Fyarro (sirolimus protein-bound particles for injectable suspension)

Humana

Pharmacy Coverage Policy

Effective Date: February 23, 2022
Revision Date: February 23, 2022
Review Date: February 16, 2022
Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

Description

Fyarro (sirolimus protein-bound particles for injectable suspension), mTOR inhibitor, is indicated for adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Sirolimus protein-bound particles for injectable suspension is available as Fyarro in 100mg as single dose vials for reconstitution.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review

includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Fyarro (sirolimus protein-bound particles for injectable suspension) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Perivascular epithelioid cell tumor

- The member had diagnosis of locally advanced unresectable or metastatic perivascular epithelioid cell tumor AND
- Fyarro (sirolimus protein-bound particles for injectable suspension) will be administered as monotherapy

Fyarro (sirolimus protein-bound particles for injectable suspension) will be approved in six month durations or as determined through clinical review.

Coverage Limitations

Fyarro (sirolimus protein-bound particles for injectable suspension)therapy is not considered medically necessary for members with the following concomitant conditions:

- Member has a history of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin.
- Member experiences disease progression on Fyarro (sirolimus protein-bound

particles for injectable suspension)

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Fyarro (sirolimus protein-bound particles for injectable suspension).

Warning/Precautions:

- Stomatitis
- Myelosuppression
- Infections
- Hypokalemia and hyperglycemia
- Interstitial lung disease
- Hemorrhage
- Hypersensitivity reactions
- Embryo-fetal toxicity
- Male infertility
- Immunizations

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Fyarro; sirolimus protein-bound particles for injectable suspension; perivascular epithelioid cell tumor

References

Fyarro [prescribing information]. Aadi Bioscience, Inc. Pacific Palisades, CA. November 2021.