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How innovative are pharmaceutical innovations? The case of medicines financed through add-on payments outside of the French DRG-based hospital payment system

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ABSTRACT

Objective: To analyze the characteristics of inpatient medicines placed on the list of innovative high-cost medicines funded in addition to DRG-based payment, and to identify whether they really are innovative and/or high-cost.
Methodology: The medicines placed on the list of innovative and high-cost medicines were analyzed on the basis of criteria describing their innovative nature and cost. They were categorized as innovative and high-cost, only high-cost, only innovative and neither innovative nor high-cost.
Results: Among the medicines financed in addition to DRG-based payment, 25.5% were classified as innovative and high-cost, 23.5% only high-cost, 22.9% only innovative and 28.1% neither innovative nor high-cost.
Conclusions: The list of innovative and high-cost medicines contains medicines other than innovative and high-cost medicines. Stricter criteria for placing medicines on this list should be considered in order to limit the increase in expenditure.

1. Introduction

To allocate financial resources to hospitals, most developed countries have introduced the DRG-based payment system. There is wide variation in the structure and setting of DRG rates between countries [1], although the fundamental features remain the same. Patients are classified in diagnosis-related groups (DRGs) based on diagnosis, procedures and demographic characteristics that have similar resource consumption patterns and are clinically meaningful [2]. The payment rate assigned to each DRG reflects the average resources required to treat patients in each group.

As a rule, the costs of pharmaceuticals and medical devices are reimbursed through the normal DRG-based payment rate. However, the DRG-based payment system is not sufficiently dynamic to cope with innovative technologies [3,4] or with innovative and particularly expensive medicines. It is not sufficiently flexible to include immediately the cost of new, "just-launched," medicines in the DRG rate. Three types of medicines encounter difficulties in being efficiently reimbursed through DRG-based hospital payment systems: high-cost medicines whose prices exceed DRG rates, innovative medicines that cannot be addressed within the existing DRG structure, and medicines that are not commonly used. To cope with this problem, expenditure for innovative and high-cost medicines are often covered by additional payments [5–7].

In France, the DRG-based hospital payment system was introduced in 2005 to pay for acute care services in order to improve the efficiency, transparency and management

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of hospital activities, as well as improving quality of care [8]. In the context of this reform, a list of innovative and high-cost medicines reimbursed in addition to the DRG rates was established [9]. These medicines are paid retrospectively, according to the actual level of prescriptions made [10]. Given the global cap on resources allocated to hospitals, a large increase in retrospectively allotted funds would need to be compensated by a reduction in resources allotted within the DRG-based payment system. DRG rates, which are subject to volume/price regulation, would thus be reduced. Thus, additional retrospective payments foster the use of innovative medicines placed on the above-mentioned list, at the expense of innovations and any other services financed within the DRG-based payment system [10,11]. Given the effect on the DRG-based payment system, care should be taken to ensure that medicines financed on the basis of retrospective payment are truly innovative.

We analyzed the characteristics of inpatient medicines placed on the list of innovative and high-cost medicines in France and funded retrospectively, in order to know whether these medicines are truly innovative and/or high-cost.

2. Background

2.1. Macro level control of innovative medicines

In the French health care system, the budget voted by Parliament limits health care expenditure. The budget covers expenditure within the DRG-based payment system, as well as additional payments that hospitals receive for certain activities and products, e.g., research, education and innovations. These additional payments are calculated on a retrospective basis and include two types of payments for innovative medicines. One type of payment is intended to finance medicines that have not yet received marketing authorization but which are permitted for use in treating patients suffering from rare or serious diseases for which there are no alternative treatments. These medicines must receive authorization for temporary usage (*Autorisation Temporaire d'utilisation*, ATU) on the basis of evidence pointing to their safety and efficacy as shown in clinical trials. The second type of additional payment is targeted at funding particularly innovative and high-cost medicines that are placed on a restricted list, termed *Liste en sus*.

For both types of medicines, economic regulation on the national level is focused on price control. Additionally, for the *Liste en sus* medicines, there is a type of non-economic regulation in the form of the national guidelines for proper use (*Referentiel de bon usage*, RBU), which define the conditions under which the use of these medicines is acceptable and uses for which it is not. Use out of the scope of the RBU is permitted if there is no alternative treatment and if it is justified by published international scientific research.

Within the overall budget allotted at the national level, an increase in expenditure for *Liste en sus* medicines would lead to a DRG rate reduction [10]. To mitigate this effect, the budget to finance the *Liste en sus* medicines has been limited since 2009 by the annual growth rate cap [12,13]. In this context, medicines to be placed on the *Liste en sus* must be carefully selected in order to foster the use of medicines with high clinical value.

2.2. Local-level control of innovative medicines

The regulation of expenditure on innovative medicine in hospitals follows macro-level regulatory measures. However, hospitals purchasing *Liste en sus* medicines can negotiate prices with manufacturers. If the negotiated price is lower than the price fixed at national level, the hospital keeps 50% of the difference. This measure was implemented to give hospitals incentives for negotiating lower prices. However, it is largely ineffective because manufacturers resist negotiating the price a second time at local level, partly because this could lead to decreases in the price fixed at national level [14]. Furthermore, reimbursement of medicines from the *Liste en sus* is governed by an agreement for proper use (*Contrat de Bon Usage des médicaments*, CBU), which is established between the hospital and the regional health agency (*Agence Régionale de Santé*, ARS) [15,16]. The agreement covers a period of 3–5 years and the hospital undertakes specific commitments regarding medicines from the list, such as nominative prescription and dispensation, prescription traceability in medical records, individual consumption monitored by the hospital pharmacists, and use of the medicines according to the RBU. For hospitals that have signed the agreement, the reimbursement rate for medicines from the *Liste en sus* is 100%. If the commitments are not met, the reimbursement rate for these medicines may be fixed between 70% and 100% for the hospital in question. All hospitals are monitored for compliance with the annual growth rate cap established at national level. If the hospital exceeds this rate, it must implement the improvements required by the ARS.

2.3. Construction of the Liste en sus

An analysis of the legal framework reveals a lack of explicit procedure and criteria for placing medicines on the *Liste en sus*. The final decision on placing medicines on this list is made by the Minister of Health. However, medicines to be placed on the list must have been previously listed as inpatient medicines on the basis of the opinion of the Transparency Committee (*Commission de la Transparence*, CT) of the French National Authority for Health (*Haute Autorité de santé*, HAS).

The Ministry of Health states that the *Liste en sus* comprises medicines that are high-cost and innovative, criteria that are rather vague [17]. The opinion of the CT comprises more specific criteria such as actual benefit of the medicine (*Service Médical Rendu*, SMR), public health benefit (*Intérêt de Santé Publique*, ISP), and improvement in actual benefit (*Amélioration du Service Médical Rendu*, ASMR). The criteria that are used for evaluating SMR, ISP and ASMR are described in Table 1. ISP is not independent criterion but is one of the components of SMR that describes the improvement in population health derived from the direct or indirect influences of the medicine [18]. ISP is assessed twice. The first assessment is performed early after market launch. At this stage, uncertainties remain regarding