ASX Announcement

2 September 2026

OncoSil Submits CMS Application for Transitional Pass-Through Payment Status Following FDA HDE Approval

Key highlights

- CMS Transitional Pass-Through (TPT) application submitted 1 September 2026 (US time), seeking separate, supplemental Medicare reimbursement for the OncoSil™ device in the dCCA indication.
- Application filed at a proposed price of US$55,000 per dose.
- CMS decision targeted for 1 January 2027, with approval — if granted — taking effect on the same date.
- If granted, TPT status would provide supplemental Medicare reimbursement for up to three years from launch, supporting hospital adoption economics during early commercialisation.
- Supports adoption at participating academic medical centres in the Company's mandatory FDA post-approval study (PAS) and underpins broader U.S. payer coverage over time.
- The Company will engage with the FDA on pathways to widespread U.S. distribution of the OncoSil™ device following completion of PAS enrolment (30 patients across five centres).

Sydney, Australia – 2 September 2026: OncoSil Medical Limited (ASX: OSL) ("OncoSil Medical" or "the Company"), a medical device company developing targeted radiation therapies for difficult-to-treat cancers, is pleased to announce that it has submitted an application to the U.S. Centers for Medicare & Medicaid Services (CMS) for Transitional Pass-Through (TPT) Payment status for the OncoSil™ device, following the U.S. Food and Drug Administration's (FDA) grant of Humanitarian Device Exemption (HDE) approval on 14 August 2026 for the treatment of unresectable, non-metastatic distal cholangiocarcinoma (dCCA).

Nigel Lange, CEO & Managing Director of OncoSil Medical, said:

"The submission of our CMS Transitional Pass-Through application is the next critical step in our US commercialisation strategy, building directly on last month's FDA HDE approval. Securing TPT status would give academic medical centres the reimbursement certainty they require to bring OncoSil™ to patients with dCCA quickly and lays the foundation for broader US payer coverage as we scale."

Following the FDA HDE approval received on 14 August 2026 for OncoSil™ device in the treatment of unresectable, non-metastatic dCCA, the Company has submitted an application to the U.S. CMS for TPT payment status. The application, submitted on 1 September 2026, seeks separate, supplemental Medicare reimbursement for OncoSil™ at a proposed price of US$55,000 per dose, with a CMS decision and, subject to approval, an effective date targeted for 1 January 2027.

TPT status strengthens reimbursement

The PAS is a mandatory condition of the HDE approval, designed to confirm the safety and probable benefit of the OncoSil™ device in real-world clinical use across a broader population than was studied pre-approval. It is a multicentre, prospective study expected to enrol 30 patients across five academic medical centres, with a follow-up period of approximately 24 months from the last patient enrolled before the Company may seek FDA consent to expand distribution beyond the five PAS centres.

If granted, TPT status would provide supplemental Medicare reimbursement for OncoSil™ for up to three years from launch, representing an important component of the Company's U.S. commercialisation and reimbursement strategy. TPT reimbursement is expected to support adoption at the academic medical centres participating in the Company's mandatory FDA post-approval study (PAS), facilitating early clinical utilisation following HDE approval while helping establish the reimbursement foundation for broader U.S. payer coverage over time.

U.S. reimbursement remains a priority

Securing durable U.S. reimbursement is a critical near-term priority for OncoSil Medical ahead of commercial launch. TPT status, if approved, would provide time-limited supplemental Medicare payment above the standard procedure reimbursement, which is intended to support hospital and physician adoption during the PAS period and to establish a foundation for long-term U.S. payer coverage.

Click **here** to view this announcement on Investor Hub.

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

For further information, please contact:

Mr. Nigel Lange CEO & Managing Director E: nigel.lange@oncosil.com T: +49 160 9642 4981	**Mr. Tim Luscombe & Ms. Nova Taylor** Joint Company Secretaries E: tim.luscombe@bio101.com & nova.taylor@bio101.com T: +61 429 707 079 & +61 414 877 703

About OncoSil Medical

About OncoSil Medical

OncoSil Medical (ASX:OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorous-32 (^{32}P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™, a single-use brachytherapy (internal radiation) device used to deliver a pre-determined dose of beta radiation directly into cancerous tissue. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.

In the United States, OncoSil™ is indicated for the treatment of patients with distal cholangiocarcinoma (dCCA) that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy.

In markets outside the United States where OncoSil™ has received regulatory approval, OncoSil™ is indicated for the treatment of patients with unresectable locally advanced pancreatic cancer, in addition to gemcitabine-based chemotherapy.

Pancreatic cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year[i]. Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term survival.

Distal cholangiocarcinoma (dCCA) is a rare form of bile duct cancer. It is often diagnosed at an advanced stage, when surgical treatment may no longer be possible, and is associated with a poor prognosis.

OncoSil™ has received CE Marking approval, providing marketing authorisation in the European Union and the United Kingdom. OncoSil™ has also received approval from the U.S. Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE) for the treatment of patients with unresectable, non-metastatic distal cholangiocarcinoma (dCCA), as an adjunct to systemic therapy. OncoSil™ has been designated as a Breakthrough Device in Europe and the United States. It is currently approved for sale in 30+ countries, including the European Union, United Kingdom, United States, Australia, Saudi Arabia, Türkiye and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK.

To learn more, please visit: www.oncosil.com/

[i] https://gco.iarc.fr/en