Subject:	Fyarro (sirolimus albumin bound)		
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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. Their 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. Individual is using for the treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa);

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.

HCPCS

J3490	Unclassified drugs (when specified as [Fyarro] (sirolimus albumin bound)
J3590	Unclassified biologics (when specified as [Fyarro] (sirolimus albumin bound)

ICD-10 Diagnosis

	All diagnoses pend

Document History

New: 12/13/2021
Document History:

- 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.

References

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: November 18, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 1, 2021.
    a. Soft Tissue Sarcoma. V2.2021. Revised April 23, 2021.

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.