIGNATURE OF PHYSICIAN OR SUPPLIER, 32. SERVICE FACILITY LOCATION INFORMATION, 33. BILLING PROVIDER INFO & PH#.

*CPT Code 96367 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure).

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba. Com. Palmetto GBA, Accessed September 16, 2025. [https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/\\$FILE/EDI_837I_v5010A2_crosswalk.pdf](https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$FILE/EDI_837I_v5010A2_crosswalk.pdf)

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IMPORTANT SAFETY INFORMATION (CONTINUED)

DRUG INTERACTIONS

Effects of Other Drugs on VYKOURA

Glucarpidase

Administer VYKOURA at least 2 hours before or 2 hours after the glucarpidase dose when administering concomitantly. Glucarpidase can decrease leucovorin concentrations, which may decrease the effect of leucovorin rescue.

Effects of VYKOURA on Other Drugs

Certain Antiepileptic Drugs

Increase monitoring for seizure activity in patients taking certain concomitant antiepileptic drugs.

Folic acid in high doses may reduce the effectiveness of certain antiepileptic drugs (e.g., phenobarbital, phenytoin, and primidone) and thereby increase the frequency of seizures.

Trimethoprim-Sulfamethoxazole

Avoid concomitant use of VYKOURA with trimethoprim-sulfamethoxazole. The effectiveness of trimethoprim-sulfamethoxazole can be decreased if used concomitantly with VYKOURA which was associated with increased rates of treatment failure and mortality in patients with HIV infection who receive trimethoprim-sulfamethoxazole for the acute treatment of *Pneumocystis jirovecii* pneumonia.

USE IN SPECIFIC POPULATIONS

Pregnancy

Agents administered in combination with VYKOURA may cause fetal harm. Refer to the Prescribing Information for agents administered in combination with VYKOURA for additional information.

Lactation

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYKOURA and any potential adverse effects on the breastfed infant from VYKOURA or from the underlying maternal condition.

Refer to the Prescribing Information for agents administered in combination with VYKOURA for breastfeeding recommendations.

Pediatric Use

VYKOURA is indicated to reduce the toxicity of MTX in pediatric patients with impaired MTX elimination, and folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose.

Geriatric Use

Clinical studies of leucovorin calcium did not show differences in safety or effectiveness between subjects over 65 and younger subjects. Other clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older patients cannot be ruled out. This drug is known to be excreted by the kidney and the risk of toxic reactions to the drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this patient population.

IMPORTANT SAFETY INFORMATION (CONTINUED)

DOSAGE AND ADMINISTRATION GUIDELINES

- VYKOURA is indicated for intravenous (IV) and intramuscular (IM) administration. **Do not administer intrathecally. VYKOURA may be harmful or fatal if given intrathecally.**
- Do NOT mix VYKOURA with other drugs or administer other drugs through the same intravenous line. A precipitate may form if VYKOURA is mixed with fluorouracil.
- Due to the calcium content of VYKOURA, do **NOT** exceed the maximum infusion rate of 160 mg/minute to avoid hypercalcemia.

Please see full Prescribing Information of VYKOURA.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

VYKOURA™ (leucovorin calcium) injection offers resources to help your patients start and stay on prescribed therapy.

We are dedicated to providing your patients with ongoing support to help them access AVYXA medications as prescribed.



Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

References: 1. VYKOURA Prescribing Information. AVYXA™ Pharma. Revised January 2026. 2. Drugs.com. National drug codes explained. Accessed August 19, 2025. <https://www.drugs.com/ndc.html#:~:text=The%20CMS%20NDC%20identifier%20is,5%2D4%2D2%20configuration> 3. American Academy of Professional Coders (AAPC). HCPCS Level II Expert: Service/Supply Codes for Caregivers & Suppliers 2025. AAPC; 2024. 4. Centers for Medicare and Medicaid Services. Billing and coding: additional claim documentation requirements for not otherwise classified (NOC) drugs and biological products with specific FDA label indications. Accessed August 21, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=54880> 5. Florida Medical Association. Article - billing and coding: complex drug administration coding (A59074). Accessed August 22, 2025. https://www.flmedical.org/florida/Florida_Public/Docs/LCA-A59074.pdf 6. Centers for Medicare and Medicaid Services. Medicare claims processing manual: chapter 26 – completing and processing the form CMS 1500 data set. Transmittal 10 – health insurance claim form CMS 1500. Accessed August 21, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf> 7. American Academy of Professional Coders (AAPC). What Are Medical Coding Modifiers? Accessed November 3, 2025. <https://www.aapc.com/resources/what-are-medical-coding-modifiers?srsId=AfmBOopepZVWxPdYT5ymJbYKZW5YxQqYM580D5a8rLdRklw3jnLvD> 8. Centers for Medicare and Medicaid Services. Billing and coding: JW and JZ modifier billing guidelines. Accessed September 3, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55932> 9. Centers for Medicare and Medicaid Services. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. Accessed November 3, 2025. <https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf> 10. American Medical Association. CPT® overview and code approval. Accessed August 19, 2025. <https://www.ama-assn.org/practice-management/cpt/cpt-code-set-overview> 11. American Medical Association. Current Procedural Terminology: CPT 2025 Professional Edition. AMA; 2024. 12. Noridian Healthcare Solutions. Revenue codes. Accessed August 21, 2025. <https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes> 13. Centers for Medicare and Medicaid Services. Place of service code set. Accessed August 20, 2025. <https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets> 14. American Academy of Professional Coders (AAPC). ICD-10-CM Expert: Diagnosis codes for providers & facilities 2025. AAPC; 2024. 15. Centers for Medicare and Medicaid Services. Medicare claims processing manual: chapter 25 – completing and processing the form CMS 1450 data set. Transmittal 75- general instructions for completion of form CMS1450 for billing. Accessed August 19, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf>

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