

Medical Policy

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

Policy Number: 049

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	X
No notification or authorization			
Not covered/payable		X (A9608)	

Overview

Pylarify (piflufolastat F18), Posluma (flotufolastat 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 (Piflufolastat F18), Posluma (Flotufolastat F18), 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 the following:

- A. Unfavorable intermediate-risk disease; or
- B. High risk disease; or
- C. Very high-risk disease; or
- D. Inconclusive bone findings on both CT/MRI and bone scan; or
- E. 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

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.
- Posluma: A multiple-dose vial containing 296 MBq/mL to 5,846 MBq/mL (8 mCi/mL to 158 mCi/mL) as flotufolastat F 18 gallium in approximately 25 mL at end of synthesis supplied as a clear, colorless solution.

- 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

Exclusions

- 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 been performed within the past 3 months
- Conventional imaging studies suggest widespread metastatic disease
- Initial treatment strategy for newly diagnosed prostate cancer except for as noted above

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan’s most recent policy review, CMS has the following NCD: Positron Emission Tomography (FDG) for Oncologic Conditions 220.6.17.**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

This list of codes applies to commercial and MassHealth plans only.

Authorized Codes	Code Description
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
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



A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9800	Gallium Ga-68 gozetotide, diagnostic (Locametz), 1mCi

Effective

January 2025: Off-cycle review. Updated Restaging/Recurrent eligibility criteria per NCCN guidelines. Clarified language in Medicare Variation. Code disclaimer added. Code list updated. Added code for Posluma. Added criteria for Posluma. References updated. Updated PA table at top of policy to reflect that MassHealth does not cover Posluma.

March 2024: Annual review.

January 2024: Off-cycle review. MassHealth coverage added to table.

October 2023: Annual review. Medicare Advantage added to table. Initial Work-up criteria edited for clarity. Medicare Variation language added. References updated.

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.

Reference

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