

Policy: MBP 262.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Fyarro (sirolimus protein-bound particles for injectable suspension) (albumin-bound)

I. Policy:

Fyarro (sirolimus protein-bound particles for injectable suspension) (albumin-bound)

II. Purpose/Objective:

To provide a policy of coverage regarding Fyarro (sirolimus protein-bound particles for injectable suspension) (albumin-bound).

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION: Sirolimus (protein bound) is an albumin-bound nanoparticle sirolimus formulation that inhibits mammalian (mechanistic) target of rapamycin (mTOR). mTOR controls key cellular processes such as cell survival, growth, and proliferation, and is commonly dysregulated in several human cancers. In cells, sirolimus forms an immunosuppressive complex, sirolimus-FKBP-12 complex, which binds to and inhibits activation of the mTOR complex 1 (mTORC1). Inhibition of mTOR by sirolimus reduces cell proliferation, angiogenesis, and glucose uptake. In preclinical models, intravenous administration of nanoparticle protein bound sirolimus has demonstrated higher intratumor accumulation, greater mTOR inhibition, and higher tumor growth inhibition compared to oral mTOR inhibitors.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Fyarro (sirolimus protein-bound particles for injectable suspension) (albumin-bound) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Fyarro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

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

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/24/22

Revised: 6/6/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/29/24

MA UM Committee approval: 12/31/23