

Medical Policy

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

Policy Number: 049

	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 (piflufolostat F18) and Gallium Ga-68 PSMA-11 (gallium Ga 68 gozetotide) 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

Mass General Brigham Health Plan may authorize coverage of Pylarify (Piflufolostat 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 ≥ 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 (Piflufolostat 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

November 2022: Off-cycle Review. Added generic name to Gallium G-68 PSMA-11. Added codes for Illuccix and Locametz.

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

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
A9596	Gallium Ga-68 gozetotide, diagnostic (Illuccix), 1 mCi
A9800	Gallium Ga-68 gozetotide, diagnostic (Locametz), 1mCi

Reference

Boreta L, Gadzinski AJ, Wu SY, et al. Location of Recurrence by Gallium-68 PSMA-11 PET Scan in Prostate Cancer Patients Eligible for Salvage Radiotherapy. *Urology*. 2019 Jul;129:165-171. doi: 10.1016/j.urology.2018.12.055. Epub 2019 Mar 27. PMID: 30928607.

Einspieler I, Rauscher I, Düwel C, et al. Detection Efficacy of Hybrid 68Ga-PSMA Ligand PET/CT in Prostate Cancer Patients with Biochemical Recurrence After Primary Radiation Therapy Defined by Phoenix Criteria. *J Nucl Med*. 2017 Jul;58(7):1081-1087. doi: 10.2967/jnumed.116.184457. Epub 2017 Feb 16. PMID: 28209912.

Kallur KG, Ramachandra PG, Rajkumar K, et al. Clinical Utility of Gallium-68 PSMA PET/CT Scan for Prostate Cancer. *Indian J Nucl Med*. 2017 Apr-Jun;32(2):110-117. doi: 10.4103/0972-3919.202255. PMID: 28533638; PMCID: PMC5439210.

van Kalmthout LWM, van Melick HHE, Lavalaye J, et al. Prospective Validation of Gallium-68 Prostate Specific Membrane Antigen-Positron Emission Tomography/Computerized Tomography for Primary Staging of Prostate Cancer. *J Urol*. 2020 Mar;203(3):537-545. doi: 10.1097/JU.0000000000000531. Epub 2019 Sep 6. PMID: 31487220.

Luiting HB, van Leeuwen PJ, Busstra MB, et al. Use of gallium-68 prostate-specific membrane antigen positron-emission tomography for detecting lymph node metastases in primary and recurrent prostate cancer and location of recurrence after radical prostatectomy: an overview of the current literature. *BJU Int*. 2020 Feb;125(2):206-214. doi: 10.1111/bju.14944. Epub 2019 Nov 29. PMID: 31680398; PMCID: PMC7383738.



Maurer T, Gschwend JE, Rauscher I, et al. Diagnostic Efficacy of (68)Gallium-PSMA Positron Emission Tomography Compared to Conventional Imaging for Lymph Node Staging of 130 Consecutive Patients with Intermediate to High Risk Prostate Cancer. *J Urol*. 2016 May;195(5):1436-1443.

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

Perera M, Papa N, Roberts M, Williams M, et al. Gallium-68 Prostate-specific Membrane Antigen Positron Emission Tomography in Advanced Prostate Cancer-Updated Diagnostic Utility, Sensitivity, Specificity, and Distribution of Prostate-specific Membrane Antigen-avid Lesions: A Systematic Review and Meta-analysis. *Eur Urol*. 2020 Apr;77(4):403-417. doi: 10.1016/j.eururo.2019.01.049. Epub 2019 Feb 14. PMID: 30773328.

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.

PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company. 2021

Rowe S, Gorin M, Saperstein L, et al. A Phase 3 study of 18F-DCFPyL-PET/CT in Patients with Biochemically Recurrent Prostate Cancer (CONDOR): An Analysis of Disease Detection Rate and Positive Predictive Value (PPV) by Anatomic Region. *J Nucl Med*. May 2021, 62 (supplement 1) 123

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.

Wu H, Xu T, Wang X, Yu YB, et al. Diagnostic Performance of 68Gallium Labelled Prostate-Specific Membrane Antigen Positron Emission Tomography/Computed Tomography and Magnetic Resonance Imaging for Staging the Prostate Cancer with Intermediate or High Risk Prior to Radical Prostatectomy: A Systematic Review and Meta-analysis. *World J Mens Health*. 2020 Apr;38(2):208-219. doi: 10.5534/wjmh.180124. Epub 2019 Apr 3. PMID: 31081294; PMCID: PMC7076316.

