Medical Policy

Fyarro™ (sirolimus albumin-bound)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-103
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Fyarro™ (sirolimus albumin-bound) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Fyarro will be provided for 6 months and may be renewed.

- Max Units (per dose and over time): 300 mg (3 vials) on days 1 and 8 of every 21-day cycle

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient does not have a severe hypersensitivity to rapamycin derivatives (i.e., sirolimus, everolimus, temsirolimus, etc.); **AND**
C. Patient will avoid concomitant therapy with any of the following:
    a. Coadministration with P-gp inhibitors and/or strong CYP3A4 inhibitors (e.g., boceprevir, itraconazole, ketoconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    b. Coadministration with combined P-gp inducers and/or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    c. Coadministration with grapefruit or grapefruit juice; **AND**
D. Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
E. Patient does not have uncontrolled or symptomatic CNS metastases; **AND**
F. Patient has had no prior treatment with or will not be used in combination with other mTOR inhibitors (i.e., sirolimus, everolimus, temsirolimus, etc.); **AND**
G. Patient does not have lymphangioleiomyomatosis (LAM); **AND**

Perivascular Epithelioid Cell Tumor (PEComa)

A. Fyarro will be used as single agent therapy; **AND**
B. Patient has locally advanced unresectable or metastatic disease.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: stomatitis, myelosuppression, infections, hypokalemia and hyperglycemia, interstitial lung disease, hemorrhage, azoospermia/oligospermia, severe hypersensitivity reactions, etc.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. FYARRO (sirolimus protein-bound particles for injectable suspension) (albumin-bound), for intravenous use. Initial U.S. Approval: 2021
    a. FYARRO (sirolimus protein-bound particles for injectable suspension) (albumin-bound) is a white to yellow, sterile lyophilized powder.

CODING

Applicable NDC Codes	
80803-0153-xx	Fyarro 100 mg of sirolimus injection, single-use vial

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drug

Applicable ICD-10 Codes	
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
D49.9	Neoplasm of unspecified behavior of bone, soft tissue, and skin
Z85.831	Personal history of malignant neoplasm of soft tissue

EVIDENCE BASED REFERENCES

1. Fyarro [package insert]. Pacific Palisades, CA; Aadi Bioscience Inc; November 2021. Accessed November 2021.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made)
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024