VALUE IN HEALTH 17 (2014) 98–108

Available online at www.sciencedirect.com

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Health Policy Analysis

A Synthesis of Drug Reimbursement Decision-Making Processes in Organisation for Economic Co-operation and Development Countries

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ABSTRACT

Background: The use of a restrictive formulary, with placement determined through a drug-reimbursement decision-making process, is one approach to managing drug expenditures. **Objective:** To describe the processes in drug reimbursement decision-making systems currently used in national publicly funded outpatient prescription drug insurance plans. **Methods:** By using the Organisation for Economic Co-operation and Development (OECD) nations as the sampling frame, a search was done in the published literature, followed by the gray literature. Collected data were verified by a system expert within the prescription drug insurance plan in each country to ensure the accuracy of key data elements across countries. **Results:** All but one country provided at least one publicly funded prescription drug formulary. Many systems have adopted similar processes of drug reimbursement decision making. All but three systems required additional consideration of clinical evidence within the decision-making process. Transparency of recommendations varied between systems, from having no information publicly available (three systems) to all information available and accessible to the public (16 systems). Only four countries did not consider cost within the drug reimbursement decision-making process. **Conclusions:** There were similarities in the decision-making process for drug reimbursement across the systems; however, only five countries met the highest standard of transparency, requirement of evidence, and ability to appeal. Future work should focus on examining how these processes may affect formulary listing decisions for drugs between countries.

Keywords: decision making, formulary management, international health care, prescription drug coverage.

Introduction

Drug expenditures are a major factor contributing to growth in health care expenditure [1]. Publicly funded drug plans continue to seek sustainable and fiscally responsible models for financing and funding drugs. Formulary systems, including the use of restrictive formularies, have been commonly adopted as one means to control unnecessary growth in drug expenditure. Formulary systems require decisions to be made about which drugs will be reimbursed for whom and for what condition. Given the increased use of drugs in general, and with the development of newer and more expensive drugs, the pressure on publicly funded drug plans continues to increase [2].

Different types of publicly available drug insurance systems have developed over time internationally. Various approaches and processes exist with respect to consideration of listing for new drugs. In all cases, information relevant to a listing decision must be considered: some jurisdictions conduct independent reviews [3], whereas others place the burden of proof on those who propose technologic change, reviewing submitted claims from manufacturers exclusively [4]. Some systems consider cost formally [5], whereas others do not [6], and some countries adopted explicit threshold values for deeming when drugs are cost-effective [7]. Information may or may not be reviewed by expert committees that make either recommendations or decisions [8,9].

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http://dx.doi.org/10.1016/j.jval.2013.10.008

Although the use of restrictive formularies and thus the need for drug-reimbursement decision-making processes appear inevitable given concerns over increasing drug expenditures, minimizing the bias of these processes is essential [10]. We sought to provide a contemporary and detailed description of the characteristics of decision-making systems for drug reimbursement decision-making processes currently used in publicly funded outpatient prescription drug insurance plans for all Organisation for Economic Co-operation and Development (OECD) nations.

Methods

Study Sample

The OECD nations formed the sampling frame because they include both developed and emerging nations from Europe, North America, Latin America, and Australasia, representing countries with varied sociocultural characteristics, budgetary restrictions, and health care systems. Only those OECD countries that offered publicly funded health care along with a publicly funded outpatient pharmaceutical insurance system to at least a portion of its citizens were included. Publicly funded drug insurance systems that focused solely on inpatient drugs or drugs for a specific clinical condition, such as cancer, were excluded.

Database Search Strategy

Two reviewers searched the following electronic databases from inception until March 2011: MEDLINE, EMBASE, and PubMed. In brief, the key terms included the following terms: *drug costs*, *formularies*, *prescription drugs*, *reimbursement mechanisms*, and *insurance*. The search was developed in consultation with an experienced librarian (see Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2013.10.008). A secondary search was undertaken in the gray literature, focusing on, but not limited to, the various drug reimbursement agency Web sites (see Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2013.10.008). Only the most recent information for each country was retained. Data collection from public documents commenced March 2011 and finished in September 2012.

Web Site Search Strategy

Concurrently with the database searching, we carried out a search of relevant drug agency Web sites, publicly funded health insurers, and relevant terms by using Google. We searched Web sites in a systematic manner, first by using the site map to identify research and/or publication links and then by using the Web site's search engine to search relevant terms. For all Web sites, we searched the following terms: *reimbursement*, *pharmaceutical*, *committee*, and *formulary*. Logs were kept of Web sites searched, with links to relevant pages saved.

Because most of the data came from the gray literature, we identified a person familiar with the process through which new prescription drugs are evaluated for inclusion within the formulary within each jurisdiction ("system expert") and verified the accuracy of subjective data elements abstracted. System experts were identified through peer-reviewed publications, agency Web sites, or appropriate contacts of the research team. A table of the collected data was e-mailed to the system expert, who was asked to confirm its accuracy or clarify any discrepancies. The experts were invited to enter additional comments and provided information between January and September 2012.

Variable Definition and Data Abstraction

Data were gathered on the pharmaceutical reimbursement decision-making systems (i.e., the process by which new drugs are considered for inclusion on the formulary). Data were extracted for each phase of the process: initiation, evidence synthesis, deliberation, and outcome. The initiation of the process for the consideration of reimbursement was categorically defined as initiation by the manufacturer, by the government, or by another entity. With respect to whether clinical evidence was required within the drug reimbursement decision-making process, we assumed that drugs considered for reimbursement previously required clinical evidence for market approval and therefore we sought whether additional clinical evidence was required for drug reimbursement (yes/no). The assessment of clinical evidence was categorized as follows: agency replicated (the agency replicates the evidence provided by the submitter by independently collecting via systematic search and by verifying and reanalyzing the data submitted); agency critique (the agency critiques the evidence provided by the submitter, but does not independently collect data); and independent review (the agency contracts an independent party to conduct a full review of the evidence). An expert committee was defined as the committee who makes a recommendation to or decision on behalf of the agency regarding the reimbursement of the drug under consideration. We also included information on whether the committee engaged in price negotiation with the manufacturer as part of the reimbursement decision-making process. The transparency of the final decision of the agency was categorized as follows: no public information available on which drugs were considered; only positive recommendations available publicly; both positive and negative recommendations available publicly; all recommendations available along with the reasons for the recommendation; and all recommendations, the reasons, and a summary of the evidence considered for the decision publicly available. Transparency was determined by searching the agency's public domain Web site.

Consideration of cost, cost-effectiveness, and the public availability of cost-effectiveness guidelines were collected. We also assessed whether jurisdictions explicitly stated cost per quality-adjusted life-year (QALY) thresholds, or other similar metric, to be used when making decisions for the reimbursement of a drug. The outcome of the process was categorized as whether the committee makes a recommendation (provided to another body that formulates the final decision) or a decision (implemented by the agency). In some cases, regulations exist such that the decision-making body cannot decide to fund a drug unless the recommendation of the agency is to fund; in these cases, the expert committee is considered a recommending body. We also documented whether or not the submitter could appeal to the same expert committee or agency after a "do not list" recommendation or decision. We define an appeal as the ability of the submitter to request a reconsideration of the final recommendation/decision exclusive of a challenge within the court system.

In an attempt to critically appraise each system, we identified, a priori, three criteria as reflecting a high standard of the drug reimbursement decision-making process. These criteria are drawn from the objectives of three internationally representative agencies—the Canadian Common Drug Review, the National Institute for Health and Care Excellence, and the Pharmaceutical Benefits Advisory Committee—and are consistent with three of the four criteria from the accountability for reasonableness, which has been used to judge a fair system. The three agencies were selected because they have each been in operation for more than 10 years and are regarded as the most advanced, highly regarded evidence-based reimbursement decision-making bodies in the world. The objectives of each agency include direct