

**Pylarify  
(Piflufolastat F 18)**

	Commercial and Qualified Health Plans	MassHealth
Authorization required	X	
No notification or authorization		
Not covered		X*

\*This is currently not covered under the MassHealth benefit.

**Overview**

Pylarify is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy, or with suspected recurrence.

**Criteria**

1. Patient Population
 

AllWays Health Partners may authorize coverage of Pylarify (Piflufolastat F 18) for adult male members with prostate cancer, when the following criteria are met:

  - The member has suspected metastasis and is a candidate for initial definitive therapy; OR
  - The member has suspected recurrence based on elevated serum prostate-specific antigen (PSA) level; AND
  - A PET/CT has not been performed within the past 3 months; AND
  - Results of conventional imaging performed within the past 60 days are negative for metastasis
2. Dosing and Administration
  - A multiple-dose vial containing 37 MBq/mL to 2,960 MBq/mL (1 mCi/mL to 80 mCi/mL) of Pylarify (Piflufolastat F 18) at calibration date and time.
3. Duration of Therapy
  - Single bolus intravenous injection
4. Monitoring
  - Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods
5. Contraindications/Exclusions
  - None

**Exclusion**

- Surveillance of patients with localized/advanced prostate cancer, who have completed definitive therapy, are in remission and/or are receiving maintenance therapy.

**Effective**



July 2022: Effective Date

### CPT/HCPC Codes

Authorized Codes	Code Description
A9595	Piflufolastat f-18, diagnostic, 1 millicurie

### Reference

Morris MJ, Rowe SP, Gorin MA, et al. Diagnostic performance of 18F-DCFPyL-PET/CT in men with biochemically recurrent prostate cancer: results from the CONDOR phase 3, multicenter study doi: 10.1158/1078-0432.CCR-20-4573

Pienta KJ, Gorin MA, Rowe SP, et al. A Phase 2/3 Prospective Multicenter Study of the Diagnostic Accuracy of Prostate Specific Membrane Antigen PET/CT with 18F-DCFPyL in Prostate Cancer Patients (OSPReY). J Urol. 2021 Jul;206(1):52-61. doi: 10.1097/JU.0000000000001698. Epub 2021 Feb 26. PMID: 33634707; PMCID: PMC8556578.

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Schaeffer E, Srinivas S, Antonarakis ES, et al. National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2022 – September 10, 2021. Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Prostate cancer V1.2022 – September 10, 2021. National Comprehensive Cancer Network, Inc.