ASX Announcement

CLEO Establishes U.S. Reimbursement Pathway Ahead of FDA Submission

Highlights

- **CLEO to enter U.S. market under miscellaneous CPT code 81599 immediately post-FDA clearance, enabling early billing and real-world utilisation data capture**
- **Reimbursement determined via cross-walking to comparable multi-biomarker tests, which have reported reimbursement levels of ~US$500-US$900 per test, supporting CLEO's initial pricing discussions**
- **Represents the first step toward securing a dedicated CPT code, supporting long-term reimbursement and commercial scale.**

20th May 2026: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to outline the first stage of its United States (**U.S.**) commercialisation and reimbursement strategy for its Pre-Surgical Ovarian Cancer Test, as it advances toward anticipated Food and Drug Administration (**FDA**) clearance.

Reimbursement Pathway Established to Support Early Revenue and Scalable Adoption

CLEO has established a defined reimbursement framework designed to enable immediate market entry and revenue generation post-FDA clearance, while building toward long-term reimbursement.

Following FDA clearance, CLEO intends to commercialise its test in the U.S. using the existing miscellaneous CPT code 81599, a standard pathway for novel diagnostic tests entering the market. This approach enables early clinical adoption and the generation of real-world utilisation data, which are key prerequisites for securing a dedicated CPT code.

Reimbursement under CPT code 81599 is determined on a payer-by-payer basis, typically using comparable diagnostic tests as pricing references. Existing multi-biomarker ovarian cancer assays, including OVA1, have reported reimbursement levels in the range of ~US$500–$900 per test (payer dependent) providing a clear reference framework for CLEO's reimbursement discussions.

Market Entry via Miscellaneous Code – Immediate Post-Clearance Commercialisation

The use of CPT code 81599 represents a key commercialisation catalyst, enabling CLEO to commence operations immediately following FDA clearance.

This pathway allows the Company to:

- Initiate revenue generation from launch through case-by-case billing
- Enable early prescribing and clinical use across U.S. healthcare settings
- Support pricing discussions with commercial and government payers

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- Generate real-world clinical and economic evidence to demonstrate value
- Establish utilisation data to underpin future CPT code applications.

Progression to Dedicated CPT Code

CLEO's use of CPT code 81599 represents the first stage of its reimbursement strategy. As clinical utilisation and supporting evidence are established, the Company intends to apply for a dedicated CPT code via the American Medical Association (**AMA**) CPT Editorial Panel.

A dedicated CPT code is expected to:

- Provide greater reimbursement consistency and transparency
- Support broader payer coverage and adoption
- Enable standardised tracking of utilisation
- Strengthen the long-term commercial value of CLEO's diagnostic platform.

Establishing reimbursement pathways is a critical component of diagnostic adoption within the U.S. healthcare system and represents an important step toward scalable commercial deployment.

Supporting Market Access and Evidence Generation

CLEO is proactively advancing its U.S. market access strategy to support reimbursement and adoption, including:

- Ongoing health economics and budget impact model development
- Strategic onboarding of key opinion leaders to support early clinical adoption
- Generation of real-world evidence through initial commercial rollout.

These activities are designed to complement data collected under CPT code 81599 and support a streamlined transition to a dedicated reimbursement code.

Timeline and Expected Sequence

Milestone	Timeline and details
Miscellaneous Code	Immediately post-FDA clearance to support early billing, clinical adoption and real-world evidence generation
CPT Application Submission	Following initial commercial utilisation (~6–12 months post-launch), submitted in line with next available AMA cycle.
Dedicated CPT Code	Upon clearance, supporting broader reimbursement and adoption.

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This ASX announcement was authorised for release on behalf of the Cleo Diagnostics Ltd Board.

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About Cleo Diagnostics Ltd ASX:COV

Cleo Diagnostics (ASX:COV) is an Australian medical technology company developing a simple blood test for the early and accurate detection of ovarian cancer – a disease with the highest five-year mortality rate of all cancers affecting women, with 51% of patients dying within five years, primarily due to late diagnosis and the lack of effective screening tools. Each year, hundreds of thousands of women are diagnosed only after the disease has advanced, highlighting a critical unmet need for earlier detection.

CLEO's patented technology is based on the CXCL10 biomarker, supported by over 15 years of scientific research and development. CXCL10 is produced early and at high levels in ovarian cancer but is largely absent in benign disease, making it a powerful discriminator between malignant and non-malignant growths.

The Company is executing a staged development strategy, starting with a pre-surgical triage test, then expanding into recurrence monitoring and ultimately global screening – creating clear value inflection points along the ovarian cancer detection pathway. CLEO is currently conducting its pivotal clinical trial, with FDA submission and commercial launch expected next year, reinforcing its goal to redefine the standard of care and enable earlier, smarter, life-changing diagnosis for women worldwide.

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