



AVOPEF[®]
(etoposide) injection

BILLING & CODING GUIDE



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The contents herein provide general coverage, coding, and payment information about AVOPEF. 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), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA Pharma, LLC 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, INCLUDING BOXED WARNING

INDICATIONS

Refractory Testicular Cancer

AVOPEF[®], in combination with chemotherapy, is indicated for the treatment of refractory testicular cancer in adult patients.

Small Cell Lung Cancer

AVOPEF, in combination with chemotherapy and immunotherapy, is indicated for the first-line treatment of small cell lung cancer (SCLC) in adult patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE MYELOSUPPRESSION

- **AVOPEF can cause severe myelosuppression resulting in infection or bleeding.**
- **Do not administer AVOPEF to patients with absolute neutrophil counts of less than 500 cells/mm³ or platelets less than 50,000 cells/mm³.**
- **Monitor complete blood cell counts, prior to the administration of AVOPEF and before each subsequent cycle, and at appropriate intervals during and after therapy.**

WARNINGS AND PRECAUTIONS

Severe Myelosuppression

AVOPEF can cause severe and fatal myelosuppression, including neutropenia, febrile neutropenia, anemia, and thrombocytopenia.

Monitor complete blood counts with differential before each AVOPEF administration and at appropriate intervals during and after treatment with AVOPEF. Do not administer AVOPEF to patients with absolute neutrophil counts of less than 500 cells/mm³ or platelets less than 50,000 cells/mm³.

Hypersensitivity and Infusion-Related Reactions

AVOPEF can cause severe and fatal infusion-related reactions including anaphylactic reactions characterized by chills, fever, tachycardia, bronchospasm, dyspnea and hypotension. Hypertension and flushing have occurred.

At the first sign of hypersensitivity, stop the infusion and administer volume expanders, corticosteroids, antihistamines, and pressor agents as appropriate. Permanently discontinue AVOPEF in patients who experience a severe hypersensitivity reaction. Hypotension due to rapid intravenous injection has also occurred. To reduce the risk of hypotension due to an infusion-related reaction, administer AVOPEF by intravenous infusion over 30 to 60 minutes.

Extravasation Resulting in Tissue Necrosis

Extravasation of etoposide can result in swelling, pain, cellulitis, and tissue necrosis.

Secondary Leukemia

Secondary leukemia has occurred with use of etoposide.

Risk of Increased AVOPEF Toxicity with Low Serum Albumin

Etoposide is highly protein-bound. Patients with low serum albumin may have increased concentrations of unbound etoposide and may be at an increased risk for etoposide associated adverse reactions. Monitor for increased adverse reactions during treatment with AVOPEF in patients with low serum albumin.

Alcohol Content

The alcohol content in a dose of AVOPEF may affect the central nervous system and should be taken into account for patients in whom alcohol intake should be avoided or minimized. Consideration should be given to the alcohol content in AVOPEF on the ability to drive or use machines immediately after the infusion. Each administration of AVOPEF at 100 mg/m² delivers 1.5 g/m² of ethanol. For a patient with a BSA of 2.0 m² this would deliver 3.0 grams of ethanol. Other etoposide products may have a different amount of alcohol or no alcohol.

Embryo-Fetal Toxicity

AVOPEF can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with AVOPEF and for 4 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions are myelosuppression, hypersensitivity, nausea/vomiting, and alopecia.

DRUG INTERACTIONS

Effect of Other Drugs on AVOPEF

CYP3A Inhibitors: Avoid concomitant use of strong CYP3A inhibitors. Etoposide is a CYP3A4 substrate. Strong CYP3A inhibitors may increase etoposide exposure, which may increase the risk of AVOPEF-associated adverse reactions.

CYP3A Inducers: Avoid concomitant use of strong CYP3A inducers. Etoposide is a CYP3A4 substrate. Strong CYP3A inducers may reduce etoposide exposure, which may decrease the effectiveness of AVOPEF.

Effect of AVOPEF on Other Drugs

Vitamin K Antagonists: Monitor INR more frequently and modify the dosage of the vitamin K antagonists as appropriate. Co-administration of AVOPEF with warfarin can result in elevated international normalized ratio (INR).



Ordering Information

To order AVOPEF® (etoposide) Injection, please contact one of the authorized specialty distributors below:



100 mg/5 mL

NDC: 83831-0144-05



500 mg/25 mL

NDC: 83831-0145-25



CardinalHealth

Cencora

McKesson

BioCare
People who care.

Highlights¹

- Free from preservative benzyl alcohol
- Supplied in multi-dose vials
- No reconstitution required and ready to use solution
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)

Unique J-CODE

J9186

Effective October 1, 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 requirements
- 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

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



**DOWNLOAD
NOW**

Commercially eligible patients
prescribed an **AVYXA Pharma,
LLC 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 Pharma, LLC aims to facilitate financial accessibility for eligible patients in need.

Copay Program Details for Eligible Patients

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

- Up to \$25,000 per patient, per drug.

*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

Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA Pharma, LLC 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. Please check with each payer to ascertain the best coding for the AVOPEF® (etoposide) injection according to their policy. AVYXA Pharma, LLC does not recommend using any particular diagnosis code in billing situations for AVOPEF. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs for AVOPEF Injection

Centers for Medicare & Medicaid Services (CMS) and private payers often require an NDC on the billing claim form. The NDC is usually found on the drug label or the medication's outer packaging. Be sure to include the NDC qualifier, 11-digit NDC number, NDC unit of measure, and number of NDC units when submitting claims. If the NDC Package code is fewer than 11 digits, it must be padded with leading zeros, as shown below.² The NDC unit of measure for this product is mL.

NDC ¹	Strength	Vial Size
83831-0144-05	100 mg/5 mL (20 mg/mL)	1 multiple-dose vial in 1 carton
83831-0145-25	500 mg/25 mL (20 mg/mL)	1 multiple-dose vial in 1 carton

HCPCS Codes

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.³

AVOPEF Injection J-Code⁴

J-Code	Description
J9186	Injection, etoposide (avyxa), 1 mg

Note: While there are several HCPCS codes associated with etoposide products, AVOPEF is assigned a unique HCPCS code (J9186). Please ensure the HCPCS code used matches the specific product purchased and administered.

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 designate specific circumstances, such as the route of administration, wasted product, and other relevant details.⁵

340B Drug Pricing Modifier⁶

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.

AVOPEF is supplied as a multi-dose vial, so no drug waste modifiers – JW, JZ – are required.⁷

CPT Drug Administration Codes

CPT codes bill for drug administration services in the physician's office and other outpatient settings. Administration of AVOPEF® varies by indication and usage. Please code based on the start and stop times listed in the patient's medical chart.⁸

CPT Code ⁹	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

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.

Revenue Codes¹⁰

Claim Item	Revenue Code	Description
AVOPEF Infusion	0636	Drugs requiring detailed coding
Drug Administration	0335	Chemotherapy administration – IV

Place of Service (POS) Codes¹¹

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

AVOPEF® is a topoisomerase inhibitor indicated, in combination with other chemotherapy and/or immunotherapy, for the treatment of adult patients with:¹

- Refractory testicular cancer
- Small cell lung cancer

It is best practice to code the most specific ICD-10-CM Code within the indication to justify medical necessity.

International Classification of Disease, 10th Edition, Clinical Modification Codes for AVOPEF Injection¹²

Indication	ICD-10-CM Codes
Encounter for Antineoplastic Chemotherapy	Z51.11
Small Cell Lung Cancer	C33, C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92
Testicular Cancer	C62.00, C62.01, C62.02, C62.10, C62.11, C62.12, C62.90, C62.91, C62.92

ICD Diagnosis Codes by Indication

AVOPEF Injection Billing and Coding Information: ICD Diagnosis Codes by Indication

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

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding¹²

ICD-10 Code	Descriptor
Z51.11	Encounter for Antineoplastic Chemotherapy

ICD Diagnosis Codes by Indication (continued)

Small Cell Lung Cancer: ICD-10-CM Diagnosis Coding¹²

ICD-10 Code	Descriptor
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

Testicular Cancer: ICD-10-CM Diagnosis Coding¹²

ICD-10 Code	Descriptor
C62.00	Malignant neoplasm of unspecified undescended testis
C62.01	Malignant neoplasm of undescended right testis
C62.02	Malignant neoplasm of undescended left testis
C62.10	Malignant neoplasm of unspecified descended testis
C62.11	Malignant neoplasm of descended right testis
C62.12	Malignant neoplasm of descended left testis
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.91	Malignant neoplasm of right testis, unspecified whether descended or undescended
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended

Sample Claim Form CMS-1450 (UB-04)^{4,9,10,12,13}

The form is a CMS-1450 (UB-04) Institutional Health Care Claim. It includes sections for Patient Information, Insurance Information, and a detailed list of services. Annotations include:

- 42**: Revenue Code (Loop 2400)
- 43**: Description (Loop 2400)
- 44**: HCPCS code (Loop 2400)
- 45**: Date of Service (Loop 2400)
- 46**: Units (Loop 2400)
- 63**: Insurance Group Name (Loop 2300)
- 67 A-Q**: CPT codes (Loop 2300)

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. [https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/\\$File/EDI_837I_v5010A2_crosswalk.pdf](https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf)

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Form Locator (FL) 42

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

List the appropriate revenue code for the drug. Match the descriptor for AVOPEF® Injection to your revenue code, 0636-Drugs requiring detailed coding.

Additionally, enter an appropriate revenue code for the administration service, such as 0335 - Chemotherapy Administration IV 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 of measure code, followed by the quantity. The NDC unit of measure code for AVOPEF is mL (milliliters).

FL 44 (Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP):

Enter the appropriate HCPCS code: **J9186, Injection, etoposide (avyxa), 1 mg.**

For administration, enter the appropriate code or codes for intravenous administration. An example for AVOPEF: **96413. Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.**

The dosing frequency and cycle length will depend on the AVOPEF dose, the primary diagnosis, and the specific regimen administered. See package insert.

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.

FL 63 (Electronic Claim Form = Loop 2300, REF/G1/02):

Enter treatment authorization code.

FL 67 A-Q (Electronic Claim Form = Loop 2300, HI01-2 (HI01-1=BK):

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

An example for AVOPEF is: **C62.01 Malignant neoplasm of undescended right testis.**

Use FL 67 C-L fields for other secondary diagnoses.

Sample Claim Form CMS-1500^{4,9,11,12,14}

Item 21 (Electronic Claim Form = Loop 2300, Segment HI01-2 through HI12=2):

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

An example for AVOPEF[®] is: **C62.01 Malignant neoplasm of undescended right testis.**

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 24 A-B (Electronic Claim Form)

Item 24 A (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 of measure code followed by the quantity in the same red shaded portion. The NDC unit of measure code for AVOPEF is mL for milliliters.

Item 24 D (Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code: **J9186, Injection, etoposide (avyxa), 1 mg.**

For administration, enter the appropriate code or codes for intravenous administration. **As an example, CPT Code 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.**

The dosing frequency and cycle length will depend on the dose of AVOPEF, the primary diagnosis, and the specific regimen administered. See package insert.

Item 24 E (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 24 G (Electronic Claim Form = Loop 2400, SV104):

Enter the number of J-Code service units for AVOPEF. It will be the number of milligrams administered to the patient.

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

1. MEDICARE ☐ **MEDICAID** ☐ **TRICARE** ☐ **CHAMPVA** ☐ **GROUP HEALTH PLAN** ☐ **FECA** ☐ **FECA** ☐ **OTHER** ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) **3. PATIENT'S BIRTH DATE** MM DD YY **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:** a. OTHER INSURED'S POLICY OR GROUP NUMBER **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 **15. OTHER DATE** MM DD YY **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 **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 ☐ **21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY** (Relate A-L to service line below (24E) ICD-10) **22. RESUBMISSION** CODE **23. PRIOR AUTHORIZATION NUMBER**

24. A. DATES OF SERVICE From MM DD YY To MM DD YY **B. PLACE OF SERVICE** **C. D. PROCEDURES, SERVICES, OR SUPPLIES** (Explain Unusual Circumstances) **E. DIAGNOSIS** **F. CHARGES** **G. DATE OF INVOICE** **H. PAYEE'S NAME** **I. NO. QUAL.** **J. RENDERING PROVIDER ID. #**

25. FEDERAL TAX I.D. NUMBER **26. PATIENT'S ACCOUNT NO.** **27. ACCEPT ASSIGNMENT?** YES ☐ NO ☐ **28. TOTAL CHARGE** \$ **29. AMOUNT PAID** \$ **30. Paid for NUCC Use**

31. SIGNATURE OF PHYSICIAN OR SUPPLIER (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** **NPI** **NPI** **NPI** **NPI**

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

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. [https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/\\$File/EDI_837I_v5010A2_crosswalk.pdf](https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf)

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IMPORTANT SAFETY INFORMATION (continued)

USE IN SPECIFIC POPULATIONS

Pregnancy

AVOPEF can cause fetal harm when administered to a pregnant woman. AVOPEF contains alcohol which can interfere with neurobehavioral development. Additionally, published studies have demonstrated that alcohol is associated with fetal harm including central nervous system abnormalities, behavioral disorders and impaired intellectual development. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose.

Lactation

Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with AVOPEF and for 1 week after the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing: Verify the pregnancy status of female patients of reproductive potential prior to initiating AVOPEF.

Contraception: Advise females of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose. Due to the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with AVOPEF and for 4 months after the last dose.

Infertility: In females of reproductive potential, AVOPEF may cause infertility and result in amenorrhea. Premature menopause can occur with AVOPEF. Recovery of menses and ovulation is related to age at treatment. In male patients, AVOPEF may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men, and in some cases, have occurred several years after the end of therapy.

Geriatric Use

Reported clinical experience demonstrated that patients 65 years and older experienced more myelosuppression, anorexia, mucositis, dehydration, somnolence, elevated blood urea nitrogen (BUN), infectious complications and alopecia compared to younger patients. In general, dosage selection for an older patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

Reduce the dose of AVOPEF in patients with creatinine clearance (CLcr) of 15 to 50 mL/min. No dosage modification is recommended for patients with CLcr > 50 mL/min.

DOSAGE AND ADMINISTRATION GUIDELINES

It is very important that the dosage, preparation and administration instructions provided in the full prescribing information are strictly followed to reduce the risk of severe adverse reactions.

Do not administer AVOPEF by rapid intravenous injection. To reduce the risk of infusion-related reactions including hypotension, administer diluted AVOPEF intravenously over 30 to 60 minutes. A longer duration of administration may be used if there is a large volume of fluid to be infused.

Before each AVOPEF administration and at appropriate intervals during and after therapy, monitor complete blood counts with differential and serum albumin.

If severe reactions occur, reduce the dosage or discontinue AVOPEF and take appropriate corrective measures according to the clinical judgment of the healthcare provider.

Please see AVOPEF full [Prescribing Information](#), including BOXED WARNING.

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

References

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2. Drugs.com. National drug codes explained. <https://www.drugs.com/ndc.html>. Updated March 20, 2025. Accessed March 18, 2026.
3. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS). <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system>. Updated July 7, 2025. Accessed March 18, 2026.
4. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations: Second Quarter, 2026 HCPCS Coding Cycle. 2026.
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Notes



AVOPEF® (etoposide) injection



100 mg/5 mL
NDC: 83831-0144-05



500 mg/25 mL
NDC: 83831-0145-25

AVYXA Pharma, LLC 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 Pharma, LLC 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.

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full [Prescribing Information](#) for AVOPEF.

