Telix: Prostate Cancer Imaging & Targeted Therapy

August, 2024

Device Overview

The American Cancer Society estimates approximately 299,010 new cases of prostate cancer will be diagnosed in the United States in 2024.[1] Screening for prostate cancer is performed utilizing a prostate specific antigen (PSA) test, which consists of measuring the level of PSA in the blood. PSA is a specific antigen made by the prostate, and increased levels can indicate the presence of prostate cancer or other prostate conditions.[2] Patients with advanced cancer or reoccurrences can benefit from additional diagnostics for staging and treatment management. Telix's portfolio offers Illuccix (imaging) and investigational targeted antibody-based therapies (TLX591, TLX592) to target prostate-specific membrane antigen (PSMA) for staging, treatment, and management of prostate cancer. On healthy cells, PSMA is either low or absent; however, in those with prostate cancer PSMA is overexpressed on cell surfaces.[3]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS
Determine current diagnostic practices related to staging and treatment. Engage key physician specialties (including urology and radiation oncology), imaging leadership, and pharmacy.

CONSIDER GUIDELINES FOR USE
Develop 'criteria for use' guidelines for patient selection and need, incorporating national clinical practice guidelines and approved indications for use.

UNDERSTAND CONCERNS
Leverage physician peer to peer conversations to understand decision making in prostate cancer care and considerations for including this portfolio.

CONNECT

SEEK CLINICAL IMPACT
Review current diagnostic and treatment practices and determine advantages of using PSMA related to patient specific risk factors and conditions.

CONDUCT ANALYSIS
Compare cost of current diagnostics. Include reimbursement information, available evidence, and potential outcomes impact to inform decision making.

DETERMINE POPULATION
Work with key stakeholders to determine appropriate utilization in patients with high risk for prostate cancer.

COMMUNICATE

EDUCATE AND TRAIN
Evaluate training needs and engage supplier for support. Educate to any change of practice, process, or developed procedures. Include rationale for initiative, safe handling, and scope of practice considerations.

PLAN AHEAD
Share guidelines, as well as data to support decision making, with key stakeholders allotting ample time for discussion/feedback.

FOLLOW-UP
Create on-going monitoring process to determine outcomes and make changes to process as needed.

Clinical Insights: HealthTrust Physician Advisors

A panel of urologists within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of Telix prostate cancer portfolio. [4]

Physician Advisor Insights

Safety and Use

- Illucix is a very safe radionucleotide for Prostate Specific Membrane Antigen (PSMA) positron emission tomography (PET).
- Illucix can be used in National Comprehensive Cancer Network (NCCN) high and very high risk for evaluation of metastatic disease in staging prior to treatment and used in the metastatic Metastasis 0 (M0) and Metastasis 1 (M1) setting to evaluate progression of disease and response to treatment.
- TLX591 and TLX592 are currently in trials for PSMA targeted therapies for metastatic castrate resistant prostate cancer. In these cases, the benefits outweigh risk as most patients have progressed on all therapies and are post-chemotherapy.

Patient Populations

- Most beneficial in the high risk and advanced prostate cancer population

Guidelines

- Illuccix is part of the American Urological Association (AUA) and NCCN guidelines for initial staging of high risk/very high-risk prostate cancer.
- TLX591 and TLX592 are in clinical trials and not part of the guidelines.

FDA Approval

Telix announced FDA approval for Illuccix in December 2021 for prostate imaging which may be found here.[5] In March of 2023 expanded indications of use were approved by the FDA which may be found here. [6] A searchable database of FDA approved drugs is avaialbe here.[7]

Illuccix indications for use: "radiolabeling with Ga 68, is 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 selection of patients with metastatic prostate cancer, for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated" [6]

Clinical Evidence

There are several published studies and articles relating to the use, safety, and efficacy of Illuccix , TLX591, and TLX592. A summary is included below.

A 2018 retrospective study by Hicks et al. assessed the diagnostic accuracy of 68Ga-PSMA-11 PET/magnetic resonance imaging (MRI) compared with multiparametric MRI for detecting prostate cancer. This retrospective study included 32 men with prostate cancer proven via biopsy undergoing simultaneous 68Ga-PSMA-11 PET/MRI and multiparametric MRI. In the study, the 68Ga-PSMA-11 PET/MRI identified 434 regions with increased uptake of the radiotracer which was found to be positive for tumor cells while the multiparametric MRI identified 287 areas that were graded as Prostate Imaging–Reporting and Data System (PI-RADS) 3, 4, or 5 which are classified as intermediate to high risk. Overall, the study showed ”the sensitivity of gallium 68–labeled prostate-specific membrane antigen–11 PET/MRI in the detection of prostate cancer is better than that of multiparametric MRI.” [8]

A 2018 retrospective study by Keidar et al. determined the role of 68Ga-PSMAPSMA in identifying metastatic patterns and frequency of involved sites in prostate cancer. The study included 438 men with prostate cancer over a 24-month period in two academic medical centers. “The incidence and location of pathological 68Ga-PSMA avid foci, suspicious to represent malignancy, as well as those of unexpected benign foci of increased 68Ga-PSMA activity were documented and analyzed.” [9] The study found that 68Ga-PSMA PET/CT is an accurate non-invasive testing option. They recommend additional studies to validate findings.[9]

Clinical Trials

TLX591 and TLX592 are currently in investigational clinical trials. More information can be found here. [12]

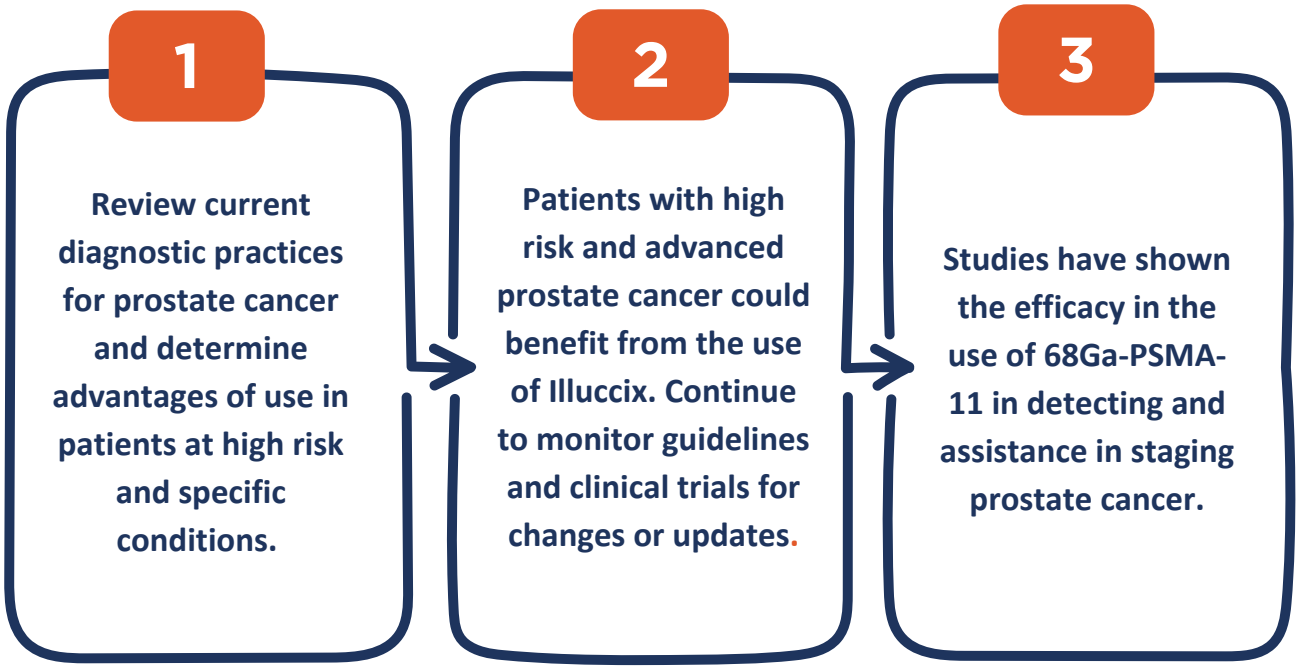
A listing of current Telix clinical studies and status can be found here. [13]

Specific studies can be searched via ClinicalTrials.gov found here. [14]

A 2023 journal article by Ramnaraign et al. reviews current data and new trials of PSMA targeted radiopharmaceuticals. This article includes at risk patient demographics, FDA approved therapies, imaging, and trials. The full article can be found here. [10]

A 2024 article by Sallam et al. reviews the PSMA targeted diagnostics in current and future medical landscapes. The article provides an overview on prostate cancer, PSMA history of development and use, and other targeted radiotheranostics. The full article can be found here. [11]

Summary



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