

Fyarro (sirolimus protein bound)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Fyarro (sirolimus protein bound) Intravenous Infusion

APPROVAL CRITERIA

Requests for Fyarro (sirolimus protein bound) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Using as a single agent; **AND**
- III. Individual is using in one of the following ways:
 - A. In soft tissue sarcoma for the treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) (Label, NCCN 2A) **OR**
 - B. In uterine sarcoma for the treatment of advanced, recurrent/metastatic or inoperable PEComa (NCCN 2A).

Requests for Fyarro may not be approved for any of the following:

- I. Individual has severe hepatic impairment; **OR**
- II. Individual has a history of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin; **OR**
- III. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 21, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 21, 2023.
 - a. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
 - b. Uterine Sarcoma. V1.2024. Revised September 20, 2023.
6. Wagner AJ, Ravi V, Riedel RF, et. al. nab-Sirolimus for patients with malignant perivascular epithelioid cell tumors. J Clin Oncol 2021;39(33):3660-3670.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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