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ScienceDirect
Health Policy 80 (2007) 369–377
HEALTH POLICY
www.elsevier.com/locate/healthpol

Prioritisation by physicians in the Netherlands—The growth hormone example in drug reimbursement decisions

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Abstract

Drug treatment and reimbursement is an area of ever growing complexity in health priority setting. This paper assesses the National Registry of Growth Hormone Treatment (LRG) responsible for making prioritisation decisions in the Dutch drug reimbursement system in the treatment of growth hormone, using the framework for fairness. We used qualitative research consisting of semi-structured interviews and focus group sessions combined with quantitative methods to audit the decisions of the forum.

The rationing decisions of the forum demonstrate accountability for reasonableness by the conditions for transparency, relevance, and appeal. Most rationales for the decisions are public and transparent. The patients and paediatricians see decisions made by the LRG as clinical and therefore relevant decisions. They also refer to extensive appeal procedures.

The case also raises important issues regarding the legitimacy of expert-based priority setting as the cyclic nature of guideline development conflicts with the need for maintaining strict rationing criteria. In 13% of the patients, the sick funds did cover treatment as the forum advised them to do, but according to guideline criteria it may be unlikely that these patients have growth hormone deficiency. According to the LRG, however, only 2% of the decisions are inconsistent with the guidelines, as some criteria on what to do in case of more uncertainty, shifted. For the forum, it seems rather unthinkable to go against the professional norms, in spite of formal national regulations. For the Health Care Insurance Board (CVZ), it was not considered possible to go against national regulations, especially as professional norms have shifted without informing policy makers and patient representatives.

Keywords: Prioritisation; Drug reimbursement; Guidelines; The Netherlands; Growth hormone

1. Introduction

Drug treatment and reimbursement is an area of ever growing importance and complexity in health priority setting [1]. Daniels and Sabin developed a framework

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doi:10.1016/j.healthpol.2006.03.016

for fairness in priority setting in health care, based on the principle "accountability for reasonableness" [2]. As the framework is gaining attention internationally we used this to formulate our criteria to evaluate the priority setting process. According to this framework, health care institutions engaged in priority setting have a claim to fairness if they satisfy three conditions [1–4]: transparency, relevance, and appeal opportunity. Rationales for priority setting decisions must be publicly accessible, fair-minded people must consider the rationales as relevant to priority setting in that context and there must be an avenue to appeal these decisions and their rationales. Although derived in part from empirical studies of managed care organisations, no one has examined its applicability to actual priority setting contexts, so far [3,4].

The purpose of this paper is to evaluate the work of an expert forum as a rationing mechanism. We do this against the background of the general policy debate how to devise appropriate tools for rationing. Here, leading questions are: "Should we impose explicit national guidelines or modulate discretionary powers to clinicians when faced with individual patients?" And "under what circumstances can the selected mechanisms work and when does not it work?" Many countries stimulate the creation and use of guidelines and guidelines [5,6]. Although protocols have become an important policy instrument for setting priorities, few drugs are reimbursed under the condition of an operational protocol. The next step then has been to make the use of a protocol a prerequisite for funding.[1] However, it is still a remaining question whether practitioners implement the clinical practice policy as intended. Usually, there is no monitoring to see whether these protocols are followed. Growth hormone and etanercept have become the exceptions, at least in the Netherlands.

In 1998, the Minister of Health has asked the Dutch Growth Foundation (NGS) to start monitoring every claim for covering a treatment with growth hormone. The task of Dutch Growth Foundation, i.e. its subdivision the National Registry of Growth Hormone Treatment[2] (LRG) has been to monitor whether paediatricians who wanted to treat a child with growth hormone are following the national guideline. Only after the LRG has concluded that the paediatrician is acting according to the guideline in his or her application for treatment this patient the insurance company will be covering treatment. The obligatory approval by experts of every application to start a growth hormone treatment is a unique experiment to bridge the gap between the rationing mechanism introduced by the government and the LRG on the macro-level and the physician's decision-making to start a treatment on the micro-level in the realities of patient care.

Several problems, however, are associated with this strategy. On the one hand, there may be problems in the implementation. Practitioners may experience tension between political and expert-based decision-making, and may not always act upon formal regulations. On the other hand, there is the risk that political decisions may be disguised as neutral clinical decisions and guidelines might end up as instruments for unjustified and covert rationing disguised as expert recommendation [2,7,8].

In the near future, the Dutch government is planning to monitor the use of professional guidelines more systematically. In 2004, a new organisation was founded called LABAG.[3] Its task is to check the use of guidelines in decisions to treat patient with specific and expensive drugs. A national rationing organisation for expensive drugs would make rationing more efficient, more effective, uniform, and fair, leading also to cost savings [9]. These assumptions, however, have never been evaluated, so far. The present study addresses this question. The Health Care Insurance Board commissioned the study to examine whether a central obligatory check of every individual decision to start a treatment with a specific, always expensive drugs, is indeed an effective rationing instrument. To answer this question we studied both the processes and the content of the rationing decisions the LRG made since its start in 1998 up to 2002. The results are presented by the three conditions for fairness in priority setting.

[1] Now, this is the case for nine drugs in the Netherlands. These drugs are: growth hormone, acetylcysteine, alglucerase and imiglurase, gabapentine, lamotrigine, levetiracetam and topiramaat, rivastigmine, apraclonidine, dorzolamide, latanoprost, etanercept, anakinra, and adalimumab.

[2] In Dutch: '*Landelijke Registratie Groeihormoon*'.

[3] In Dutch: LABAG, *Landelijke Beoordeling Aanvragen Geneesmiddelen*.