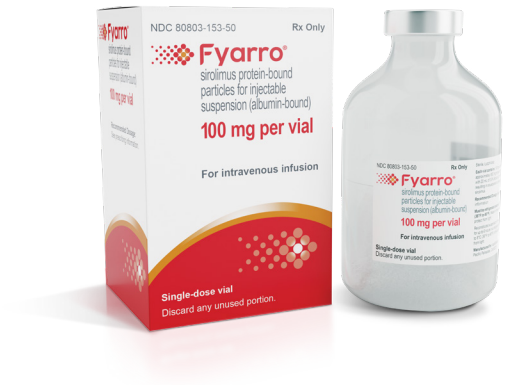
REIMBURSEMENT, BILLING, CODING, AND ORDERING GUIDE FOR FYARRO®

Fyarro®
sirolimus protein-bound particles for injectable suspension (albumin-bound)



Product name and description

FYARRO® (sirolimus protein-bound particles for injectable suspension) (albumin-bound) is sirolimus formulated as albumin-bound nanoparticles

Product indication and usage

FYARRO is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)

Product Dispensing

Pack Quantity

One single-dose vial containing 100 mg of sirolimus formulated as albumin-bound particles per package

Ordering Information

Specialty Distribution

Name	Phone Number	Website
ASD Healthcare	1-800-746-6273	https://www.asdhealthcare.com/
McKesson Plasma & Biologics	1-877-625-2566	https://www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics/
McKesson Specialty	1-800-482-6700	https://mscs.mckesson.com/
Oncology Supply	1-800-633-7555	https://www.oncologysupply.com/

Specialty Pharmacy

Name	Phone Number	Website
Biologics by McKesson	1-800-850-4306	https://biologics.mckesson.com/providers/

IMPORTANT SAFETY INFORMATION

FYARRO is contraindicated in patients with a history of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin.

FYARRO can cause serious adverse reactions including stomatitis, myelosuppression, infections, hypokalemia, hyperglycemia, interstitial lung disease or non-infectious pneumonitis, hemorrhage, hypersensitivity reactions, embryo-fetal toxicity, and infertility.

Please see full Prescribing Information and additional Important Safety Information on page 3.

Coding Information

NDC Coding

Code	Number
10-digit NDC	80803-153-50
11-digit NDC	80803-0153-50

HCPCS Code*

Code	Description
J9331	Injection, sirolimus protein-bound particles, 1 mg

Procedure Codes*

Code	Description
CPT 96413	Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug
CPT 96415	Chemotherapy administration, intravenous infusion technique, each additional hour, single or initial substance (list separately in addition to code 96413 for initial hour of infusion services)

Commonly Used Diagnosis Codes†

Code	Description
ICD-10 C49	**Malignant neoplasm of other connective and soft tissue**
ICD-10 C49.0	Malignant neoplasm of connective and soft tissue of head, face, and neck
ICD-10 C49.1	Malignant neoplasm of connective and soft tissue of upper limb, including shoulder
ICD-10 C49.2	Malignant neoplasm of connective and soft tissue of lower limb, including hip
ICD-10 C49.3	Malignant neoplasm of connective and soft tissue of thorax
ICD-10 C49.4	Malignant neoplasm of connective and soft tissue of abdomen
ICD-10 C49.5	Malignant neoplasm of connective and soft tissue of pelvis
ICD-10 C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
ICD-10 C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
ICD-10 C49.9	Malignant neoplasm of connective and soft tissue, unspecified

***Billing and Coding Considerations.** This resource is intended as a reference for coding and billing. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

†There are no ICD-10 codes for malignant PEComa; the codes listed here are examples only. Please use codes appropriately. The responsibility for ensuring accuracy and validity of billing and claims lies with the healthcare provider and should be supported with detailed documentation in the medical record. Consult ICD-10 coding resources for additional information.

Please see full Prescribing Information and Important Safety Information on page 3.

Fyarro®
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

INDICATION

FYARRO® is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

IMPORTANT SAFETY INFORMATION

Contraindications

- History of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin.

Warnings and Precautions

FYARRO can cause serious adverse reactions. Withhold, resume at reduced dose, or permanently discontinue FYARRO based on severity (See Dosage and Administration of full Prescribing Information).

- **Stomatitis:** Stomatitis, including mouth ulcers and oral mucositis, occurred in 79% of patients, including 18% Grade 3.
- **Myelosuppression:** FYARRO can cause myelosuppression including anemia, thrombocytopenia and neutropenia. Anemia occurred in 68% of patients; 6% were Grade 3. Thrombocytopenia and neutropenia occurred in 35% of patients each. Obtain blood counts at baseline and every 2 months for the first year of treatment and every 3 months thereafter, or more frequently if clinically indicated.
- **Infections:** FYARRO can cause infections. Infections such as urinary tract infections (UTI), upper respiratory tract infections and sinusitis occurred in 59% of patients. Grade 3 infections occurred in 12% of patients, including a single case each of a UTI, pneumonia, skin, and abdominal infections. Monitor for signs and symptoms of infection.
- **Hypokalemia:** FYARRO can cause hypokalemia. Hypokalemia occurred in 44% of patients, including 12% Grade 3 events. Monitor serum potassium prior to starting FYARRO and supplement potassium as medically indicated.
- **Hyperglycemia:** FYARRO can cause hyperglycemia. Hyperglycemia occurred in 12% of patients, all of which were Grade 3 events. Monitor fasting serum glucose prior to starting FYARRO. During treatment, monitor serum glucose every 3 months in non-diabetic patients, or as clinically indicated. Monitor more frequently in diabetic patients.
- **Interstitial Lung Disease (ILD)/Non-Infectious Pneumonitis:** FYARRO can cause ILD/non-infectious pneumonitis, which occurred in 18% of patients, all Grades 1 or 2. Monitor for new or worsening respiratory symptoms or radiological changes.
- **Hemorrhage:** FYARRO can cause serious and sometimes fatal hemorrhage. Hemorrhage occurred in 24% of patients, including Grade 3 and Grade 5 events in 2.9% of patients each. Monitor for signs and symptoms.
- **Hypersensitivity Reactions:** FYARRO can cause hypersensitivity reactions, including anaphylaxis. Anaphylaxis, angioedema, exfoliative dermatitis and hypersensitivity vasculitis have been observed with use of oral sirolimus. Monitor for hypersensitivity during and following each FYARRO infusion. Monitor for at least 2 hours following completion of the first infusion and as clinically indicated for each subsequent infusion. Reduce the rate, interrupt infusion, or permanently discontinue based on severity.
- **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise patients of the potential hazard to the fetus and to use effective contraception while using FYARRO and for 12 weeks after the last dose.
- **Male Infertility:** Azoospermia or oligospermia may occur.
- **Immunizations:** Avoid live vaccines.

Adverse Reactions

- The most common (≥30%) adverse reactions were stomatitis, fatigue, rash, infection, nausea, edema, diarrhea, musculoskeletal pain, decreased weight, decreased appetite, cough, vomiting, and dysgeusia.
- The most common (≥6%) Grade 3 to 4 laboratory abnormalities were decreased lymphocytes, increased glucose, decreased potassium, decreased phosphate, decreased hemoglobin, and increased lipase.

Drug Interactions

- **Strong CYP3A4 and/or P-gp Inhibitors or Inducers:** Avoid concomitant use.
- **Moderate or Weak CYP3A4 Inhibitors:** Reduce FYARRO dose.

Use in Specific Populations

- **Hepatic Impairment:** Reduce the dose of FYARRO in patients with mild or moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.
- **Lactation:** Advise not to breastfeed.
- **Females and Males of Reproductive Potential:** May impair fertility in females and males.

Please see full Prescribing Information.

AADI assist

CONTACT US

For more information call
1-855-AADIHUB (1-855-223-4482)
Monday-Friday, 8 AM-8 PM ET

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