FAVLYXA®
(fluorouracil) injection

BILLING & CODING GUIDE

AVYXA

TABLE OF CONTENTS

The contents herein provide general coverage, coding, and payment information about FAVLYXA®. 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

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full Prescribing Information for FAVLYXA.

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

FAVLYXA® is indicated for the treatment of patients with:

- Adenocarcinoma of the Colon and Rectum
- Adenocarcinoma of the Breast
- Gastric Adenocarcinoma
- Pancreatic Adenocarcinoma

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS ADVERSE REACTIONS OR DEATH IN PATIENTS WITH COMPLETE DPD DEFICIENCY

- **Increased risk of serious adverse reactions or death in patients with complete DPD deficiency.**
- **Test patients for genetic variants of *DPYD* prior to initiating FAVLYXA unless immediate treatment is necessary. Avoid use of FAVLYXA in patients with certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency.**

WARNINGS AND PRECAUTIONS

Serious Adverse Reactions or Death from Dihydropyrimidine Dehydrogenase (DPD) Deficiency

Patients with certain homozygous or compound heterozygous variants in the *DPYD* gene known to result in complete or near complete absence of DPD activity (complete DPD deficiency) are at increased risk for acute early-onset toxicity and serious, including fatal adverse reactions due to FAVLYXA (e.g., mucositis, diarrhea, neutropenia, and neurotoxicity). Patients with partial DPD activity (partial DPD deficiency) may also have increased risk of serious or fatal adverse reactions.

Prior to initiating FAVLYXA, test patients for genetic variants of the *DPYD* gene unless immediate treatment is necessary. Serious adverse reactions may still occur even if no *DPYD* variants are identified.

Avoid use of FAVLYXA in patients with certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency.

Withhold or permanently discontinue FAVLYXA based on clinical assessment of the onset, duration, and severity of adverse events in patients with evidence of acute early-onset or unusually severe reactions. No fluorouracil dose has been proven safe for patients with complete DPD deficiency. For patients with partial DPD deficiency, individualize the dosage and modify based on tolerability and intent of treatment.

An FDA-authorized test for the detection of genetic variants of the *DPYD* gene to identify patients at risk of serious adverse reactions with FAVLYXA treatment is not currently available. Currently available tests used to identify *DPYD* variants may vary in accuracy and design (e.g., which *DPYD* variant(s) they identify).

Cardiotoxicity

FAVLYXA can cause cardiotoxicity, including angina, myocardial infarction/ischemia, arrhythmia, and heart failure, based on postmarketing reports. Reported risk factors for cardiotoxicity are administration by continuous infusion rather than intravenous bolus and presence of coronary artery disease. Withhold FAVLYXA for cardiotoxicity. The risks of resumption of FAVLYXA in patients with cardiotoxicity that has resolved have not been established.

Hyperammonemic Encephalopathy

FAVLYXA can cause hyperammonemic encephalopathy in the absence of liver disease or other identifiable cause, based on postmarketing reports. Signs or symptoms of hyperammonemic encephalopathy began within 72 hours after initiation of FAVLYXA infusion; these included altered mental status, confusion, disorientation, coma, or ataxia, in the presence of concomitant elevated serum ammonia level. Withhold FAVLYXA for hyperammonemic encephalopathy and initiate ammonia-lowering therapy. The risks of resumption of FAVLYXA in patients with hyperammonemic encephalopathy that has resolved have not been established.

Neurologic Toxicity

FAVLYXA can cause neurologic toxicity, including acute cerebellar syndrome and other neurologic events, based on postmarketing reports. Neurologic symptoms included confusion, disorientation, ataxia, or visual disturbances. Withhold FAVLYXA for neurologic toxicity. There are insufficient data on the risks of resumption of FAVLYXA in patients with neurologic toxicity that has resolved.

Diarrhea

FAVLYXA can cause severe diarrhea. Withhold FAVLYXA for Grade 3 or 4 diarrhea until resolved or decreased in intensity to Grade 1, then resume FAVLYXA at a reduced dose. Administer fluids, electrolyte replacement, or antidiarrheal treatments as necessary.

Palmar-Plantar Erythrodysesthesia (Hand-Foot Syndrome)

FAVLYXA can cause palmar-plantar erythrodysesthesia, also known as hand-foot syndrome (HFS). Symptoms of HFS include a tingling sensation, pain, swelling, and erythema with tenderness, and desquamation. HFS occurs more commonly when fluorouracil is administered as a continuous infusion than when fluorouracil is administered as a bolus injection, and has been reported to occur more frequently in patients with previous exposure to chemotherapy. HFS is generally observed after 8 to 9 weeks of fluorouracil administration but may occur earlier. Institute supportive measures for symptomatic relief of HFS. Withhold FAVLYXA administration for Grade 2 or 3 HFS; resume FAVLYXA at a reduced dose when HFS is completely resolved or decreased in severity to Grade 1.

FAVLYXA®
(fluorouracil) injection

Ordering Information

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

2,500 mg/100 mL
NDC: 83831-0164-10

250 mg/10 mL
NDC: 83831-0143-01

CardinalHealth cencora McKESSON BioCare People who care.

Highlights[1]

- No pre-heating required due to reduced risk of precipitation when exposed to low storage temperatures
- Stable liquid formulation available in a 25 mg/mL concentration
- Supplied in multi-dose vials (2,500 mg/100 mL)
- No reconstitution required
- Ready to use as direct intravenous bolus injection or intravenous infusion solution with the following diluents:
  - 5% Dextrose Injection, USP
  - 0.9% Sodium Chloride Injection, USP
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)

Unique J-CODE

J9191

Effective October 1, 2026

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full Prescribing Information for FAVLYXA.

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

ENROLL NOW

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*

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.

ENROLL NOW

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. All codes should be verified between the healthcare professional and the payer. AVYXA Pharma, LLC does not recommend using any particular diagnosis code in billing situations for FAVLYXA® (fluorouracil) Injection. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs for FAVLYXA 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
83831-0164-10	2,500 mg/100 mL (25 mg/mL)	1 multiple-dose vial in 1 carton
83831-0143-01	250 mg/10 mL (25 mg/mL)	1 single-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]

FAVLYXA Injection J-Code[4]

J-Code	Description
J9191	Injection, fluorouracil (avyxa), 10 mg

Note: While there are several HCPCS codes associated with fluorouracil products, FAVLYXA is assigned a unique HCPCS code (J9191). Please ensure the HCPCS code used matches the specific product purchased and administered.

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full Prescribing Information for FAVLYXA.

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]

Drug Waste Modifiers[6]

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

FAVLYXA® Injection is packaged as a multi-dose and a single-dose vial. Medicare will pay for drug waste on single-use items that are medically necessary and appropriately documented in the patient's medical record. Medicare does not reimburse for drug waste from multi-dose vials.

When administering a FAVLYXA single-dose vial, Medicare requires that any discarded drug be reported with the -JW modifier on a separate line. If there is no waste, FAVLYXA Injection must be billed on one line with the -JZ modifier. Because FAVLYXA does not currently have a permanent J-Code, the single-dose vial is billed as a single service unit. There is no way to record waste, so one would attach Modifier -JZ to the claim line. Medicare requires this; please confirm whether other payers require the -JZ and -JW modifiers.

340B Drug Pricing Modifier[7]

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.

CPT Drug Administration Codes

CPT codes bill for drug administration services in the physician's office and other outpatient settings. Administration of FAVLYXA 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
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
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)
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
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)

Revenue Codes[10]

Claim Item	Revenue Code	Description
FAVLYXA Injection	0636	Drugs requiring detailed coding
Drug Administration	0335	Chemotherapy administration – IV
	0261	IV Therapy – Infusion Pump

Place of Service (POS) Codes[11]

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

FAVLYXA® is a nucleoside metabolic inhibitor indicated for the treatment of patients with: Adenocarcinoma of the Colon and Rectum; Adenocarcinoma of the Breast; Gastric Adenocarcinoma; Pancreatic Adenocarcinoma.[1]
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 FAVLYXA Injection[12]

Indication	ICD-10-CM Codes
Breast Cancer	C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929
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
Encounter for Antineoplastic Chemotherapy	Z51.11
Gastric Cancer	C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C16.9
Pancreatic Cancer	C25.0, C25.1, C25.2, C25.3, C25.7, C25.8, C25.9

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full Prescribing Information for FAVLYXA.

ICD Diagnosis Codes by Indication

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

Breast Cancer: ICD-10-CM Diagnosis Coding[12]

ICD-10 Code	Descriptor
C50.011 – C50.019	Malignant neoplasm of nipple and areola, female
C50.021 – C50.029	Malignant neoplasm of nipple and areola, male
C50.111 – C50.119	Malignant neoplasm of central portion of breast, female
C50.121 – C50.129	Malignant neoplasm of central portion of breast, male
C50.211 – C50.219	Malignant neoplasm of upper-inner quadrant of breast, female
C50.221 – C50.229	Malignant neoplasm of upper-inner quadrant of breast, male
C50.311 – C50.319	Malignant neoplasm of lower-inner quadrant of breast, female
C50.321 – C50.329	Malignant neoplasm of lower-inner quadrant of breast, male
C50.411 – C50.419	Malignant neoplasm of upper-outer quadrant of breast, female
C50.421 – C50.429	Malignant neoplasm of upper-outer quadrant of breast, male
C50.511 – C50.519	Malignant neoplasm of lower-outer quadrant of breast, female
C50.521 – C50.529	Malignant neoplasm of lower-outer quadrant of breast, male
C50.611 – C50.619	Malignant neoplasm of axillary tail of breast, female
C50.621 – C50.629	Malignant neoplasm of axillary tail of breast, male
C50.811 – C50.819	Malignant neoplasm of overlapping sites of breast, female
C50.821 – C50.829	Malignant neoplasm of overlapping sites of breast, male
C50.911 – C50.919	Malignant neoplasm of breast of unspecified site, female
C50.921 – C50.929	Malignant neoplasm of breast of unspecified site, male

Colorectal Cancer: ICD-10-CM Diagnosis Coding[12]

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

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding[12]

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

Gastric Cancer: ICD-10-CM Diagnosis Coding[12]

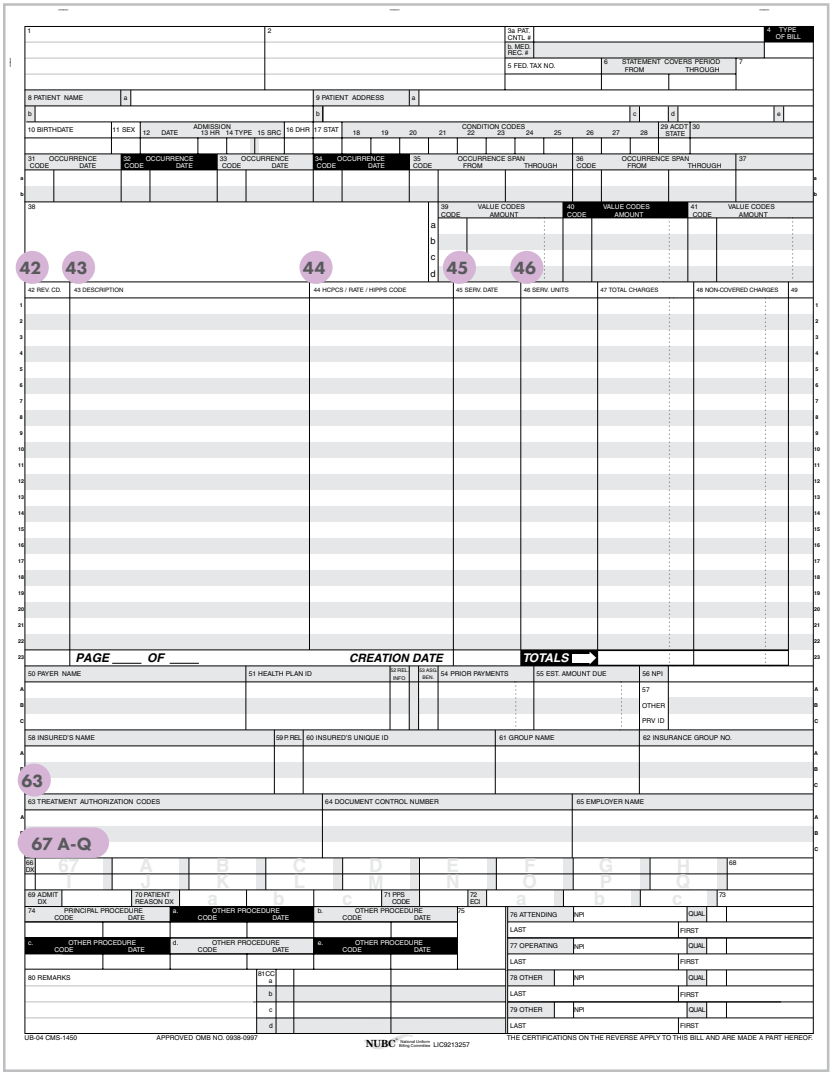
ICD-10 Code	Descriptor
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified

Pancreatic Cancer: ICD-10-CM Diagnosis Coding[12]

ICD-10 Code	Descriptor
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

Please see Important Safety Information including Boxed Warning, on pages 3 and 13 and full Prescribing Information for FAVLYXA.

Sample Claim Form CMS-1450 (UB-04)[4,9,10,12,13]



[1] CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

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

Form Locator (FL) 42

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

List the appropriate revenue code for the drug. Match the descriptor for FAVLYXA® 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 FAVLYXA is ML (milliliters).

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

Enter the appropriate HCPCS code: ***J9191, Injection, fluorouracil (avyxa), 10 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 FAVLYXA, 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 billed HCPCS code. 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 FAVLYXA is: ***C18.2 Malignant neoplasm of ascending colon.***

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 FAVLYXA® is: ***C18.2 Malignant neoplasm of ascending colon.***

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 FAVLYXA is ML for milliliters.

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

Enter the appropriate HCPCS code: ***J9191, Injection, fluorouracil (avyxa), 10 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.***

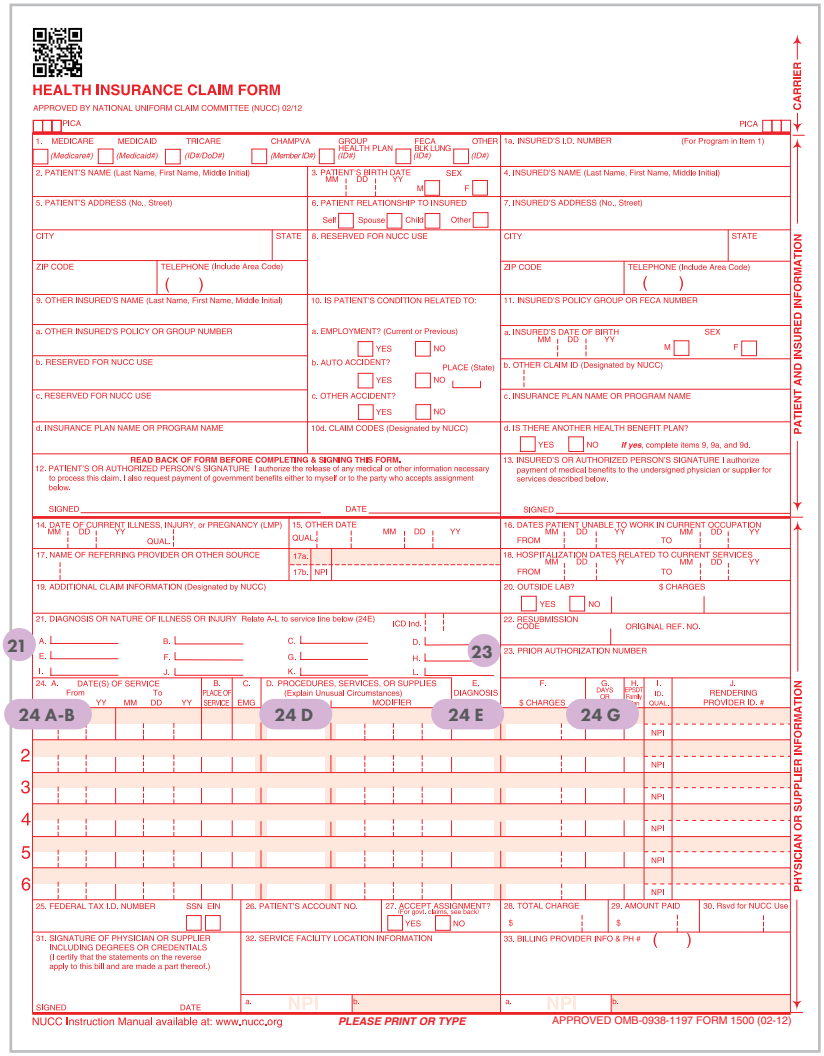
The dosing frequency and cycle length will depend on the dose of FAVLYXA, the primary diagnosis, and the specific regimen administered. See package insert.

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 FAVLYXA. It will be the number of milligrams administered to the patient.



[1] CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

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

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression

FAVLYXA can cause severe and fatal myelosuppression which may include neutropenia, thrombocytopenia, and anemia. The nadir in neutrophil counts commonly occurs between 9 and 14 days after fluorouracil administration. Obtain complete blood counts prior to each treatment cycle, weekly if administered on a weekly or similar schedule, and as needed. Withhold FAVLYXA until Grade 4 myelosuppression resolves; resume FAVLYXA at a reduced dose when myelosuppression has resolved or improved to Grade 1 in severity.

Mucositis

FAVLYXA can cause mucositis, stomatitis or esophagopharyngitis, which may lead to mucosal sloughing or ulceration.

The incidence is reported to be higher with administration of fluorouracil by intravenous bolus compared with administration by continuous infusion. Withhold FAVLYXA administration for Grade 3 or 4 mucositis; resume FAVLYXA at a reduced dose once mucositis has resolved or decreased in severity to Grade 1.

Increased Risk of Bleeding with Concomitant Use of Warfarin

Altered coagulation parameters and/or bleeding, including death, have been reported during concomitant use of warfarin and fluorouracil. Monitor INR more frequently and adjust the dose of warfarin in patients receiving concomitant warfarin.

Embryofetal Toxicity

FAVLYXA can cause fetal harm when administered during pregnancy. Advise females of reproductive potential to use effective contraception during treatment with FAVLYXA and for

6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with FAVLYXA and for 3 months after the last dose.

ADVERSE REACTIONS

Please see the Warnings and Precautions listed above, and full prescribing information for FAVLYXA.

DRUG INTERACTIONS

Effect of FAVLYXA on Other Drugs

Vitamin K Antagonists

Monitor INR and PT more frequently in patients receiving FAVLYXA and warfarin. Elevated INR and PT have been reported in patients taking fluorouracil concomitantly with warfarin.

USE IN SPECIFIC POPULATIONS

Pregnancy

FAVLYXA can cause fetal harm when administered during pregnancy.

Lactation

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

Females and Males of Reproductive Potential

FAVLYXA can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing: Verify that females of reproductive potential are not pregnant prior to initiating FAVLYXA.

Contraception: Advise females of reproductive potential to use effective contraception during treatment with FAVLYXA and for 6 months after the last dose. Based on genotoxicity findings, advise males with female partners of reproductive potential to use effective contraception during treatment with FAVLYXA and for 3 months after the last dose.

Infertility: Based on animal studies, FAVLYXA may impair fertility in females and males of reproductive potential.

OVERDOSAGE

Administer uridine triacetate within 96 hours following the end of FAVLYXA infusion for management of fluorouracil overdose.

DOSAGE AND ADMINISTRATION

FAVLYXA is a hazardous drug. Follow applicable special handling and disposal procedures.

Prior to initiating FAVLYXA, test patients for genetic variants of the *DPYD* gene unless immediate treatment is necessary. An FDA-authorized test for the detection of the *DPYD* gene to identify patients at risk of serious adverse reactions with FAVLYXA is not currently available. Currently available tests used to identify *DPYD* variants may vary in accuracy and design (e.g., which *DPYD* variant(s) they identify).

Avoid use of FAVLYXA in patients known to have certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency. No FAVLYXA dose has been proven safe for patients with complete DPD deficiency. For patients with partial DPD deficiency, individualize the dosage and modify based on tolerability and intent of treatment.

Please see FAVLYXA 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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Notes

FAVLYXA®
(fluorouracil) injection

2,500 mg/100 mL
NDC: 83831-0164-10

250 mg/10 mL
NDC: 83831-0143-01

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.

AVYXA

US-FAV-0004-2 I September 2026