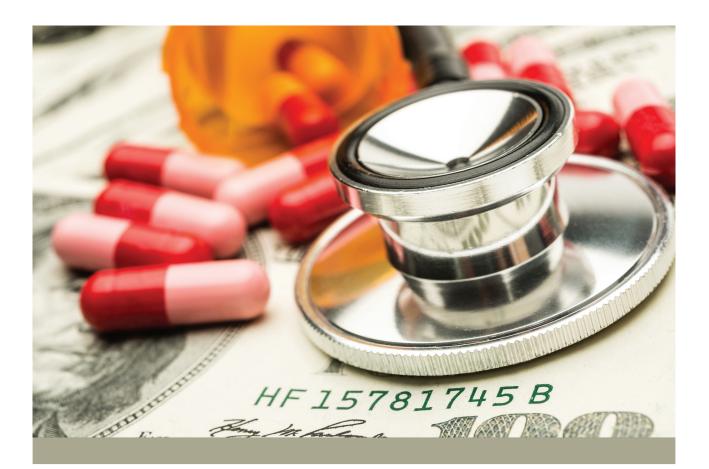
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Center for Research in Healthcare Innovation Management



Public Procurement Models for Medicine

Analysis of Alternatives and Experiences in Europe

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1. Introduction

Providing fast and fair access to innovative drugs for patients who need them presents a challenge to the Healthcare Administration that requires new responses.

Public administrations and the industry agree on the need for formulas to guarantee financing for therapeutic innovation in order to improve the healthcare system in a sustainable way.

The solution must necessarily be based on a new model of interaction among the parties, with the understanding that both sides need to see a return on their investment: the public administration in health outcomes, and the industry in profitability for its shareholders. [1]

This new relationship should be supported by different concepts: A shift in the industry's role toward offering additional services and acting more as a partner than a provider. Measurement of outcomes and risk sharing. Definition and consensus regarding the value of drugs, not only taking into account their cost-effectiveness, but also analyzing their economic impact in the medium and long term, as well as their qualitative impact on the health of patients and on society.

Numerous reports on innovative models of drug procurement have been published, most of which focus on risk-sharing agreements and models of payment by outcomes. [2, 3]

Although this study also analyzes the relationship between reimbursement and outcomes, in *Chapter 3 – Conceptual Framework*, we survey a broader range of possibilities, from traditional methods to innovative frameworks that incorporate the concept of value in a more general sense, where it is not based only on the clinical outcomes of treatment.

Likewise, *Chapter 4 – Analysis of Models* presents a guide to help determine which model or models may be the most advisable for a given situation.

Finally, *Chapter 5 – Existing Models in Europe* describes the solutions used most often by the industry in Europe, as well as several examples of value-based procurement models that have been put into practice in other areas of the healthcare sector.

2. Working Method and Participants

A number of experts, both national and international, participated in this study, which was led by a team from the IESE Center for Research in Healthcare Innovation Management (CRHIM).

The vision and knowledge contributed by those experts, complemented by an exhaustive literature survey (*see Chapter 7 – Bibliography*), served as the foundation for this study.

Below is a list of the individuals who participated:

Professionals from IESE-CRHIM

Jaume Ribera

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Ramón Maspons Director of Innovation at the Agency for Health Quality and Assessment of Catalonia (AQuAS)

Vicente Fernández Director of Procurement at the Public Health Service of Murcia

The following also provided their perspectives in sessions with the working team:

Heads of Pharmacy and Procurement from Regional Health Authorities

Jon Iñaki Betolaza Basque Country

Encarnación Cruz Community of Madrid

Antoni Gilabert Catalonia

Antonio Peinado and M.ª Dolores Bejarano Andalusia

José Manuel Ventura and Carolina Conesa Valencia

3. Conceptual Framework

3.1. Dimensions

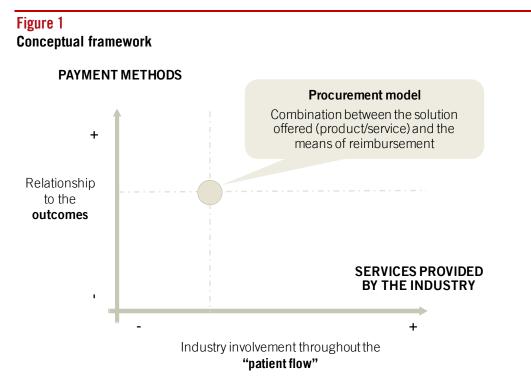
There are a wide variety of drug procurement models. They range from the procurement of a drug at a set price to the contracting of a more or less complex service that includes medication, where the reimbursement is based on the value that is generated.

In order to organize and analyze all of the alternatives, we have defined a two-dimensional conceptual framework that enables us to classify and compare the different models.

The first dimension in the framework corresponds to the services that the industry can offer the public health service throughout the patient flow or the stages in an illness. This axis represents the different cooperation frameworks with the pharmaceutical companies, either just supplying the drug or also offering pre- or post-treatment support services.

The second dimension focuses on payment methods, ordered according to the degree of correlation between the product/service offered and the outcomes. This axis helps us classify the types of reimbursement agreements with the industry.

The combination of values in each of the dimensions determines the procurement model (see Figure 1 - Conceptual framework).



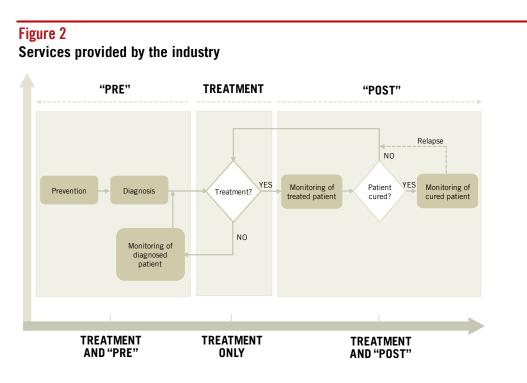
Source: Prepared by the authors.

3.2. Services Provided by the Industry

The industry's involvement throughout the healthcare process is the first axis in the conceptual framework.

It is increasingly frequent for pharmaceutical companies to offer services in addition to treatment, either because the drug requires it or as a differentiation strategy. [4, 5]

Using patient flow as the basis, the study distinguishes between the pre-treatment services (prior to administration of the drug) and post-treatment services (see **Figure 2** – Services provided by the industry).



Source: Prepared by the authors.

Pre-Treatment Services

In this form of cooperation, the pharmaceutical company not only offers its product to patients who require it but also provides services to citizens – regardless of whether or not they are the company's patients – related to the illness and prior to treatment.

The three types of pre-treatment services are as follows:

- **Prevention**. Services targeted at healthy groups who are at risk of suffering from the disorder.
- **Diagnosis**. Support in detecting affected members of the population who are asymptomatic.
- Monitoring patients who have been diagnosed. Monitoring services for patients who have been diagnosed but have yet to receive treatment.

Post-Treatment Services

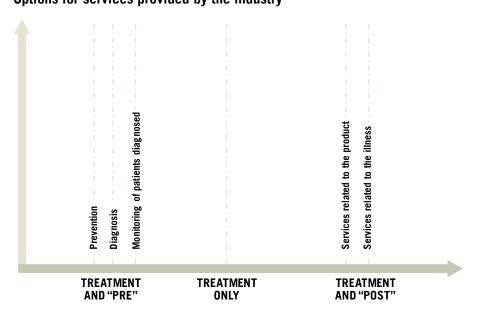
This category includes the services offered by the industry to patients who have already received treatment or are currently undergoing treatment.

A distinction should be made between:

- Services related to the product. Provided only to patients who are being treated with products from the laboratory providing the services.
- Services related to the illness. Services provided to all patients receiving treatment, whether it is with the company's product or with a product from the competition.

Therefore, looking at the first axis of the conceptual framework, we have five options for services provided by the industry (see **Figure 3** – Options for services provided by the industry) beyond supplying the treatment.

Figure 3 Options for services provided by the industry

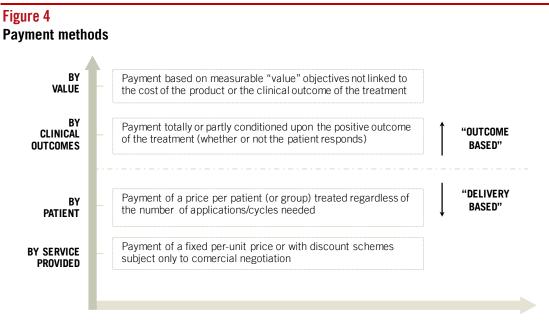


Source: Prepared by the authors.

3.3. Payments Methods

The second axis of the conceptual framework corresponds to the different methods of reimbursement for the products/services. [1]

Depending on the degree of correlation with the outcomes achieved, there are four forms of payment: two of them are based on the product/service supplied and the other two are based on the impact generated (see **Figure 4** – Payment methods).



Source: Prepared by the authors.

Payment by Supply

In payment by supply contracts, a price is set for the product/service based solely on a commercial negotiation between the parties, regardless of the clinical outcomes that the drug may achieve.

This is the method where the industry takes on the least risk.

Payment by supply is the most widely used scheme. Depending on the nature of the product/service provided, we can distinguish between:

- **Payment by product**. Reimbursement for the product according to the agreed upon conditions. Volume discounts, a budget ceiling and auctions are some of the variations used. Sometimes negotiations encompass a set of products. In this scheme, which is called payment by portfolio, further options are added, such as cross selling conditions, selective growth and inclusion on official drug lists.
- **Payment by service**. Reimbursement includes not only the drug but also, in a separate item, a specific payment for the services associated with administering it.

Payment by Patient

Payment by patient schemes consist of the payment of a specific, set price for the treatment for one patient, regardless of the number of applications or cycles it requires.

In this kind of agreement, the industry may share patient management with the public Healthcare Administration and take on part of the risk. [6, 7]

Depending on the patient category to which the agreement applies, there are two kinds:

- **Payment by patient treated**. When the agreement is defined for each individual patient.
- **Payment by group of patients**. In this case, the industry takes responsibility for treating a community of patients. This is also known as payment per capita.

Payment by Clinical Outcomes

In payment by clinical outcome schemes or risk-sharing agreements, the laboratory receives partial or total payment for the drug supplied depending on the outcome of the treatment.

In this kind of agreement, the industry acts more as a generator of clinical outcomes than as a product supplier, since it only receives compensation if the drug has the expected effect.

Although the main focus of this study is not to provide a detailed description of these payment methods [2, 3, 8], we will mention the three most common kinds of agreements [9, 10, 11]:

- **Guarantee of outcome**. The payment is made at the time the drug is supplied, but in the case of patients who do not respond positively, a corresponding reimbursement or payment adjustment is later made.
- **Conditional upon generating evidence**. The laboratory is reimbursed once it has been proven that the patients' outcomes are positive.
- **Guarantee of process**. The laboratory finances the means required for administering the treatment and/or accepts the consequences of an unfavorable response on the part of the patient, and it may be responsible for covering additional services and costs.

Payment by Value

The method of payment by value or performance is the most innovative and is still the least common. In this case, the product/service reimbursement is determined by achieving measurable value objectives, which are previously agreed upon between the parties and are not solely linked to the clinical outcomes of the treatment.

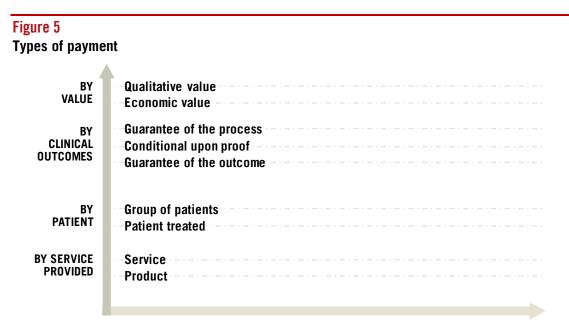
In these models, which are only now beginning to be implemented, the industry becomes yet another stakeholder in the system, and its outcomes and contribution are tied to the interests of the public Healthcare Administration. [6, 12, 13]

The key issue, and also the major difficulty of this kind of framework, has to do with agreeing on a definition of the concept of value.

Bearing in mind its nature, we can distinguish between:

- **Payment by economic value**. Reimbursement is related to future "savings" or costs avoided in the middle/long term. This kind of agreement may figure in both direct costs (doctor visits, hospital admissions, tests, stays, treatments) and indirect costs (leaves of absence from work, absenteeism, disabilities, early retirements).
- **Payment by qualitative value**. This payment is conditioned upon the qualitative outcomes associated with patients' health, such as an increase in their satisfaction and compliance or improvements in certain health indicators among the population.

Payment by value is the last of the different variations on the second axis of the conceptual framework, with its nine reimbursement methods (see **Figure 5** – Types of payment).



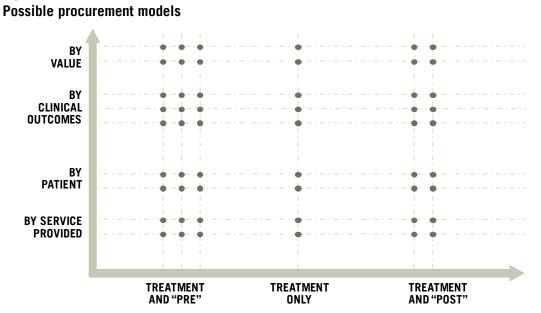
Source: Prepared by the authors.

3.4. Possible Models

As described in point 3.1., Dimensions of the Conceptual Framework, and following the methodology of this study, a purchase model is defined by taking into account the solution offered by the industry (product/services) and the method of reimbursement. In other words, it is based on a combination of the values on both axes of the conceptual framework.

Bearing in mind the five options for services provided by the industry, plus the option of exclusively supplying the drug without any additional services, along with the nine payment methods, we conclude that there are 54 possible procurement models (see **Figure 6** – Possible procurement models).

Figure 6



Source: Prepared by the authors.

Although all these combinations are possible in theory, some of them make more sense than others, and their suitability depends on a series of factors related to the disorder in question and the characteristics of the drug being used.

There are neither better nor worse models, therefore, only the right solutions for each situation.

In the following chapter, we take each payment method and option for services provided by the industry and we analyze the circumstances under which their use is most recommendable.

4. Analysis of Models

4.1. Factors for Characterization

As mentioned in the previous chapter, the most innovative payment methods are not necessarily better than the traditional methods, nor is there always a need for a complete range of complementary services in addition to treatment.

The right solution has to be found for each situation. A drug for a highly prevalent illness is not the same as an orphan drug. Nor is a recently launched drug, whose real effectiveness is not fully known, equivalent to a drug that has been on the market for several years and whose outcomes have been proven.

Another factor taken into consideration for this study is the existence of drugs with more than one indication. In these cases, we have analyzed the model recommended for the main indication and adjusted it to account for its positive effects on other disorders.

There is no magical formula in the search for the ideal procurement model. However, certain characteristics of the product and the disorder to which it is targeted offer us clues as to the possible solution.

We have identified a series of factors that point to the options which it makes the most sense to consider. If the origin of an illness is unknown, we cannot prevent it. For a product with a very low cost, it seems illogical to suggest complex payment methods based on clinical outcomes or value.

As indicated above, these factors can be divided into two types, the ones describing the illness and the ones related to the drug in question.

Below is a list of 10 factors that characterize the illness and 15 factors that define the drug.

Factors Related to the Illness

- 1. **Prevalence**. Number of patients likely to receive treatment.
- 2. Incidence. Annual number of new cases.
- 3. Type. Acute or chronic disorder.
- 4. Quality of life. Degree to which the illness affects the patient's life (life expectancy, quality of life).
- 5. **Urgency**. Importance and urgency of receiving treatment once the illness has been diagnosed or when it reaches a given stage.
- 6. **Origin**. Knowledge of the causes and/or risk factors of the illness and the possibility of acting on them to prevent the illness.
- 7. Contagiousness. To what extent the illness is contagious.
- 8. **Underdiagnosis**. Volume of patients with the illness who are not diagnosed.

- 9. Location. Main location where the illness is managed and the impact on the burden of care (hospital, primary care facility or home).
- 10. **Cost of the illness**. Direct healthcare cost per patient (emergencies, doctor visits, hospitalization, tests, medication, etc.).

Factors Related to the Drug

- 1. Therapeutic gap. Product's level of response to uncovered needs.
- 2. Alternatives. Existence of alternative products with a similar level of effectiveness.
- 3. Evidence. Level of scientific evidence.
- 4. **Uncertainty**. Level of uncertainty regarding the drug's real effectiveness.
- 5. **Efficacy**. Improvement in the real response to treatment compared with the alternatives.
- 6. Personalization. Level of variability of the outcomes of the drug between patients.
- 7. **Product cost**. Product cost and its relationship to the total cost of the disorder.
- 8. Complexity. Complexity of administering the drug.
- 9. Cure rate. Cure rate of the illness when treated with the product.
- 10. Improvement in condition. Level of improvement of the chronic condition.
- 11. **Dispensing.** Drug dispensed in hospital or pharmacy.
- 12. Monitoring. Possibility of evaluating the clinical outcome through markers and/or clearly defined tests.
- 13. Avoided cost. Short-term reduction in the consumption of healthcare resources.
- 14. Adverse effects. Number of adverse effects of the drug and their associated costs.
- 15. Comorbidity. Generation of indirect positive effects for comorbidities other than the main indication.

4.2. Applicability of Models

Sections 4.3 and 4.4 below present the factors that favor each of the five service options and nine payment methods, making them more recommendable.

This analysis, which was developed with input from the experts (*see Chapter 2 – Working Method and Participants)*, is based on qualitative criteria, and the outcomes were checked against real cases.

In short, this is a guide targeted at both the public Healthcare Administration and pharmaceutical companies, which can help them decide which procurement models will generate the most value for patients in each case, while also contributing to the sustainability of the system. [2, 8, 9, 14]

Finally, section 4.5 illustrates several examples of how this guide can be applied.

4.3. Services Provided by the Industry

Below are the characteristics that favor the use of each of the options for pre- and post-treatment services. We distinguish between the following factors:

- **Obligatory** (**). If this characteristic is not present, this option is not recommendable.
- Relevant (*). This characteristic plays a significant role in the choice of this option.
- Desirable (). This characteristic favors the use of this option.

Pre-Treatment Services

Prevention

Preventative services make sense in cases where the origins or risk factors of the disorder are known and avoidable.

It must also have a high incidence, which indicates that many people are exposed to the illness.

Characteristics of the disorder	Product characteristics
 Medium/high incidence** Known origin or risk factors** Medium/high risk of contagion* Medium/high cost of the illness 	Not applicable to pre-treatment services

Diagnosis

A highly prevalent disorder that is infradiagnosed has the right profile for industry to make a contribution with early detection services.

Characteristics of the disorder	Product characteristics
Medium/high prevalence**Medium/high underdiagnosis**	Not applicable to pre-treatment services
High incidence	
 Medium/high cost of the illness 	

Monitoring of patients who have been diagnosed

The circumstance most relevant to the applicability of this service is that patients who have been diagnosed, but do not yet require medication according to the protocol, must be treated urgently once the illness reaches a particular stage.

Depending on the disorder, this wait time can last months and even years. This is why it is essential to monitor the patient continuously.

Characteristics of the disorder	Product characteristics
 Medium/high urgency in receiving the treatment** 	 Not applicable to pre-treatment services
 Medium/high prevalence* 	
 Affects quality of life* 	
Chronic disorder	
Medium/high cost of the illness	

Post-Treatment Services

Services related to the product itself

Post-treatment services related to the product itself are highly relevant when compliance with the treatment is essential. This is especially the case when failure to complete the therapy can lead to complications and a serious deterioration in the patient's health. [15]

It is also worthwhile to provide this kind of service when the drug must be taken in a very precise way or administration requires instruments that may be complex for the patient to use.

Characteristics of the disorder	Product characteristics
 Affects quality of life** 	 High complexity of administration*
 Medium/high prevalence* Non-hospital management of the illness* 	 Personalization of the outcomes by patient
Medium/high cost of the illness	Medium/high product costDrug dispensed in pharmacy

Services related to the illness

These are services targeted at patients who suffer from a particular disorder and receive an equivalent kind of treatment. [7, 16]

In order for this service to be applicable, the demand must be high and somewhat stable. High prevalence and categorization as a chronic disorder are therefore key conditions.

Characteristics of the disorder	Product characteristics
 Medium/high prevalence** Chronic disorder** Home management* Affects quality of life Medium/high cost of the illness 	 There are equivalent alternative treatments* No personalization of the outcomes by patient Product cost low compared with the cost of the disorder Drug dispensed in pharmacy

4.4. Payment Methods

Below are the factors that favor the use of each of the payment methods, distinguishing between them depending on whether they are:

- **Obligatory** (**). If this characteristic is not present, this option is not recommendable.
- Relevant (*). This characteristic plays a significant role in the choice of this option.
- **Desirable** (). This characteristic favors the use of this option.

Payment by Supply

Payment by product

As mentioned above, this is the traditional payment formula and the one that is used most often in its different variations because of its clarity and simplicity.

It is the best method when the product cost is low and no complementary services are provided, or to the contrary if the cost is high but there are no equivalent alternative therapies on the market.

Characteristics of the disorder	Product characteristics
Low cost of the illness	 Low product cost* High product cost combined with no alternatives* Low uncertainty High efficacy

In the particular case of payment by portfolio, the conditions that must be met by products in the portfolio are the following:

- None of the products is dominant.
- The products in the portfolio are preferably from the same therapeutic area.
- There are negotiated "exchanges" for some of the products in the portfolio.

Payment by service

This method of payment is applicable under the following conditions:

- The cost of the service provided is much higher than the cost of the drug.
- The service is necessary in order for the drug to be administered properly, and at times it may even be an intrinsic part of the treatment.

Payment by Patient

Payment by patient treated

This is a good solution for products with a medium/high cost and evidence that is not fully confirmed or outcomes that are uncertain. On the other hand, it is important for the clinical outcomes to be easily and objectively measurable.

Characteristics of the disorder	Product characteristics
 Hospital management of the disorder* Medium/high cost of the illness 	 Medium/high product cost** Objective monitoring* Low/medium evidence* Medium/high uncertainty*
	 Drug dispensed in hospital* Low/medium efficacy Medium/high personalization

Payment by group of patients

This method is advisable in cases where one of the product conditions in the previous method is fulfilled, and the disorder in question also guarantees a high-volume, stable demand. That is, high prevalence, and preferably cases where the disorder is chronic.

Characteristics of the disorder	Product characteristics
 High prevalence** 	Clear monitoring*
Chronic disorder*	Low product cost compared with the cost
 Management of the disorder in primary care 	of the illness Drug dispensed in pharmacy

Payment by Clinical Outcomes

Models of payment by clinical outcome are also often called risk-sharing agreements.

This approach uses a new patient-centered vision, which suggests shared objectives and commitments between the public Healthcare Administration and the industry.

However, it also carries some difficulties, so its application should be limited to situations that meet certain clear conditions.

These conditions include a high-cost product that covers a therapeutic gap and high uncertainty regarding its effectiveness. Finally, as in the payment by patient methods, and even more so in this case, monitoring of the clinical outcomes should be clear, easy and objectively measurable. [2]

Below are the factors that must be present to favor the use of this kind of payment method. In the following pages we also outline which factors can help decide between the three most common methods of payment by clinical outcomes.

Characteristics of the disorder	Product characteristics
 Hospital management of the disorder** Medium/high cost of the illness* 	 Clear monitoring** Drug dispensed in hospital* Medium/high uncertainty* Medium/high product cost* Low/medium efficacy Partial therapeutic gap There are therapeutic alternatives

Payment conditional upon generating evidence

This is a variation in which payment is deferred until there is enough evidence that patients are responding positively to a new treatment.

This solution is recommended when, in addition to the conditions shared by other methods of payment by outcomes, there is also no totally proven evidence of the treatment and it can be used by a large population.

Characteristics of the disorder	Product characteristics
 Medium/high prevalence* 	 Medium/high evidence**

Payment by guarantee of the process

This method of payment by clinical outcomes is primarily applicable when, in addition to the circumstances shared by other payment methods by clinical outcomes, each patient shows a different response, the administration process is complex or the treatment is associated with side effects.

Characteristics of the disorder	Product characteristics
No additional	 Medium/high existence of adverse effects* Medium/high complexity of administration* Medium/high personalization of the outcome by patient

Payment by guarantee of outcome

Finally, payment by guarantee of outcome is the method to be applied in cases when the conditions for the use of payment by clinical outcomes are in place but the specific circumstances required for the other two methods of this kind do not exist.

Payment by Value

Payment by economic value

Payment by economic value should only be considered in disorders with a high cost, or with a medium cost but high prevalence, and when the treatment shows a very favorable return on investment. [17, 18, 19]

Another essential condition is that measurement of the benefits must be clear, objective and possible to determine in isolation, without considering other effects caused by additional measures or changes in the environment.

Characteristics of the disorder	Product characteristics
Medium/high cost of the illness*High prevalence*	 High avoided cost** Objective measurable monitoring** Medium/high product cost

Payment by qualitative value

This payment method is difficult to implement because it can be difficult to reach a consensus among the parties on the definition of value and how to measure it.

The application of this model should be limited to products with a high cost which substantially increase patients' life expectancy or quality of life, treatments which cure complex disorders or significantly improve the condition of chronically ill patients and, in all cases, when the value can be objectively measured. [20]

On the other hand, the criterion of qualitative value can be used to make a comparison between therapeutic alternatives in situations where only one of them must be selected.

Characteristics of the disorder	Product characteristics
 Affects life expectancy/quality of life** 	 Partial/total therapeutic gap**
Chronic disorder	 Objective monitoring**
	 Medium/high product cost*
	Does cure*
	 Significant improvement of chronic condition*
	There are therapeutic alternatives
	Positive indication for other comorbidities
	Shows no adverse effects

4.5. Examples of Recommended Models

Finally, in order to complete *Chapter 4, Analysis of Models*, below we present three examples in which the previous criteria are applied in order to find the most recommendable procurement model.

In each example we will provide a value for the factors related to both the illness and the drug, highlighting in bold the characteristics that have the most influence on the choice of a procurement model.

Example 1

Insulin to treat Type-2 Diabetes [21]

Characteristics of the disorder	Product characteristics
High prevalence	Partial therapeutic gap
Very high incidence	There are alternatives
Chronic type	Medium/high evidence
Affects quality of life and life expectancy	Low uncertainty
Medium urgency	Medium efficacy
Partly manageable origin	Personalization by patient only in some cases
Zero contagiousness	Low product cost
Underdiagnosis exists	Medium complexity
Management of the disorder in primary care	No cure
 Medium/low cost of the illness 	 High improvement in condition
	Drug dispensed in pharmacies
	 Objective and measurable monitoring
	Medium avoided cost
	Very few adverse effects
	Zero comorbidity

Most appropriate procurement model according to the characteristics described:

- Payment method: BY PATIENT / Group of patients
- Services provided by the industry: POST-TREATMENT / Related to the illness

Example 2

New oncologica	I treatment for	r a somewhat	rare form of	f cancer [22]
----------------	-----------------	--------------	--------------	----------------------

Characteristics of the disorder	Product characteristics
Low prevalence	Total therapeutic gap
Low incidence	There are alternatives
Chronic type	Proven evidence
Affects quality and life and life expectancy	High uncertainty
High urgency	Medium efficacy
Unmanageable origin	 High personalization by patient
Zero contagiousness	Medium/high product cost
Low underdiagnosis rates	High complexity
Hospital management of the disorder	No cure
High cost of the illness	High improvement condition
	 Drug dispensed in hospital
	Objective and measurable monitoring
	High avoided cost
	There are adverse effects
	Zero comorbidity

Most appropriate procurement model according to the characteristics described:

- Payment method: BY CLINICAL OUTCOMES / Process scheme
- Services provided by the industry: POST-TREATMENT / Related to the product itself

Example 3

New treatment for multiple sclerosis that reduces future cycles

Characteristics of the disorder	Product characteristics
Medium prevalence	Partial therapeutic gap
Medium incidence	There are alternatives
Chronic type	 Evidence not totally confirmed
Affects quality of life and life expectancy	Low uncertainty
High urgency after diagnosis	Medium efficacy
Largely unmanageable origin	 Personalization by patient
Zero contagiousness	High product cost
Low underdiagnosis rates	High complexity
Hospital management of the disorder	No cure
High cost of the illness	High improvement in condition
	 Drug dispensed in hospital
	Objective and measurable monitoring
	 High avoided cost
	Some adverse effects
	Zero comorbidity

Most appropriate procurement model according to the characteristics described:

- Payment method: BY VALUE / Economic
- Services provided by the industry: **PRE-TREATMENT / Monitoring of patients who have been diagnosed**

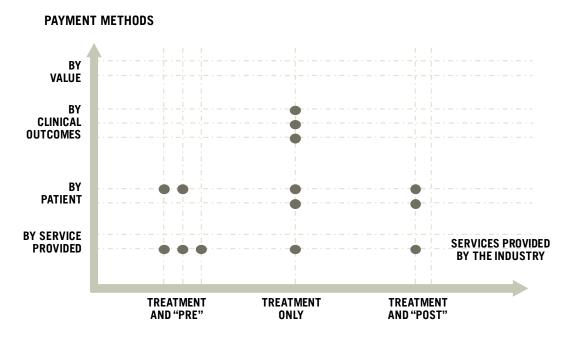
5. Existing Models in Europe

5.1. Models in the Industry

The pharmaceutical industry uses a wide variety of public drug procurement models. As shown in **Figure 7** – Models in the industry, they cover most of the options proposed by the conceptual framework.

Although the scenario is ever-changing, we would say that right now the United Kingdom, Italy, Scandinavia and Spain have made the most headway in applying some of the most innovative agreements.

Figure 7 Models in the industry

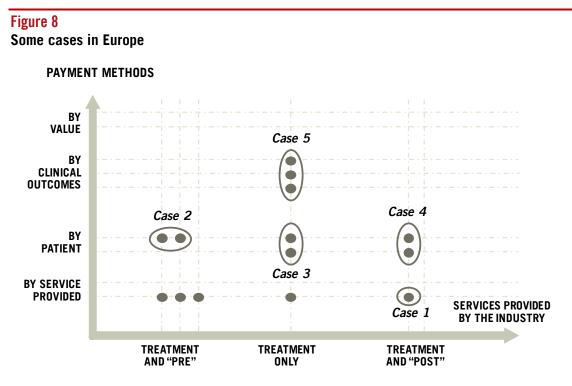


Source: Prepared by the authors.

In Europe, the most frequent alternatives [20, 23, 24, 25] are:

- Payment by product, combined with pre- or post-services or not. This is and will continue to be the most widespread model. We have examples for all the options, except for post-treatment services related to the illness where there is a limited offering, despite a demand from the public Healthcare Administration.
- Payment by patient, with pre- and post-treatment services. The per capita models tend to include prevention and diagnosis services.
- Payment by clinical outcomes in all three variations, but without including additional services.
- Payment by value is not used. Even though this is a future solution, and one that is very interesting for the public Healthcare Administration, its complexity, associated risk and the need for a medium/long-term vision prevent it from becoming more widespread.

Below, for illustrative purposes, we describe several examples of models found in Europe which fall into the aforementioned types (see **Figure 8** – Some cases in Europe).



Source: Prepared by the authors.

Case 1. Payment by Product – Post-Treatment Services

New technologies play a crucial role in this model. Digital healthcare services are evolving very quickly, and they are increasingly being used to support patients. Websites, apps, wearables, devices, etc., are the new healthcare tools today. A few illustrative examples [5]:

- (UK) App + Call center. Remote monitoring service combined with a call center to reduce the number
 of doctor's visits, wait times, commutes, etc. Targeted at chronic patients who are following a course
 of treatment using the laboratory's own product, and to support home healthcare units.
- **(UK) Chip on a pill.** Edible chip inside a pill that records its ingestion and sends wireless data via a biometric sensor. Its purpose is to improve compliance.

Case 2. Payment by Patient – Pre-Treatment Services

Public-private partnership between the industry and Firmley Park Hospitals, one of the Foundation Trusts of the NHS.

(UK) Mobile Community Eye Care Center is a mobile unit that detects and, if needed, treats macular degeneration.

This initiative reflects the pharmaceutical company's desire to offer a unique added value over other drugs with similar effectiveness, cost and safety ratios. The partnership contract consists of a per capita reimbursement which includes the cost of additional services.

Case 3. Payment by Patient – Without Services

The examples of payment by patient described below correspond to models applied in some countries, although the procurement formula of the same product may vary in different regions. [2]

- **(UK) Ranibizumab.** Drug for macular degeneration. In this agreement, the public Healthcare Administration pays the entire price up to a given number of administrations, which is the number predicted to be necessary. If the patient has to extend the treatment period, the pharmaceutical companies pays for subsequent cycles.
- (Italy) Sunitinib. Treatment for stomach tumors or advanced renal cell cancer. In this case, the first cycle of treatment is free of charge due to the uncertainty regarding its effectiveness.

Case 4. Payment by Patient – Post-Treatment Services

In Spain, we have examples of this model in several different autonomous communities [18]:

- (Spain) Oxygen therapy. Comprehensive services for patients with CPOD. Contract that includes the provision of equipment and services in addition to the drug, including home care. The cost of the drug is low compared with the other parts of the service. The agreement tends to encompass a community or group of patients.
- (Spain) Dialysis. Comprehensive services for patients with advanced renal insufficiency. Cooperation agreement with the involvement of several stakeholders, such as companies specializing in dialysis, the pharmaceutical company that provides the drug and the banks that cover the operation.

Case 5. Payment by Clinical Outcomes – Without Services

As mentioned above, there are numerous experiences and publications on risk-sharing agreements in Spain [2, 3, 8]. Below we describe three international cases:

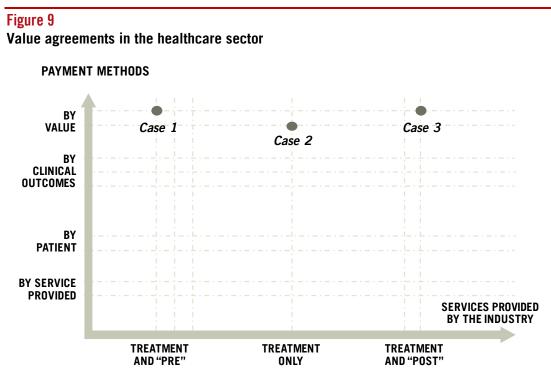
- **(UK)** Bortezomib. Guarantee of the outcome. Treatment indicated for multiple myeloma. The NHS pays for the first four cycles. If the patient's response is not adequate, the pharmaceutical company reimburses that cost.
- **(Sweden) Risperidona.** Conditioned upon the evidence generated. Drug for schizophrenia. Temporary financing with the condition that enough information be generated to weigh its RCE.
- (Germany) Zoledronic acid. Guarantee of the process. Drug for osteoporosis. The laboratory shares the billing costs of patients during the first year. In exchange, the public administration pledges to replace current therapies with company's until a given market share is reached.

5.2. Models of Payment by Value in the Healthcare Sector

As described in point 3.2 of the Conceptual Framework, the models for payment by value are those in which the reimbursement is related to either future savings or costs avoided in the medium/long term (payment by economic value) or to the improvement in the patients' health outcomes (payment by qualitative value).

Right now, we are aware of no experiences with this procurement model in the pharmaceutical industry. However, it is being successfully applied in other activities that are related to the healthcare sector.

The following section describes three cases (see Figure 9 – Value agreements in the healthcare sector).



Source: Prepared by the authors.

Case 1. Payment by Qualitative Value – Pre-Treatment Services

NetMark, by the U.S. Agency for International Development (USAID), has different stakeholders in the healthcare industry participating in the program. [26, 27, 28]

The goal and main indicator of qualitative value achieved is a 50% reduction in the incidence of contagion.

Likewise, in addition to its vast social impact, in this case the return on investment associated with the healthcare costs that these non-infected patients would have in the future was estimated.

Case 2. Payment by Economic Value – Without Services

In Spain, there have been experiments with innovative approaches in public contracts driven by economic savings. [19]

One good example involves **energy efficiency services** in hospitals within the Madrid Healthcare Administration.

Under this agreement, the entire supplier contract budget is tied to reaching measurable goals in lowering the costs of the electrical bill.

Case 3: Payment by Qualitative Value – Post-Treatment Services

Comprehensive services for patients with an ICD (implantable cardioverter defibrillator). In this case, the service encompasses defibrillation and cardiac resynchronization therapy for the entire reference area of the Hospital de la Santa Creu i Sant Pau in Barcelona (population area + reference hospitals) and includes provision of the service and comprehensive technical assistance. [29]

In this contract, the supplier of devices offers support to all patients in the community with an ICD, including technology updates as needed.

Two aspects of this agreement are unique. First, the manufacturer pledges to provide the service even to patients who have an ICD implanted by the competition. Second, part of the payment is conditioned upon the attainment of quality objectives (e.g., incidences and complications for the patient stemming from the improper functioning of the device).

6. Conclusions

Below is a brief, schematic illustration of the study's **10 main conclusions**:

- 1. There are a wide variety of public drug procurement models and therefore an array of combinations between the solutions offered by the industry (product/service) and their methods of reimbursement.
- 2. It is increasingly **frequent for pharmaceutical companies** to **offer other services in addition to treatment**, either because the drug requires it or as a strategy to stand out from the competition.
- 3. These services may be targeted at patients or people at risk of contracting a given disorder, they may occur pre- or post-treatment, and they may be either limited to patients medicated with the company's own product or also available to patients being treated with drugs from the competition.
- 4. The **reimbursement methods may range** from traditional schemes based on **payment by product** to more advanced ones **focusing on the patient**, the **clinical outcomes or the value generated**, either economic or a qualitative improvement in health indicators.
- 5. The role of the industry and its function as a key agent in the system varies considerably in each model. In payment by product, the pharmaceutical company's responsibility is limited to providing the right drug. In payment by patient, it takes on a more prominent and committed role by sharing patient management. Finally, in risk-sharing agreements, the industry acts as a generator of clinical outcomes and it is maximally involved.
- 6. There are neither better nor worse models, only the right solutions for each situation. The most innovative payment methods do not necessarily have advantages over the traditional ones, nor is the provision of services in addition to treatment always needed.
- Certain characteristics of the drug and the disorder help us choose the models that best fit each circumstance. This study provides orientative guidelines to help determine the right models in each case.
- 8. The drug procurement models that are the most frequent in Europe are payment by product, with or without pre- and post-treatment services, payment by patient with pre- and post-treatment services, and payment for clinical outcomes without services.
- 9. Even though it is a future solution which may be very beneficial to the Healthcare Administration, **payment by value is not used** in drug procurement. Its **complexity, associated risk** and the need to have a **medium/long-term vision** are just some of the **obstacles** hindering its spread.
- 10. However, there have been some successful experiences in payment by value, both economic and qualitative, in the procurement of other products and services also related to the healthcare sector.

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