HEALTH EQUITY AND HTAs: AGENCIES ARE ASKING FOR EQUITY DATA – BUT ARE THEY USING IT?

HTA51

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Summary

- Of the 7 markets examined (EU4 + UK, CAN, AUS), **AUS, CAN, ESP, and GBR** HTA authorities **reference health equity considerations** in agency guidance documentation
- Of six recent launches examined in this analysis, HTA reports published by **NICE, CDA, and PBAC referenced health equity** in their evaluations
- **NICE** and CDA most consistently referenced health equity, with **clear evidence of health equity considerations impacting NICE assessment** outcomes

Introduction & Objectives

Increasingly, HTA agencies ask manufacturers to include reference to health equity in their submissions. The aim of this study is to understand how frequently HTA agencies (in Europe, Canada and Australia) ask manufacturers to provide evidence relating to health equity, and how frequently they refer to that evidence in their assessment reports.

Methods

A comparison of HTA agency guidance (including submission templates) and assessment reports was undertaken to examine the role of health equity in HTA assessments. Through a comprehensive search through HTA websites and guidance documents, we assessed the presence and relevance of equity-related elements. Using search terms related to health equity on the NICE website, we also identified 6 pharmaceuticals to analyze the impact of health equity on HTA assessments across markets. Across markets, these pharmaceuticals were assessed between September 2021 and September 2024. We considered elements of value in two broad categories; therapy area-related value (e.g. investment in indications that disproportionately impact vulnerable or underserved populations) and intervention-related value (including clinical trial diversity, patient support initiatives, and intrinsic features of the intervention that may impact equitable access).

Results

Market	HTA Agency	Equity included in Guidance	Guidance Document	Health Equity Language	Submission Guidance Relating to Health Equity
	PBAC	✓	Evidence Submission Guidance	"Equity and ethical assumptions, such as age, or socioeconomic and geographic status"[1]	"Discuss how the proposed medicine might **promote (or hinder) patient equity or access**"[1]
	CDA-AMC	✓	Procedures for Implementation Advice for Health Technologies / Agency Position Statement	"Health equity", "Equity and accessibility issues"[2]	"Patient and clinician groups… are encouraged to focus their input on the perspectives and issues of patients and/or their caregivers…. This includes… **addressing equity and accessibility issues.**" "Manufacturers will be permitted to provide input."[2]
	agencia española de medicamentos y productos sanitarios	✓	Economic Evaluation Guidance (published by CAPF, an advisory committee)	"Ethical, equity, and other considerations considered relevant to decision-makers"[3]	**"If it is considered relevant to admit arguments for prioritising individuals or groups (for example, for reasons of social justice or vulnerability)** [in the economic evaluation], it is recommended to justify this qualitatively. All relevant populations should be described in order to be able to **discuss and justify decisions that affect the distribution of resources**."[3]
*	NICE	✓	Evidence Submission Guidance / Agency Position Statement	"Equality Considerations" regarding "people with particular protected characteristics"[4]	"Provide an assessment of whether the use of this technology is **likely to raise any equality issues**", e.g., "could lead to recommendations that have **a different impact on people**… making it **more difficult** in practice **for a specific group to access** the technology"[4]
	HAS	✗	***No mentions of providing evidence related to health equity considerations as part of the HTA assessment were found***		
	AIFA	✗			
	Gemeinsamer Bundesausschuss	✗			

Figure 1 | Health Equity Considerations by HTA Authorities across EU4 + UK, CAN, and AUS

Of the 7 markets assessed, FRA, ITA and DEU did not publish guidance or documentation regarding the provision of evidence related to health equity in their assessments of health technologies.

AUS, CAN, ESP, and GBR HTA agencies reference health equity, and the primary consideration of health equity relates to addressing or discussing equitable access or equitable opportunity to healthcare for different populations.

Of note, equity is mentioned not by the main HTA agency in ESP (AEMPS) but by an advisory committee (CAPF).

Figure 2 | Impact of Health Equity Considerations on Select Therapeutics

Outside of NICE, CDA, and PBAC, **no other HTA agencies mentioned health equity** in their assessment reports of the six products included in this review.

Of NICE, CDA, and PBAC, **NICE is the most consistent** with regards to examining health equity**. All six assessments examined considered health equity.

Additionally, three of six assessments clearly stated how equity considerations **positively impacted patient access in NICE recommendations**, either by including a wider population than supported by the cost-effectiveness analysis, or by having a positive impact on the decision.

While both the **CDA and PBAC mention equity considerations** in their assessments, the **actual impact on the assessment outcome is unclear**.

Drug	Indication	Health Equity Value	HTA Agency	Health Equity Considered	Impact	Quotes from HTA Decisions Regarding Impact of Health Equity on Outcome
VYALEV 240 mg/mL+12 mg/mL solution for infusion foslevodopa/foscarbidopa	Parkinson's Disease	Intervention Related	NICE	**Increased accessibility** for rural/remote patients (due to current SoC being only available in specialist centers in major urban centers given their complicated administration)	**Positive** Access improvements noted as potential 'uncaptured benefits'	"[The committee] acknowledged the many potential benefits [VYALEV] could bring and that **some benefits** [innovative aspects and healthcare system benefits] **were not captured in the [economic] modelling [for cost-effectiveness]**."[5]
			CDA-AMC		**Uncertain** Access issue acknowledged	The CDA noted that "**existing treatments for advanced PD could be difficult to access…** because these are typically provided in major urban treatment centres."[6]
			PBAC		**Uncertain** Improved access acknowledged	"The committee recognized that [VYALEV]… **would provide benefits to regional and rural patients** who otherwise may need to travel significant distances to access current treatment options."[7]
tepkinly epcoritamab	Relapsed / Refractory DLBCL	Intervention Related	NICE	**Increased accessibility** (due to access barriers for comparator CAR-Ts; e.g., specialist center requirements)	**Uncertain** Improved access with an additional treatment to existing CAR-Ts acknowledged	**"NICE has due regard to promote the reduction of health inequalities…** the **addition of epcoritamab as another treatment option** that [avoids] travel to a specialist centre **could help ensure more people have access to effective treatments**."[5]
			CDA-AMC			"[The committee] acknowledged… the **need for additional treatments that are easier to access** and noted that **epcoritamab may meet this need**."[6]
Evkeeza (evinacumab-dgnb) Injection	Homozygous familial hypercholes-terolaemia	Intervention Related / Therapy area related	NICE	**Discrimination against patient characteristic (age)**	**Positive** To prevent potential inequality of access due to age, a positive recommendation was awarded to patient population despite being not cost-effective	"NICE guidance and standards… emphasize the importance of **considering the distribution of health resources fairly within society** as a whole, and factors other than relative costs and benefits alone. The committee concluded that… **a negative recommendation in young people could be discriminatory**… this potential inequality had been an important factor in [the] decision to **recommend [EVKEEZA] for the full population in its marketing authorization**."[5]
			CDA-AMC	**Increased accessibility** (due to geographic barriers for access to current SoC)	**Uncertain** Access issue acknowledged	"The committee discussed how **[EVKEEZA] may involve fewer geographic barriers to access** than those associated with apheresis. The committee discussed the **need to consider distributive justice** or the **fair allocation of benefits** and burdens in the potential implementation of [EVKEEZA]."[6]
idefirix (imlifidase)	CKD: Desensitisation treatment before kidney transplant	Therapy area-related	NICE	**Disproportionate incidence / prevalence** among certain populations	**Uncertain** Access issue acknowledged	"The committee was **mindful of its responsibilities** for people with protected characteristics…. It concluded that people with these **protected characteristics** [Black, Asian, or minority ethnic family backgrounds, and people who have been pregnant] have an increased chance of becoming highly sensitized, and **this should be taken into account in its decision making**."[5]
casgevy (exagamglogene autotemcel) suspension for IV infusion	Transfusion-dependent β-thalassaemia	Therapy area-related	NICE	**Disproportionate impact and incidence / prevalence** among certain populations	**Positive** A higher cost-effectiveness estimate was used for decision making due to the disproportionate impact	"The committee concluded that it was **willing to take health inequality into account** in its decision making by **accepting a higher cost-effectiveness estimate** than it otherwise would have done."[5]
Apretude cabotegravir 200 mg/mL	Preventing HIV-1 (PrEP)	Therapy area-related	NICE	**Disproportionate incidence / prevalence** among certain populations	**Neutral** Issue acknowledged, but not considered to impact the final recommendation (*in draft guidance published)*	"The committee noted that **issues related to differences in prevalence or incidence** of a condition [HIV] **cannot be addressed** in this technology appraisal. The committee also noted that **its recommendation does not restrict access** to treatment for some people over others. The committee agreed that these were **not potential equality issues that could be addressed** in the recommendations."[5]

* NICE guidance is applied across the UK, however, Scotland and Wales also have their own HTA agencies which can publish their own assessments
** NICE guidance includes sections on Equality Considerations and Other Considerations where health equity issues are discussed

Conclusions

Health equity considerations are beginning to impact HTA decision making. Multiple agencies are already referencing or considering health equity in their decision making; other agencies are likely to follow.

However, direct evidence of health equity considerations and their impact on assessments is still relatively rare, and at the time of writing, medical benefit focused markets (such as DEU and FRA) have not yet taken health equity into consideration in their evaluations.

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Abbreviations

AEMPS: Agencia Española de Medicamentos y Productos Sanitarios
AIFA: Agenzia Italiana Del Farmaco
CAPF: Comité Asesor para la Financiación de la prestación Farmacéutica del SNS
CAR-T: Chimeric Antigen Receptor T-Cell Therapy
CDA: Canadian Drug Agency
CKD: Chronic Kidney Disease
DLBCL: Diffuse Large B-Cell Lymphoma
HAS: Haute Autorité de Santé
HEOR: Health Economics and Outcomes Research
HIV-1: Human Immunodeficiency Virus 1
HTA: Health Technology Assessment
NICE: National Institute for Health and Care Excellence
PBAC: Pharmaceutical Benefits Advisory Committee
PrEP: Pre-exposure prophylaxis
SoC: Standard of Care

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