Patient Access Delays in Multi-Indication Medicines: A Review of Health Technology Assessment Timelines

Jorge Mestre-Ferrandiz[1], Coby Martin[2], Rachel Gamburg[2], Divya Tamminina[3], Matthew Hodgson[4], Keiko Higuchi[5], Hugo Dubucq[6], Gaelle Bego Le Bagousse[7], Zhixiao Wang[8], Donia Bahloul[7]

[1]Universidad Carlos III, Madrid, Spain, [2]Axtria Inc., Berkeley Heights, NJ, USA, [3]Axtria India Pvt. Ltd., Gurugram, India, [4]Sanofi, Reading, United Kingdom, [5]Sanofi, Morristown, NJ, USA, [6]Sanofi, Barcelona, Spain, [7]Sanofi, Gentilly, France, [8]Regeneron Pharmaceuticals, Inc., Sleepy Hollow, NY, USA.

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Objective

Analyse trends in reimbursement timelines between marketing authorisation and Health Technology Assessment (HTA) and compare them with publicly available average timelines.

Background

- Multi-indication (MI) medicines face several patient-access-related challenges, including numerous HTA assessments and administration burden for payers, value assessment variation between reimbursement bodies, and managing budget uncertainty.[1]
- The duration of HTA processes and reimbursement negotiations can lead to delayed patient access to innovative products.[2]
- There is limited evidence comparing timelines of MI medicines to all medicines, so we aimed to address this gap.

Conclusions

- **Delays in evaluating MI therapies was observed relative to industry averages.**
- **NICE and CDA approved reimbursement for more restricted populations compared to the average across other HTA bodies, potentially limiting access for eligible patients.**
- **The observed evaluation patterns for MI therapies may reflect the complexity of assessing innovative treatments within existing HTA frameworks, suggesting a need for continued dialogue between stakeholders on optimal evaluation approaches.**

Methods

- Six HTA bodies were selected based on their variety of framework and perspective: England's and Wales' National Institute for Health and Care Excellence (NICE), France's Haute Autorité de Santé (HAS), Germany's Institute for Quality and Efficiency in Health Care (IQWiG)/Gemeinsamer Bundesausschuss (G-BA), Canada's Drug Agency (CDA), Agenzia Italiana del Farmaco (AIFA), and South Korea's Health Insurance Review & Assessment (HIRA).
- Six MI therapies were selected based on global market presence and variety of therapy types and therapeutic areas: adalimumab, dupilumab, mepolizumab, pembrolizumab, risankizumab-rzaa, and upadacitinib.
- Assessments for each MI therapy were searched on HTA body[3-9] and supplementary websites[10-12] between 2004 and 2024. Data was collected on marketing authorisation, evaluation, and reimbursement decision, followed by analysis on the time between marketing authorisation and HTA decision, which were compared to industry averages found in literature.

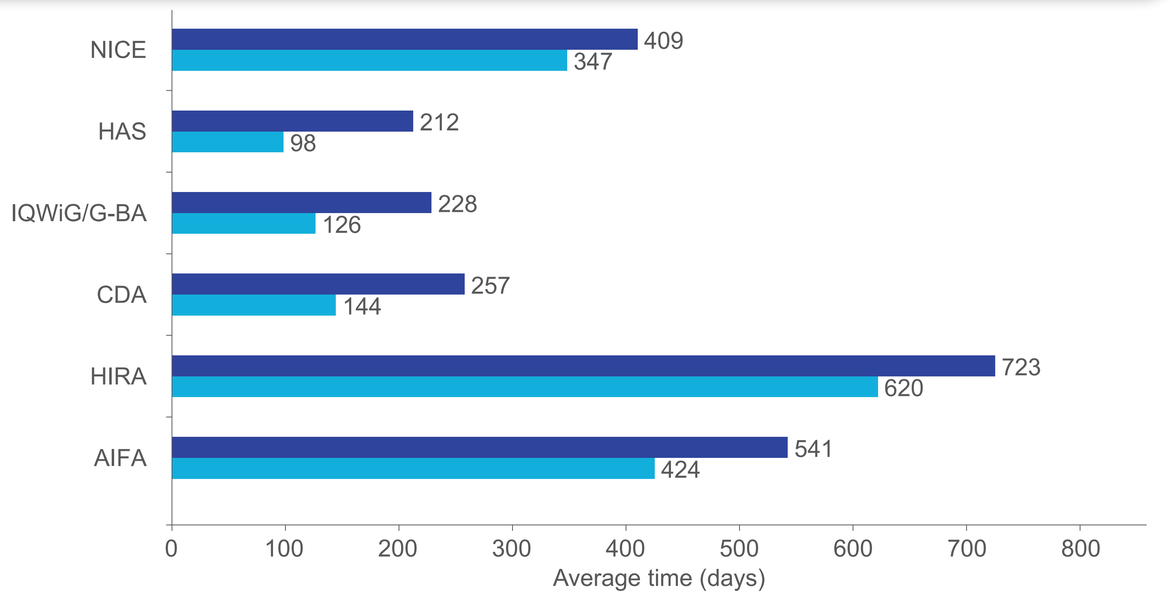
Results

- A total of 503 assessments were reviewed across all HTA bodies (**Figure 1**).
- Observed time (days) were consistently greater for MI medicines compared to the industry average of all medicines (**Figure 2**).

Figure 1. Number of assessments reviewed per HTA body and MI therapy

* Adalimumab assessments were not publicly available with IQWiG/G-BA.

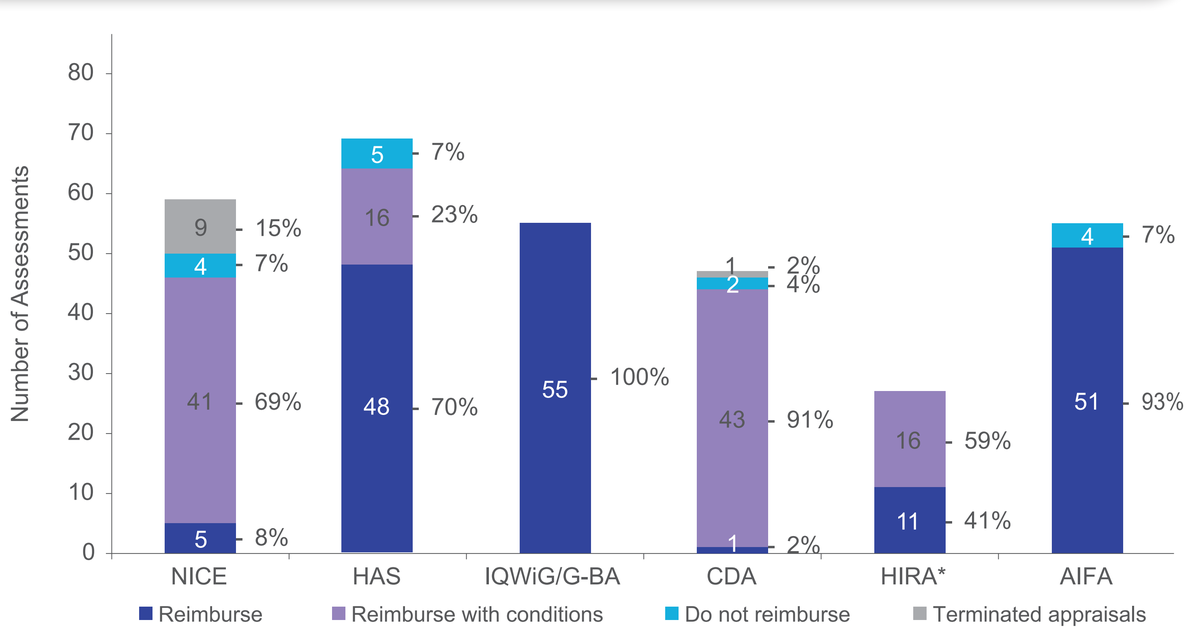
Figure 2. Average time (days) from marketing authorisation to HTA body reimbursement decision



AIFA, Agenzia Italiana del Farmaco; CDA, Canada's Drug Agency; HAS, Haute Autorité de Santé; G-BA, Gemeinsamen Bundesausschuss; HIRA, Health Insurance Review and Assessment Service; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care; NICE, National Institute for Health and Care Excellence.

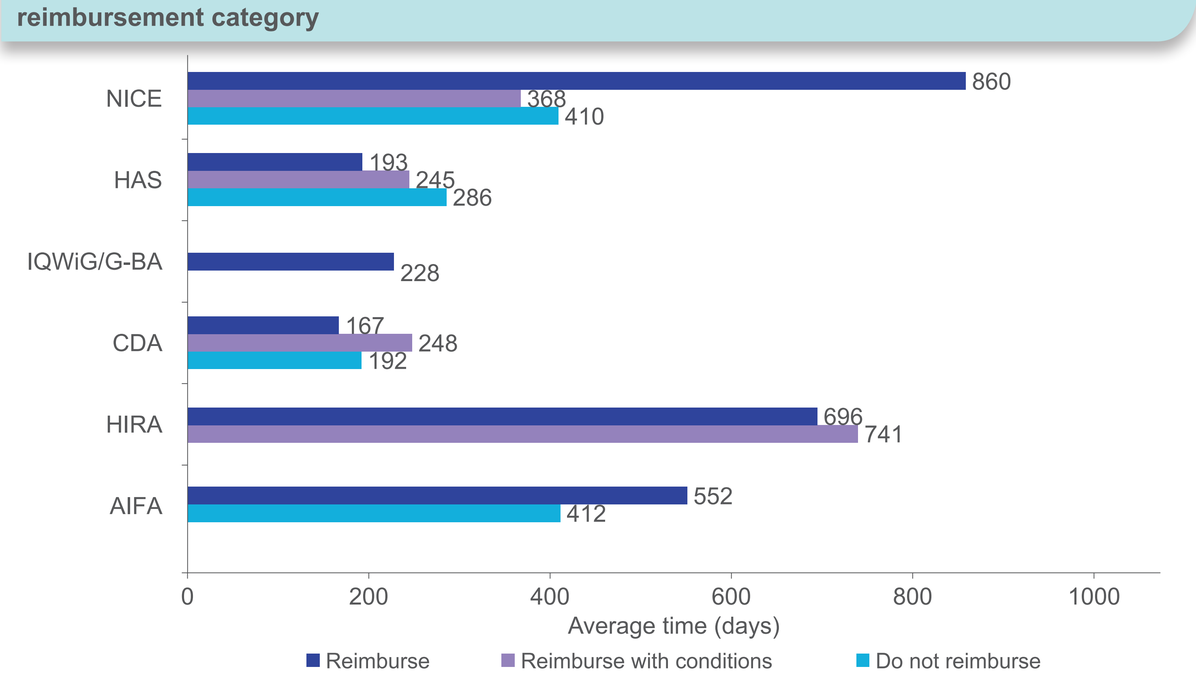
- Cost-effectiveness HTA archetypes were observed to reimburse more restricted populations for MI therapies, than typical decision-making in technology appraisals (NICE: 69% vs 24%; CDA: 91% vs 77%)[17,18] and clinical effectiveness HTA archetypes did not generally apply restrictions (HAS: 23%; AIFA: 0%; G-BA: 0%) (**Figure 3**).
- AIFA took an average of 552 days for reimbursement but was more likely to grant access for the label population (93%) compared to NICE and CDA, which are most likely to reimburse with conditions (69% and 91%, respectively), taking an average of 368 days and 248 days, respectively (**Figure 4**).

Figure 3. Number of Reimbursement Decisions (excluding reevaluations)



*Assessments for HIRA only reported reimbursed indications.

Figure 4. Average time (days) from marketing authorisation to HTA body decision, by reimbursement category



AIFA, Agenzia Italiana del Farmaco; CDA, Canada's Drug Agency; HAS, Haute Autorité de Santé; G-BA, Gemeinsamen Bundesausschuss; HIRA, Health Insurance Review and Assessment Service; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care; NICE, National Institute for Health and Care Excellence.

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