TEMPLATE FOR PRIOR AUTH/PRE-DETERMINATIONS

FOR USE BY PROVIDER THROUGH REQUEST TO ILLUCCIX® HOTLINE

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[Date]

ATTN: [Dept Name]

[Name of Insurance Company]

FAX #: [fax #]

**RE: Prior Authorization/Pre-Determination request for PSMA-targeted PET imaging with Illuccix®**

ICD10 Diagnosis Code(s):

CPT / HCPCS Code(s):

Patient Name:

Subscriber ID#:

Group #:

Date of Birth (DOB):

Anticipated Date of Service:

Pending Ref #:

Dear Medical Reviewer:

I am writing to request prior authorization/pre-determination for 68Gallium PSMA-11 PET (also known as Gallium Ga 68 gozetotide) imaging prepared with Illuccix® for my patient [patient name] who has confirmed prostate cancer, [add ICD.10CM code for patient’s diagnosis here].

PSMA-targeted PET imaging can assist in determining if his prostate cancer has spread to other parts of the body and can potentially impact his recommended treatment. The purpose of using PSMA-targeted PET imaging with 68Gallium-PSMA 11 injection is to detect and locate metastatic spread of cancer as 68Gallium PSMA-11 binds to the prostate specific membrane antigen protein found on the surface of over 90% of prostate cancer cells.

Based on the results of PSMA-targeted PET imaging with Illuccix, we believe we will be able to provide a more personalized and appropriate treatment and management plan for [name of patient].

Numerous data supports 68Gallium PSMA-11 targeted PET imaging as a sensitive diagnostic agent for initial staging and in disease recurrence, including men whose conventional imaging fails to detect prostate cancer.1,2,4-6 Additionally, Illuccix (kit for the preparation of gallium Ga 68 gozetotide injection) for intravenous use was approved by the FDA based on its sensitivity, specificity, positive and negative predictive value3 for identifying metastatic disease at initial diagnosis and recurrence at low prostate specific antigen (PSA) levels. This includes detection in the clinically important range of low PSA values (<0.5ng/mL) compared to conventional imaging.7-9 Conventional imaging (CT; MRI; bone scintigraphy) perform poorly in localizing sites of disease recurrence in patients with BCR, particularly when PSA values are low (<2.0 ng/mL).7-9

Conventional imaging modalities (CT; MRI; bone scintigraphy) were historically used to determine the extent of lymph node involvement and presence of metastases. Because of the increased sensitivity and specificity of 68Ga PSMA-PET tracers compared to conventional imaging techniques, NCCN guidelines have been updated to include a recommendation for 68Ga PSMA-PET for front-line imaging without the prerequisite use of conventional imaging at both initial staging and biochemical recurrence.10

The selection of appropriate therapies is contingent upon the accurate assessment of the patient’s “true” burden of disease. It is estimated that 30-40% of patients will fail initial therapy and require additional treatment with many of these patients harboring occult metastatic disease. Therefore, accurate imaging at the time of diagnosis would help better identify patients likely to benefit from first line potentially curative treatment while also identifying patients with metastatic spread of disease who would no longer be candidates for curative intent therapies.

Given PSMA-targeted PET imaging with 68Gallium PSMA 11 injection’s demonstrated ability to accurately detect prostate cancer lesions, both at initial diagnosis and at recurrence of the disease after treatment failure, utilization of 68Gallium PSMA-11 has been shown to enable and improve disease assessment for patients for patients across the spectrum of prostate cancer.1,2

The safety and efficacy of 68Gallium PSMA-11 Injection were established in two prospective, open-label studies (PSMA-PreRP and PSMA-BCR) in men with prostate cancer.3

**PSMA-PreRP**

This two-center study enrolled 325 patients with biopsy-proven prostate cancer who were considered candidates for prostatectomy and pelvic lymph node dissection. All enrolled patients met at least one of the following criteria: serum prostate-specific antigen (PSA) of at least 10 ng/mL, tumor stage cT2b or greater, or Gleason score greater than 6. Each patient received a single Ga 68 PSMA-11 PET/CT or PET/MR from mid-thigh to skull base.3

Approximately 24% of subjects studied were found to have pelvic nodal metastases based on histopathology (95% confidence interval: 17%, 32%).3

**PSMA-BCR**

This two-center study enrolled 635 patients with biochemical evidence of recurrent prostate cancer after definitive therapy, defined by serum PSA of >0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy. All patients received a single 68Gallium PSMA-11 PET/CT or PET/MR from mid-thigh to skull base. Three members of a pool of nine independent central readers evaluated each scan for the presence and regional location (20 subregions grouped into four regions) of abnormal 68Gallium PSMA-11 uptake suggestive of recurrent prostate cancer. The readers were blinded to all clinical information other than type of primary therapy and most recent serum PSA level.3

Of the 210 evaluable patients, 192 patients (91%) were found to be true positive in one or more regions against the composite reference standard (95% confidence interval: 88%, 95%). Among the pool of nine readers used in the study, the proportion of patients who were true positive in one or more regions ranged from 82% to 97%. The prostate bed had the lowest proportion of true positive results at the region-level (76% versus 96% for non- prostate regions).3

Approved by the FDA as of December 17, 2021, the labeled indication is as follows:3

ILLUCCIX, after radiolabeling with Ga 68, 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.
* with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

For the reasons stated above, I strongly believe that PSMA-targeted PET imaging with 68Gallium PSMA-11 injection is appropriate and required for [patient name] and should be a covered benefit.

Thank you for your time and consideration. If you have any questions and/or concerns, regarding the procedure or this patient’s medical condition, please do not hesitate to contact me at the number listed below.

We look forward to [payer name]’s timely, positive response.

Sincerely,

[MD Name]

[Practice Group Name]

[Street Address]

[City/Town, State Zip]

Phone#:

Fax#:

TIN:

NPI#:

Imaging/Hospital Facility info:

[Facility Name]

TIN:

NPI #:

Enclosures

References:

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3. Telix Prescribing Information, http://illuccixhcp.com/s/illuccix-prescribing-information.pdf
4. Hofman MS, Lawrentschuk N, Francis RJ, Tang C, Vela I, et al., Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. Lancet. 2020 Apr 11;395(10231):1208-1216.
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