Medical Drug Clinical Criteria

Subject:	Fyarro (sirolimus albumin bound)		
Document #:	CC-0205	**Publish Date:**	~~12/21/2022~~12/18/2023
Status:	Revised	**Last Review Date:**	~~11/18/2022~~11/19/2023

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Overview

This document addresses the use of Fyarro (sirolimus protein bound) for use in the treatment of adults with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). Fyarro is a nanoparticle albumin-bound mTOR inhibitor that is given intravenously. It is the first agent to received FDA approval for PEComa. Sirolimus oral, everolimus oral, and temsirolimus intravenous are mTOR inhibitors recommended by the National Comprehensive Cancer Network (NCCN) as single-agent therapies for the treatment of PEComa. These agents use is supported by case studies and retrospective analyses and is considered off-label.

Definitions and Measures

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Unresectable: Unable to be removed with surgery.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to prior authorization, the review will determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Fyarro (sirolimus protein bound)

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. ~~Individual is using for~~In soft tissue sarcoma for the treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) (Label, NCCN 2A); **OR**~~AND~~
    ~~II.~~B. In uterine sarcoma for the treatment of advanced, recurrent/metastatic or inoperable PEComa (NCCN 2A)

~~III. Individual is using as a single agent~~.

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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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HCPCS	
J9331	Injection, sirolimus protein-bound particles, 1 mg
ICD-10 Diagnosis	
C49.4-C49.9	Malignant neoplasm of connective and soft tissue of abdomen

Document History

Revised: 11/19/2023
Document History:

- 11/19/2023 – Annual Review: Clarify use in disease states. Add NCCN 2A use in uterine sarcoma. Coding Reviewed: No changes.
- 11/18/2022 – Annual: Update Fyarro's criteria with use as a single agent. Coding Reviewed: No changes.
- 02/25/2022– Select: No change. Coding Reviewed: Removed HCPCS J3490, J3590. Added HCPCS J9999, C9091. Effective 7/1/2022 Added HCPCS J9331. Removed HCPCS J9999, C9091. Removed All diagnoses pend. Added ICD-10-CM C49.4-C49.9.
- 12/13/2021– New: Add new clinical criteria document for Fyarro prior authorization. Coding Reviewed: Added HCPCS J3490 and J3590 for Fyarro. All diagnoses pend. Effective 4/1/2022 Added HCPCS C9091.

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 polices may take precedence over the application of this clinical criteria.