Telix Welcomes CMS Decision to Improve Payments for Diagnostic Radiopharmaceuticals

04 Nov 2024

Telix today welcomes the announcement by the United States (U.S.) Centers for Medicare & Medicaid Services (CMS) that it will pay separately for specialised diagnostic radiopharmaceuticals[1] for Medicare Fee for Service patients in the hospital outpatient setting, beyond the transitional pass-through payment period ("pass-through"). This is a significant decision for patients and hospitals, with the change facilitating equitable access to advanced imaging agents for all patients into the future.

In 2025, the separate payments under the Hospital Outpatient Prospective Payment System (OPPS) will be based on Mean Unit Cost (MUC), derived from hospital claims data and apply to any specialised diagnostic radiopharmaceutical without pass-through status and with a threshold per day cost greater than US$630.

The new rule ensures consistent reimbursement for Medicare Fee for Service patients, following expiry of pass-through status. For physicians and patients in the hospital outpatient setting this will enable purchasing decisions to be made based on the latest clinically significant diagnostic tools and evidence of utility, and not on purely on reimbursement structure. For commercial radiopharmaceutical innovators such as Telix, this provides greater certainty and consistency in pricing policy across all customer segments.

The new separate payment rule will apply to Illuccix® after its pass-through status expires, from July 1, 2025. It will also apply to Telix's pipeline of investigational diagnostic imaging agents – TLX007-CDx, a new product for PSMA imaging of prostate cancer, TLX250-CDx (Zircaix®[2]) for kidney cancer imaging, and TLX101-CDx (Pixclara®[2]) for brain cancer (glioma) imaging – if approved and reimbursed under CMS, and after pass-through expires.

Telix has continued to invest in innovation in prostate cancer imaging for the benefit of physicians and patients. Should TLX007-CDx be approved in the U.S.[3], Telix will be the only company with two PSMA-PET imaging agents on the market, enabling broader patient reach, including into currently underserved populations, and with greater flexibility to offer the product most suitable for a patient based on their clinical profile, indication and eligibility for reimbursement. This may be particularly beneficial for any Medicare patients currently subject to a copayment in hospital outpatient settings.

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, "Telix welcomes the decision by CMS to unbundle payments for diagnostic radiopharmaceuticals, as it will provide certainty for patients and physicians seeking access to safe and effective diagnostic radiopharmaceuticals. Moreover, it will promote continued investment in bringing new imaging agents to market across a range of disease states, as there is a clear commercial pathway to recouping the investment in innovation and the significant infrastructure and operational costs of delivering high quality service to patients. As a leading innovator in precision medicine and diagnostic radiopharmaceuticals, we are pleased to see the reimbursement landscape change in favour of patients. This will ensure continued access to advanced imaging agents that provide meaningful information to drive treatment decisions and outcomes for cancer patients."

Read the full ASX release here

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[1] CMS press release 1 November 2024: https://www.cms.gov/newsroom/press-releases/cms-announces-new-policies-reduce-maternal-mortality-increase-access-care-and-advance-health-equity; CMS fact sheet 1 November 2024: https://www.cms.gov/newsroom/fact-sheets/cy-2025-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0

[2] Brand name subject to final regulatory approval.

[3] TLX007-CDx Prescription Drug User Fee Act (PDUFA) goal date March 24, 2025. Telix ASX disclosure 23 July 2024. Fee Act (PDUFA) goal date March 24, 2025. Telix ASX disclosure 23 July 2024.

Illuccix® has been approved by the U.S. Food and Drug Administration (FDA), by the Australian Therapeutic Goods Administration (TGA), and by Health Canada. No other Telix product has received a marketing authorisation in any jurisdiction. Pixclara and Zircaix brand names subject to final regulatory approval.