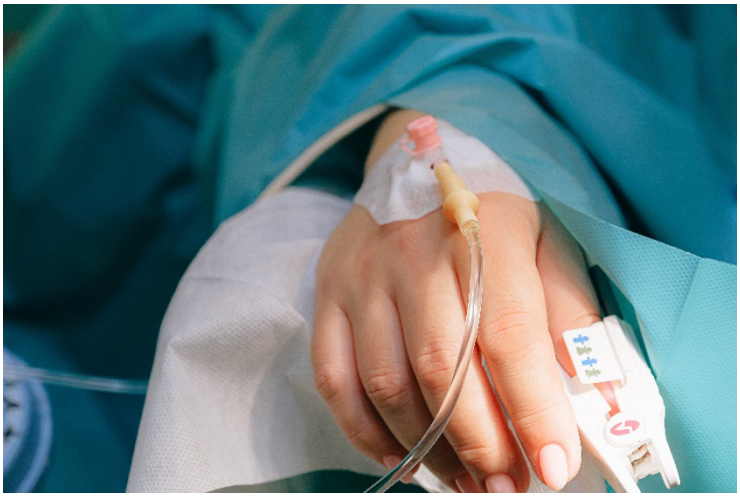
BLOG NOTE

Add-on payments mechanism: challenges and opportunities for access of innovative drugs in the hospital setting



One of the main drivers of healthcare spending is the cost of treatments delivered in hospitals, which account for more than 30%[1,2] of the total healthcare spending. In most countries, hospitals are allocated a global budget within which they set their budget for hospital care services and for medicines they dispense. In the hospital setting, the reimbursement of hospital care services is provided via the DRG (Diagnosis-Related Group)[3] reimbursement system. In general, the DRG tariffs for hospitals cover all the costs linked to a hospital stay, including personal costs, material costs, drugs, and devices. Thus, the hospitals receive a fixed amount for a specific DRG, regardless of how much money it actually spent on treating the patient. This activity-based funding has become the most common mechanism for reimbursing hospitals in most European countries[4] (e.g., G-DRG system in Germany, HRG system in the United Kingdom) and the US (e.g., MS-DRG or Medicare's DRG system)[5].

However, innovative, high-cost medicines are often not sufficiently reimbursed by DRG payment systems at launch for two basic reasons: first, DRG tariffs are calculated retroactively, taking up to 3 years for the data collection to update the payment rate, and second, innovative medicines are expensive, and therefore they usually greatly exceed the existing DRG payment rate. **Consequently, hospitals are frequently disincentivized to adopt and use expensive innovative drugs.**

What are add-on payments?

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Add-on payment mechanisms are reimbursement models used in the hospital setting that offer funding for innovative medicines to ensure: (1) sufficiently reimbursement to hospitals for the services they provide, and (2) patients' access to innovative medicines.

What are the key requirements that a new drug must fulfill to be eligible to be part of an add-on payment system?

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Although inclusion criteria vary among countries, recurrent criteria include:

1. The use of the drug is frequent.
2. The existing DRG tariff does not properly cover the price of the drug.
3. The cost of the drug leads to significant costs to the hospital stay.
4. The drug demonstrates added value over existing drugs.
5. The drug is innovative.

What does innovativeness and added-value mean?

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A drug is considered new if it has a novel mechanism of action when compared to an existing drug or if it is treating a different type of disease or patient population.

Generally, value refers to the potential of a drug to offer an option for a patient population unresponsive or ineligible for current treatments, that improves substantially the clinical patient's outcomes and health.

Different markets...

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Many countries use these systems to encourage hospital utilization of innovative therapies. Some examples include the Neue Untersuchungs- und Behandlungsmethoden (NUB) and the Zusatzentgelte (ZE) systems in Germany[6], the "Liste en sus" system in France[7], the High-Cost Drug and NHS ex-Drug Lists in the UK[8], and the New Technology Add-On Payments (NTAP) in the US[9]. Although similar in purpose at a very high level, the key requirements to be included on these add-on payment lists can vary from country to country.

In France, the main hurdle of a drug to be included in the "Liste en sus" is proving added therapeutic value over the current SoC for a given indication. For determining the level of reimbursement, HAS Transparency Committee (CT) assesses the clinical added value of the drug and grants an SMR, and an ASMR rating. A high ASMR score is hard to achieve but crucial for fast market access and favorable pricing. Importantly, to be included in the "Liste en sus", drugs will have to receive an SMR Important and an ASMR I to III. After HAS CT assessment, each French hospital reviews the drug via internal appraisal and negotiates the price, process that last a few more months. Contrarily, in Germany, inclusion in the NUB list is a rather fast process that favorably impacts the time to drug access in the hospital setting. Each German hospital must apply for NUB funding via InEK (Institut für das Entgeltsystem im Krankenhaus), which is the agency that assesses drug eligibility for NUB funding. Once approved, the annual NUB fee is negotiated between the hospital and the sickness funds (GKV-SV). Importantly, each hospital must re-apply annually for the NUB supplement.

On the other hand, while in Germany the previous inclusion of a drug on the NUB list may favorably influence the inclusion of a similar new drug, in the US, a drug must be new, and it cannot be substantially similar to existing technologies (known as "newness" criterion) to be included on the NTAP list. Moreover, the time that a drug can stay listed on an add-on payment list also varies from country to country - While in France and the UK a drug can be listed for an indefinite period of time, in the US the NTAP provides additional payment for innovative drugs for no more than three years.

… Different challenges and opportunities

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The existence of add-on funding mechanisms for reimbursement of inpatient innovative drugs, the speed of the inclusion in an add-on payment list, the specific requirements for a drug to be eligible for add-on funding (e.g., added clinical value, and innovativeness), and the funding time limitation, will positively or negatively impact the time to access and the market uptake in the hospital setting. Since the reimbursement procedures of high-priced medicines in the inpatient sector vary in every market, knowing their differences will be crucial to understanding the opportunities and challenges the innovative drug will face in the commercialization process.

Balancing value and innovation for assuring long-term funding

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Because of the increase in the number of expensive drugs listed on add-on payment systems over the last few years, payers and policymakers will continue to face challenges to balance innovation and affordability. Although no changes to the add-on payment mechanisms have been recently announced, some countries have already introduced other policies for the efficient use of resources. In France, the new Authorization for Temporary Use (ATU) reform has included the innovative status as a key criterion which will more likely control spending by limiting the number of drugs included in the program[10].

Since payers may become stricter when deciding if a drug will be included in an add-on payment, manufacturers of innovative medicines risk facing more difficulty to get their products reimbursed in the hospital setting. Proving innovativeness and demonstrating substantial clinical benefit may be key to positive funding via add-on payment mechanisms. Moreover, evidence of the effectiveness and cost-effectiveness of the drug may also come into play to ensure efficient use of resources.

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About LatticePoint Consulting:

LatticePoint is a boutique consulting firm that focuses on pricing and market access for innovative medicines and medical devices. We understand how to plan for the political, scientific, and financial realities that will be pivotal in negotiating product access. We work with biopharma companies and investors to help define, negotiate, and defend the value of their products in key markets around the world. Led by former industry market access leaders and a high-caliber team with significant experience in the sciences, licensing, M&A due diligence and integration, venture capital and international affiliate operations, we have a depth of experience, both at the global and regional levels. Our multilingual staff of native German, French, Italian, Spanish, Portuguese and English speakers is experienced at handling negotiations in many key countries while keeping an eye on cross-border implications. We engage with payers, providers, hospitals, HTA bodies and EMA for early access, give feedback on clinical program design, and create and execute in-country reimbursement strategy negotiations in key markets around the world. We retain a Global Payer Panel for market research interviews.

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