

Kinase Inhibitors
Fyarro (sirolimus injection)
Effective 09/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	<p>Fyarro (sirolimus injection) is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.</p> <p>Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.</p>		

Overview

Fyarro (sirolimus injection) is indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets **ALL** following criteria and documentation has been submitted:

1. Diagnosis of locally advanced or metastatic malignant perivascular epithelioid cell tumor (PEComa)
2. Appropriate dosing

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

References

1. Fyarro® [package insert]. Pacific Palisades (CA): Aadi Bioscience, Inc.; 2022 Jun.

Review History

11/16/2022 – Reviewed and updated for Nov P&T; matched MH UPPL. Effective 11/1/22. Combined criterias: Ayvakit, Balversa, Cabometyx, Cosela, Fotivda, Gavreto, Koselugo, Lenvima, Qinlock, Retevmo, Xospata. Added drugs: Afinitor, Afinitor Disperz, Caprelsa, Cometriq, Inlyta, Nexavar, Rydapt, Sutent, Truseltiq, Votrient. Renamed policy to “Kinase Inhibitors.” Updated QLs to match MH UPPL. Recent update included designating Nexavar as a brand preferred product. Effective 2/1/23. Added age limit to the Koselugo (selumetinib) for Plexiform Neurofibromas in Adult patients with Neurofibromatosis Type 1 appendix. Clarified Cosela reauthorization approval duration to 3 months. Effective 2/1/23.

01/11/2023 – Reviewed and updated for Jan P&T. Approval criteria updated for everolimus for renal angiomyolipoma with tuberous sclerosis complex (TSC), advanced pancreatic neuroendocrine tumors (PNET), advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin, or subependymal giant cell astrocytoma (SEGA) with TSC- to allow appropriate specialist for the requested indication (in place of just oncology specialist). Removed step criteria of Inlyta + Keytruda for the indication of advanced RCC (clear cell histology) for Cabometyx and Lenvima approval criteria. Retevmo updated to include expanded indication of adults with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion. Ayvakit updated to require BOTH: 1) aggressive SM without the D816V c-Kit mutation or with c-Kit mutation status unknown + t/f with imatinib 2) D816V c-Kit mutation positive. Several off-label indications for use of agents within this guideline moved from appendix section to Coverage Guidelines. Removed preferred status from both Inlyta and Sutent. Added ‘Brand over Generic’ list. Effective 3/1/23.

03/15/23 - Reviewed and updated for Mar P&T. Added Fyarro®(sirolimus injection), Hyftor®(sirolimus gel), Rezurock. Added quantity limits to Hyftor (10gm/30 days). Effective 4/1/23.

05/10/23 – Reviewed and updated for P&T. Added Lytgobi as requiring PA with same criteria as Truseltiq for the indication of treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. Criteria update on Hyftor®(sirolimus gel) to expand eligible prescriber to neurologist, and to increase quantity limit for patients < 12 years of age to 2 tubes per 30 days and increase quantity limit for patients ≥ 12 years of age to 3 tubes per 30 days. Fyarro, Lytgobi, Rezurock, Truseltiq will be approved for 6 months for initial requests. Effective 6/5/23.

12/13/23 – Reviewed and updated for P&T. Votrient will have brand preferred designation. No clinical changes. Effective 1/2/24

09/11/24 – Reviewed and updated for P&T. Separated out MB policy for Fyarro while Rx policy will be available on MHDL. No clinical changes. Effective 10/1/24

08/13/25 – Reviewed and updated for P&T. Updated reauth criteria language. Effective 9/1/25

