

**Medical Policy**  
**Pylarify and Gallium Ga-68 PSMA-11 Imaging**  
**for Patients with Prostate Cancer**

	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 (piflufolastat F18) and Gallium Ga-68 PSMA-11 are radioactive diagnostic agents 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) or Gallium Ga-68 PSMA-11 for adult male members with prostate cancer, when the following criteria are met:

**Initial work up**

Localized prostate cancer with unfavorable intermediate risk to very high-risk groups when any of the following are met:

- A. Inconclusive bone findings on both CT/MRI and bone scan; or
- B. Conventional imaging studies (CT and bone scan) suggest minimal or low volume metastatic disease that needs further evaluation.

**Restaging/Recurrence**

Non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, when **all** of the following are met:

- A. PSA rises on two consecutive measurements above post-treatment baseline or PSA is  $\geq 1$  ng/mL; and
- B. The member is a candidate for salvage local therapy; and
- C. Recent CT scan and bone scan are negative for metastatic disease; or
- D. There are inconclusive findings on CT, MRI or bone scan suggesting possible recurrence or metastatic disease that need further evaluation

2. Dosing and Administration

- Pylarify: 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.
- Gallium Ga-68 PSMA-11: A multiple-dose vial containing 30 mL 18.5 MBq/mL to 185 MBq/mL (0.5 mCi/mL to 5 mCi/mL) at calibration 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.
- A PET/CT has not been performed within the past 3 months
- PET/CT scan is not indicated if conventional imaging studies suggest widespread metastatic disease
- Initial treatment strategy for newly diagnosed prostate cancer except for as noted above

**Effective**

July 2022: Effective Date. Added criteria for Gallium Ga-68 PSMA-11.

**CPT/HCPC Codes**

Authorized Codes	Code Description
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie

**Reference**

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