

Sirolimus protein-bound suspension  
(Fyarro™)

Place of Service  
Office Administration  
Outpatient Facility Infusion Administration  
Infusion Center Administration

HCPCS: J9331 per 1 mg

**Conditions listed in policy (see criteria for details)**

- [Perivascular epithelioid cell tumor \(PEComa\)](#)

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** mTOR inhibitor

**(1) Special Instructions and pertinent Information**

**Covered under the Medical Benefit**, please submit clinical information for prior authorization review via fax.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Fyarro™ (protein-bound sirolimus) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**Perivascular epithelioid cell tumor (PEComa)**

1. Being used as a single agent

**Covered Doses**

Up to 100 mg/m<sup>2</sup> IV infusion on days 1 and 8 of each 21-day cycle

**Coverage Period**

Indefinite

**ICD-10:**

C48.0-C48.2, C48.8, C49.4, C49.5, C49.8, C49.9, D49.2, Z85.831

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Fyarro™ (protein-bound sirolimus) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 100 mg (single-dose vial)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>  
PHP Medi-Cal Sirolimus Protein-Bound Suspension (Fyarro™)

- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Fyarro™ (sirolimus protein-bound particles for injectable suspension) [Prescribing Information]. Pacific Palisades, CA: Aadi Bioscience, Inc; 12/2021.

### **(7) Policy Update**

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*