ATMP Reimbursement: A targeted review of Global HTA assessment trends

HTA36

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SUMMARY

OBJECTIVES

- In light of modifications to processes, increased political focus, and financial pressures, we sought to carry out a targeted review of health technology assessments. We reviewed HTA reports from Australia, Canada, England, France, Germany, and Italy to examine whether HTA bodies are positively assessing ATMP products. We also examined general trends in these markets to identify if ATMP products achieve positive recommendations at a different rate.

METHODS

- We performed a targeted review of HTA reports published during 2023, selecting for ATMPs. The outcome of these assessments was recorded, as well as the key rationale for the decision. This review included assessments carried out in 2022 for which an outcome was not published until 2023, and excluded assessments published in 2024.

FINDINGS

- A total of 58 assessment procedures were identified for ATMP products during 2023, of which 54 resulted in positive outcomes (Australia 6, Canada 6, England 10, France 10, Germany 17, and Italy 5). This represents a 93% positive recommendation rate, compared to 89% across all products. It is worth noting that the positive recommendation rate dropped to 84% for orphan drugs, suggesting ATMP drugs are finding more favourable reimbursement conditions compared to general pharmaceuticals, which in turn attract better reimbursement outcomes than orphan drugs.
- Most of the favourable ATMP recommendations were observed in oncology, with 24 (44%) in haematology, 10 (19%) in solid cancer, and 6 (11%) in neurology..

RECOMMENDATIONS

- While this research suggests conditions for ATMP reimbursement are improving, it also highlights previously reported issues for orphan drugs, most notably lower reimbursement rates (often due to data paucity). Further research is required to explore these issues.

BACKGROUND & AIMS

- In light of process modifications, increased political focus, and financial pressures, we sought to carry out a targeted review of health technology assessments (HTAs). Given the evolving landscape of healthcare technologies, particularly the emergence of Advanced Therapy Medicinal Products (ATMPs), understanding how HTA bodies evaluate these innovations is crucial. Therefore, our study examined assessment methodologies employed by HTA bodies across different countries, including Australia, Canada, England, France, Germany, and Italy, to determine whether ATMP products receive favourable evaluations.
- The analysis involved a meticulous examination of HTA reports from each of the aforementioned countries, focusing on assessment criteria, decision-making processes, and the outcome of evaluations concerning ATMPs. By scrutinising these reports, we aimed to discern any patterns or discrepancies in how ATMPs are perceived and evaluated across different healthcare systems and regulatory environments.
- Alongside the specific evaluation of ATMPs, our study encompassed an investigation into general trends within these healthcare markets. By analysing historical data and trends, we sought to identify whether ATMP products, in comparison to conventional therapies, receive positive recommendations at a different rate. This comparative analysis aimed to shed light on the acceptance and adoption of innovative therapies within established healthcare systems, considering factors such as efficacy, safety, cost-effectiveness, and patient outcomes.
- In essence, our targeted review aimed to provide comprehensive insights into the HTA landscape concerning ATMPs, offering valuable implications for policymakers, healthcare providers, industry stakeholders, and patients alike. By understanding the assessment processes and outcomes across various jurisdictions, we aimed to facilitate informed decision-making, foster innovation, and ultimately enhance patient access to cutting-edge therapies in the evolving healthcare landscape.

METHODS

- A targeted review was conducted of HTA reports published during 2023, filtering for assessments pertaining specifically to Advanced Therapy Medicinal Products (ATMPs). Within the analysis, the outcomes of these ATMP assessments were recorded, documenting the key rationales that underpinned each decision.
- It should be noted that the review encompassed assessments conducted in the preceding year, 2022, for which the outcomes were not officially published until 2023. This inclusion of delayed publications ensured a thorough examination of all relevant data available within the designated timeframe. However, assessments published in 2024 were purposefully excluded from the analysis to maintain the temporal integrity of the study and maintain focus on the insights derived from the preceding year's evaluations.
- By adhering to a meticulous selection process and strict time boundaries, a comprehensive and contemporaneous overview of the HTA landscape regarding ATMPs was produced, enabling a nuanced understanding of the evolving evaluation processes and outcomes within this dynamic realm of healthcare innovation.

RESULTS

- A total of 58 assessment procedures were identified for Advanced Therapy Medicinal Products (ATMPs) throughout the entirety of 2023. Among these assessments, a substantial majority (54) yielded positive outcomes, resulting in a 93% positive recommendation rate across various healthcare jurisdictions. (Figure 2)
- Breaking down the distribution of positive recommendations across different countries, a consistent endorsement of ATMP products was observed, with notable contributions from Australia (6 assessments), Canada (6), England (10), France (10), Germany (17), and Italy (5). This collective affirmation underscores the international recognition and acceptance of ATMPs as promising therapeutic interventions across a diverse range healthcare systems. (Table 1)
- This high positive recommendation rate for ATMPs surpasses the overall recommendation rate of 89% across all evaluated products. Notably, this analysis revealed a disparity in recommendation rates, with ATMPs exhibiting a higher rate of positive endorsements than orphan drugs (84%), which, in turn, outperform general pharmaceuticals in terms of reimbursement outcomes. (Figure 1)
- Delving deeper into the therapeutic domains, the majority of favourable recommendations for ATMPs were concentrated within the field of oncology, with a substantial 44% (24 assessments) focused on haematological malignancies, followed by 19% (10 assessments) in solid tumours, and 11% (6 assessments) in neurological disorders. This distribution underscores the fact ATMPs can addressed unmet medical needs across a spectrum of complex and challenging disease categories, further emphasising their pivotal role in reshaping the landscape of modern medicine.(figure 3)

Figure 1: Comparative reimbursement rates

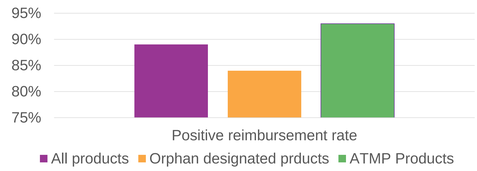

Figure 2. Country decisions

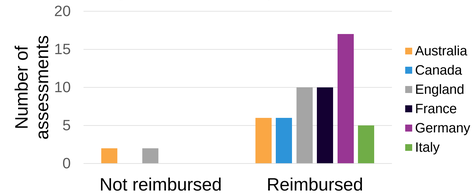

Figure 3. Reimbursement decisions

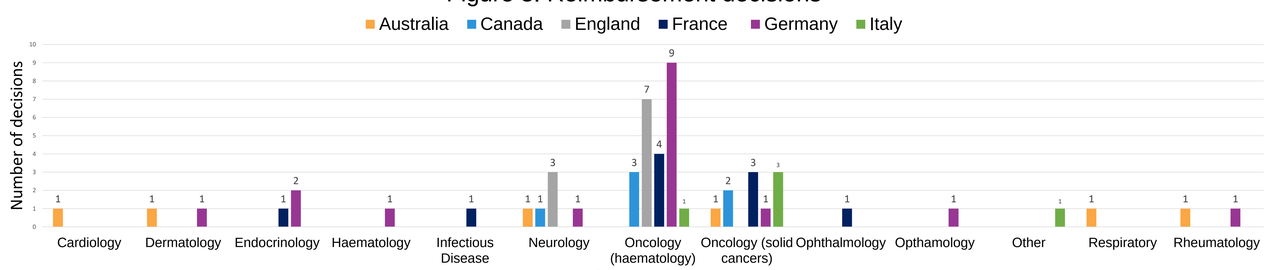

Table 1. ATMP Reimbursements 2023.

Therapeutic area	Australia	Canada	England	France	Germany	Italy	Total
Cardiology	1						1
Dermatology	1				1		2
Endocrinology				1	2		3
Haematology					1		1
Infectious disease				1			1
Neurology	1	1	3		1		6
Oncology (haematology)		3	7	4	9	1	24
Oncology (solid cancers)	1	2		3	1	3	10
Ophthalmology				1			1
Opthamology					1		1
Other						1	1
Respiratory	1						1
Rheumatology	1				1		2
Grand total	**6**	**6**	**10**	**10**	**17**	**5**	**54**

CONCLUSIONS

- ATMP products appear to be gaining positive reimbursement at a rate higher than other products.
- Further research is required to explore these findings further and to ascertain the value levers accompanying reimbursement decisions. Levers such as price, discount, or complex payment schemes may be primary drivers of this greater emphasis on reimbursement strategies and their implications on healthcare delivery and patient outcomes.
- Whilst this research suggests that conditions for ATMP reimbursement are improving, it also highlights previously reported issues for orphan drugs, most notably lower reimbursement rates (often based upon data paucity). Further research is required to explore these issues.

References

International reimbursement databases searched:

Australia: https://www.pbs.gov.au/pbs/home

Canada: https://www.cadth.ca/

England: https://www.nice.org.uk/

France: https://www.has-sante.fr/

Germany: https://www.g-ba.de/

Italy: https://www.aifa.gov.it/

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