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## LITERATURE REVIEW

# Barriers to access and use of high cost medicines: A review

Philip Wahlster<sup>a</sup>, Shane Scahill<sup>b</sup>, Christine Y. Lu<sup>c</sup>,  
Zaheer-Ud-Din Babar<sup>d,\*</sup>

<sup>a</sup>Department for Health Services Research, University of Bremen, Bremen, Germany

<sup>b</sup>School of Management, Massey University, Auckland, New Zealand

<sup>c</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

<sup>d</sup>School of Pharmacy, University of Auckland, Auckland, New Zealand

**KEYWORDS**

Stakeholder perspective;  
Affordability;  
Decision-making;  
Reimbursement

**Abstract**

**Background:** The objective of this literature review was to identify barriers to access and use of high cost medicines (HCMs).

**Method:** A literature review was performed in common electronic databases (Medline, PubMed, Springer Link, Embase, Science Direct, and Google Scholar). We identified original studies published between 1999 and 2011 relating to access to and use of HCMs. Three hundred and seventy four relevant articles were found. Forty-three original articles matched inclusion criteria.

**Results:** We categorized access barriers into three levels: health system, regional/hospital, and patient levels. Barriers to access included the affordability of the healthcare system, the decision-making process for funding HCMs and eligibility criteria for access, geographic variation in funding and access, communication between physicians and patients, and patient out of pocket costs.

**Conclusion:** Barriers to access HCMs are inter-related. These barriers are also relevant for other medicines but are escalated in the case of HCMs. Overall, healthcare systems are facing barriers related to high out-of-pocket cost for patients and/or barriers regarding the decision-making process and the effects of reimbursement decisions (i.e., restricted, delayed or denied access, particularly the latter for socialized systems with a universal coverage scheme). Inadequate access to HCMs may lead to subsequent use of unnecessary medical treatments. Barriers to access HCMs can also lead to treatment disparities between patients who can overcome these barriers and those who cannot. Improvements in the decision-making process can increase acceptance of the need to prioritize access to HCMs.

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\*Correspondence to: School of Pharmacy, Faculty of Medical and Health Sciences, University of Auckland, Private Mail Bag 92019, Auckland, New Zealand.

E-mail address: [z.babar@auckland.ac.nz](mailto:z.babar@auckland.ac.nz) (Z.-U.-D. Babar).

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## Introduction

Access to healthcare is a fundamental human right and is one of the most important determinants of health outcome [1]. Many healthcare systems face the challenge of rationing medicines and health services in light of growing healthcare expenditures, in part due to ageing populations [2]. Access to high cost medicines (HCMs) in both public and private health systems is gaining attention [3,4].

Access to HCMs is often limited, and follows different patterns to that of conventional medicines. HCMs are defined by “disproportionately high cost compared to the other expected costs of care” [5]. HCMs are mostly new, specialized medicines for complex conditions such as cancers and inflammatory diseases [6]. These medicines include biological agents, which selectively target specific molecular sites [7] and therefore are effective with fewer side effects. Biopharmaceuticals promise to effectively treat many diseases but they are often much more expensive than conventional drugs [8]. Less than optimal access to HCMs may negatively affect patient outcomes [9]. Given their high price, use of HCMs can substantially increase pharmaceutical expenditure [10]. This raises the important question of whether the incremental benefits of HCMs justify their additional costs.

Many health care systems implement the “fourth hurdle” that requires economic evaluations to demonstrate the value for money of new technologies to be reimbursed [11]. On the one hand, the approach of “value for money” encourages manufacturers to develop drugs which provide

increasing benefit for patients. Therefore, experts see advantages of the “fourth hurdle” as it may “accelerate the development of new clinically meaningful treatments [12]. On the other hand, cost-effectiveness may be difficult to determine due to uncertain evidence at the time decisions are being made about reimbursement [13]. This is especially the case with biological medicines, many are approved under accelerated mechanisms [14]. Additionally, the ongoing discussion about the appropriateness of the quantitative health economic concepts such as Quality Adjusted Life Years (QALY) shows that there is still much work to be done to improve measures in economic evaluations for reimbursement decisions [15,16].

Research to understand access to HCMs is important to inform policy and practice to optimize access and use of HCMs. Due to the complexity of the problem, examination of one or two studies will not yield generalizable findings [17]. A review of the literature surrounding access to HCMs can provide a comprehensive summary of the available evidence [18]. This article reports a literature review to identify factors that influence access to HCMs and their use in healthcare systems. This is part of a larger project that reviews the broader literature pertaining to access of HCMs. The research question was built using the PICO-Scheme (Population, Intervention, Comparator, Outcome) [19]. Another part of this project summarizes perspectives of stakeholders regarding access to HCMs, which has been reported elsewhere [20].

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