Reference number(s)
5080-A

SPECIALTY GUIDELINE MANAGEMENT

FYARRO (sirolimus protein-bound particles for injectable suspension) (albumin-bound)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Fyarro is indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

B. Compendial Uses
1. PEComa
2. Uterine Sarcoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Perivascular Epithelioid Cell Tumor (PEComa)
Authorization of 12 months may be granted for the treatment of locally advanced unresectable or metastatic malignant PEComa when used as a single agent.

B. Uterine Sarcoma
Authorization of 12 months may be granted for the treatment of advanced, recurrent, metastatic or inoperable uterine sarcoma (PEComa) when used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Fyarro [package insert]. Pacific Palisades, CA: Aadi Bioscience, Inc; December 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 6, 2023.