HPR178

Provisional and Time-limited Access Pathways: A Comparative Analysis of Canada, UK, EU, and Australia

Venkatesh S[1], Uddin J[1]

1 LCP Health, Lane Clark & Peacock LLP. London, UK

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Key Insights

- Rapid access pathways aim to balance earlier patient access with uncertainty regarding long-term clinical and economic value.
- Among the mechanisms reviewed, Canada's linked TLR–pTAP model provides the clearest formal connection between conditional regulatory status, time-limited HTA recommendations, temporary payer negotiation, evidence generation and reassessment.
- The UK/England represents the most mature managed access system evaluated - Since July 2016, 60 CDF managed access agreements have been agreed. Of 39 treatments reappraised by NICE after data collection, 34 (87.2%) were recommended for routine commissioning in the population referred to the CDF.
- Australia and the EU accelerate regulatory access and evidence generation respectively, but reimbursement remains less tightly integrated than in Canada and the UK/England.
- Alignment between regulatory approval, reimbursement, and evidence generation remains a key challenge across all markets.

Background

- Regulators and payers increasingly face pressure to provide earlier access to innovative medicines for serious conditions while managing uncertainty regarding long-term clinical benefit and cost-effectiveness.[1-4]
- Several jurisdictions have introduced mechanisms intended to enable earlier access while additional clinical, real-world and economic evidence is generated.
- These include Canada's Time-Limited Reimbursement Recommendation (TLR) and Temporary Access Process (pTAP)[1], UK's (England) Cancer Drugs Fund (CDF)[5], the EMA adaptive pathways concept[3], and Australia's Therapeutic Goods Administration (TGA) provisional registration pathway with parallel Pharmaceutical Benefits Advisory Committee (PBAC) review[6].
- Although all aim to accelerate patient access, they differ substantially in their integration of regulatory approval, health technology assessment (HTA), price negotiation, and reimbursement processes.

Objective

- To compare Canada's pTAP and TLR Recommendation framework with selected managed- or conditional-access mechanisms in England, the European Union and Australia, focusing on evidence requirements, regulatory and reimbursement timelines, negotiation mechanisms, and reimbursement outcomes.

Methods

We conducted a targeted cross-jurisdictional review of publicly available regulatory, HTA, payer and managed-access documentation, supplemented by peer-reviewed literature.

Canada (TLR/pTAP): Product-level analysis using Epcoritamab and Trastuzumab deruxtecan, the first publicly identified therapies to enter the pathway. Evaluation focused on timelines from NOC/c to provincial reimbursement, evidence requirements, and reassessment obligations.

UK example using England's CDF: Programme-level analysis of managed access agreements (MAAs), focusing on uncertainty resolution and transition to routine commissioning through NICE reassessment.

Australia (TGA-PBAC Parallel Process): Pathway-level analysis of provisional registration and parallel HTA review, focusing on alignment between regulatory approval and reimbursement decision-making.

European Union (EU): Framework-level analysis of the EMA adaptive pathways concept, focusing on iterative evidence generation, early stakeholder dialogue and interactions between regulatory and HTA processes.

Results

- Because early-access pathways differ substantially in structure and objectives across jurisdictions, analyses focused on the key access and evidence-generation milestones most relevant to each pathway. **(Figure 1)**

Figure 1: Provisional and Time-Limited Access Process

	Canada[7]	UK/England[2]	Australia[5]	EU[3]
Model	Temporary reimbursement	Managed access funding	Accelerated review	Iterative development concept
Evidence Requirements	NOC/c; ongoing confirmatory phase III trial; reassessment submission within 270 calendar days of trial completion	Data collection agreement required to address uncertainty	Preliminary evidence and confirmatory evidence required	Iterative evidence generation and real-world evidence
Negotiation	Temporary pTAP letter of intent, followed by jurisdiction-specific product listing agreements and risk-sharing arrangements[7]	MAA and confidential commercial agreement	PBAC/PBS negotiation after review[8]	National pricing and reimbursement decisions in individual member states
Re-assessment	Mandatory	Mandatory	TGA dossier submission	Early scientific advice

- Although all four jurisdictions aim to accelerate patient access, they differ in how uncertainty is managed, reimbursement is negotiated, and evidence is generated. **Figure 2** highlights the key outcomes and lessons identified for each pathway.

Figure 2: Comparative Insights from Accelerated Access and Managed Access Pathways

Canada	UK/England	Australia	EU
As of September 2026, two medicines - epcoritamab and trastuzumab deruxtecan had concluded pTAP negotiations with LOIs. (Status current to 28/09/26) • Epcoritamab achieved first provincial listing 306 days after Health Canada issued the NOC/c - 275 days faster than the reported 581-day Canadian oncology benchmark.[9] • For HER2+ advanced gastric or gastro-oesophageal junction adenocarcinoma, trastuzumab deruxtecan received a TLR and pTAP LOI; INESSS issued a negative listing recommendation in July 2025.[9]	The UK (England) represents the most mature managed access system evaluated. • Cancer Drugs Fund: Since July 2016, 60 MAAs have been agreed through the CDF. Of 39 treatments reappraised by NICE, 34 (87.2%) were recommended for routine commissioning.[5,10]	The Australian process permits parallel regulatory and HTA evaluation, which may reduce sequencing delays before PBS listing • Brentuximab vedotin progressed from TGA registration in Dec 2013 to a positive PBAC recommendation in Mar 2014, demonstrating successful use of the parallel review process.[9] • Despite parallel TGA-PBAC review, trastuzumab emtansine received an initial negative PBAC recommendation in Sep 2013 and a positive one in Nov 2019.[9]	The EMA Adaptive Pathways concept explored iterative evidence generation, potential restricted population access, and early dialogue with HTA bodies. It was not a standalone regulatory or reimbursement pathway; reimbursement decisions remain the responsibility of individual Member States.[3]
Key insight: Among the mechanisms reviewed, Canada's linked TLR–pTAP model provides the clearest formal connection between conditional regulatory status, time-limited HTA recommendations, temporary payer negotiation, evidence generation and reassessment.	**Key insight:** The UK/England has demonstrated successful conversion of managed access treatments into routine NHS funding. In a separate historical analysis of 39 CDF cases, 17 data collection agreements (43.6%) addressed all uncertainties identified at entry.[5]	**Key insight:** Australia permits parallel regulatory and HTA processing, which may reduce sequencing delays. However, publicly subsidised access remains dependent on PBAC advice and subsequent pricing and PBS listing processes.	**Key insight:** The framework promotes evidence development but lacks a unified mechanism for translating accelerated regulatory approval into timely reimbursement.

Conclusions

- Early-access mechanisms differ in how they link regulatory authorisation, HTA, price negotiation, evidence generation and reassessment.
- Among the mechanisms reviewed, Canada's linked TLR–pTAP model provides the clearest formal connection between conditional regulatory status, temporary negotiated access arrangements, evidence generation and reassessment.
- England's CDF demonstrates a mature managed-access model, whereas the EU and Australian approaches illustrate that accelerated regulatory processes do not necessarily result in equally rapid reimbursed access.

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Abbreviations: AU, Australia; CDA-AMC, Canada's Drug Agency; CDF, Cancer Drugs Fund; EMA, European Medicines Agency; EU, European Union; HTA, Health Technology Assessment; INESSS, Institut national d'excellence en santé et en services sociaux; MAA, Managed Access Agreement; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; NOC/c, Notice of Compliance with Conditions; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Scheme; pCPA, pan-Canadian Pharmaceutical Alliance; PSD, Public Summary Document; pTAP, Temporary Access Process; TGA, Therapeutic Goods Administration; TLR, Time-Limited Reimbursement Recommendation; UK, United Kingdom

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