

Association of Managed Entry Agreements and Drug Reimbursement Timing in Taiwan

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KEY POINTS

Question. Is implementation of managed entry agreements (MEAs) associated with changes in early reimbursement and time to reimbursement for oncologic vs non-oncologic drugs?

Findings In this cohort study of 5,177 drug records (2013–2026), following MEA implementation, oncologic drugs gained a relative advantage in 12-month reimbursement compared with non-oncologic drugs, partly reflecting declining reimbursement among non-oncologic drugs. This difference was not sustained at 24 months, while drugs requiring MEAs had longer time to reimbursement.

Meaning MEAs may facilitate prioritization of earlier access for oncologic therapies under constrained reimbursement capacity, rather than expanding access across therapeutic areas.

METHODS

Design: Retrospective cohort study using difference-in-differences (DiD) and survival (Cox) analysis.

Data: TFDA approvals linked to NHI reimbursement, PBRS minutes, and CDE HTA reports.

Sample: 5,177 TFDA-approved drug records, Jan 2013–Feb 2026 (4,828 for the 12-month outcome; 4,468 for 24-month; 313 PBRS-reviewed, 89 MEA-required, 222 with HTA budget-impact data).

Exposure: Pre-MEA vs post-MEA policy period (before vs after September 2018).

Outcomes: Reimbursement within 12 and 24 months of TFDA approval (DiD); time to NHI reimbursement (Cox proportional hazards).

Covariates: Dosage form, Taiwan manufacturer status, approval-year fixed effects; PBRS-subset models additionally adjusted for budget impact, HTA availability, and prior authorization.

Sensitivity: Placebo cutoffs, alternative fixed effects, logistic DiD, and triple-difference analyses.

RESULTS

- Among 313 PBRS-reviewed drugs (6.0%), 89 (28.4%) were assigned MEA requirements; MEA-required drugs were more often oncologic, Class 1 breakthrough products, and higher-priced.
- DiD: oncologic drugs approved after Sept 2018 were 11.1 percentage points more likely to be reimbursed within 12 months than non-oncologic drugs (95% CI, 3.8–18.3; P=.003); no significant difference at 24 months.
- Cox: oncologic drugs were nearly twice as likely as non-oncologic drugs to be reimbursed at any time (HR, 1.93; 95% CI, 1.71–2.17; P<.001); this advantage predated MEAs and did not change significantly afterward.

FIGURE 2. POST-POLICY REIMBURSEMENT DECLINED AMONG NON-ONCOLOGIC DRUGS

Kaplan-Meier cumulative reimbursement incidence, oncologic vs non-oncologic drugs, pre- vs post-MEA policy (log-rank P<0.0001 for non-oncologic drugs; P=0.98 for oncologic drugs).

BACKGROUND

- Public payers face a growing tension between expanding access to high-cost innovative therapies and maintaining fiscal sustainability under constrained budgets.
- Taiwan’s National Health Insurance (NHI) provides universal coverage under a global budget; the PBRS Joint Committee determines new-drug listing timing after TFDA approval, using HTA conducted by the Center for Drug Evaluation.
- Managed entry agreements (MEAs) were introduced in September 2018 to facilitate reimbursement of therapies with substantial clinical or financial uncertainty. For oncologic drugs, MEA negotiation is generally required when projected 5-year expenditure exceeds NTD \$500 million.
- Evidence gap: Longitudinal evidence on whether MEAs actually accelerate reimbursement remains limited.

FIGURE 1. DID TRENDS & EVENT-STUDY ESTIMATES

(A) % of TFDA-approved drugs reimbursed within 12 months, by approval year and cancer status.
(B) Event-study coefficients: differential 12-month reimbursement probability, oncologic vs non-oncologic, by approval-year cohort (ref. 2017).

FIGURE 3. MEA-REQUIRED DRUGS HAD LONGER TIME TO REIMBURSEMENT

Kaplan-Meier cumulative reimbursement incidence, MEA-required vs no-MEA drugs among PBRS-reviewed products (log-rank P=0.0016).

OBJECTIVE

To examine the association between MEA policy implementation and (1) reimbursement within 12 and 24 months of TFDA approval, and (2) time to NHI reimbursement, for oncologic and non-oncologic drugs.

5,177

TFDA-approved drug records analyzed

+11.1pp

12-mo reimbursement, oncologic vs non-oncologic (post-MEA, P=.003)

HR 0.49

MEA-required vs no MEA: longer time to reimbursement (P=.011)

DATA & CODE AVAILABILITY

Data were obtained from publicly available TFDA, NHIA, CDE (HTA reports), and PBRS meeting-minutes. Processed analytical datasets and statistical code (R version 4.4.0) are available from the corresponding author upon reasonable request.

DISCUSSION & CONCLUSION

- Following MEA introduction, oncologic drugs gained a relative advantage in early reimbursement compared with non-oncologic drugs; this difference was not sustained at 24 months.
- MEA-required drugs experienced longer reimbursement timelines, likely reflecting prolonged negotiation, administrative complexity, and the underlying clinical/financial uncertainty of drugs selected for MEAs — a pattern that persisted despite Taiwan’s MEAs being predominantly financial rather than outcome-based.
- Policy implication:** Given existing oncology-specific pricing premiums and willingness-to-pay thresholds, further selective prioritization through MEAs could widen therapeutic-area disparities as high-cost innovation expands beyond oncology.
- MEAs alone cannot resolve the structural tension between expanding access and fiscal sustainability; broader functions (e.g., outcome-based contracts, dynamic reassessment) would require further investment in HTA/PBRS capacity and post-listing data infrastructure.

Conclusion: MEAs appear to facilitate prioritization under resource constraints rather than expand system-wide reimbursement capacity.

Selected References

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Full reference list, data sources, and statistical code availability are provided in the manuscript (data sharing statement: processed datasets and code available from the corresponding author upon reasonable request).

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