# Reimbursement and Pricing


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The achievable price always plays a central role—also for digital health applications as, multiplied by the sales volume—it determines achievable sales revenues and thus the company's income.

In principle, the price for a digital health solution can first be set on the basis of the costs incurred in producing the service. This is particularly relevant for companies that want to be the cost leader for their product and create added value solely by comparing costs with the reference price. Secondly, pricing can be oriented towards the value of the added value created. This so-called value-based pricing is usually more desirable from a company's perspective and might also be associated with quality leadership or niche specialization. Thirdly, strategic considerations of the company can flow into the pricing, regardless of cost savings or benefits gained from the respective service. For example, a price can be chosen below the manufacturing costs at market entry to deter competitors from entering the market on the one hand and to make a profit at a later point in time due to the high unit numbers on the other hand. The most prominent example might be Amazon in various business areas.

Depending on the market segment, the achievable price can be very different. The more customers (segments) one wants to reach with the DiGA, the lower the achievable price usually is. The optimal price, therefore, also depends on the number of units that can be realized with it. Furthermore, price comparators or socalled price

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anchors are taken into account here insofar as added value or cost savings are always analyzed in comparison to competitors and their prices.

Health economic evaluation offers a structured method to determine both savings and value-based prices for the healthcare system which are generally based on three central and successive categories of economic evaluation. These are the costing of individual services, the modelling of care pathways and associated total costs and finally, the synthesis of all the information on the costs and effects of a service in the form of a cost-effectiveness estimate.

Pricing in the SHI is initially cost-based. If a digital health service is included in the reimbursement catalogue, the expenditure associated with the service is calculated to determine the reimbursement. Such a reimbursement could (theoretically) be linked to the development and production cost of a new service. However, the pricing of an innovation is often based on whether and how high cost savings can be achieved by applying the innovation compared to the reimbursement of current care. For this purpose, an entire care process with all the individual services contained therein may have to be mapped in a mathematical model, which represents a central step in the implementation of economic evaluations. Value-based pricing is of great importance, especially for new digital health services with (to be) proven additional benefits. It might be carried out for price negotiations, in special cases on the basis of an economic evaluation. Value-based decision-making represents the ideal type of use of health economic evaluations, in which all the evidence justifying the value proposition (both on costs and health benefits) is quantitatively summarised in a calculation and usually expressed as a cost-effectiveness ratio. The chapter gives a brief supplementary introduction to economic evaluation and refers to further literature. Finally, strategic aspects independent of the direct added value of a service also play an important role in pricing in the healthcare system.

## 1 Pricing for Digital Health Solutions

### *1.1 Cost-Based Pricing*

Regardless of the market situation for a new digital health application, the absolute long-term price floor must first be determined from the company's point of view. It results from the so-called cost price. In planning, it must be taken into account that a value-based surcharge for the DiGA may not be possible (e.g. in a market with many competitors or with an already available maximum reimbursement amount). In such a scenario, profitable maintenance of the DiGA can only be attained by optimizing the cost structure. In this case, operational costs can be saved in production (e.g. by means of optimized development cost for newer versions of the DiGA) or in sales (e.g. optimization of marketing expenses, sales force optimization, etc.) and profits can be increased accordingly even with constant sales.

## *1.2 Value-Based Pricing*

Value-based pricing means that the price of a good is based on the value of the good to the customer. From an economic perspective, this is the reference model for ideal pricing. The amount of added value is expressed in the customer's maximum willingness to pay for the good. The (added) value created by the company is defined as the difference between the maximum willingness to pay and the (long-term) unit costs.

In principle, patients can also be imagined as customers, especially for digital health and thus be understood as consumers who privately demand healthcare goods. In addition, individual health insurance funds or the SHI system as a whole can be relevant customers if digital health goods are directly reimbursed, e.g. in the case of new DiGA with proven additional benefits. It is true that these must ultimately orient themselves to the added value for end customers of the first (SHI) and second (private demand) healthcare market. However, depending on the importance of these two end customers for their own sales, their own cost position or their own preferences, they may be able to bring additional individual dimensions of added value into the purchase decision and, for example, be prepared to pay a premium for a device with an especially elegant design or colour scheme in the style of the practice rooms or with particular user-friendliness.

Pricing determines which share of this created value remains with the company itself (the so-called "producer surplus")—i.e. increases profits in the form of a surcharge. The other part of the value is left with the customer (the so-called "consumer surplus")—in most cases customers would have bought a product even if it had cost a little more. The difference between the maximum willingness to pay and the market price is, therefore, the customers' "profit" (Fig. 1).

When skimming off a higher price compared to an existing product, it remains to be noted that the assumed added value of a product can be assessed differently by a company than by the buyer of the product, and that buyers only have a limited interest in revealing their maximum willingness to pay or in paying the maximum price. In the case of an anonymous mass market, this leads to a price-sales function: the producer must choose a sales price based on the presumed behaviour of customers, and depending on its level, more or fewer customers demand the product. In

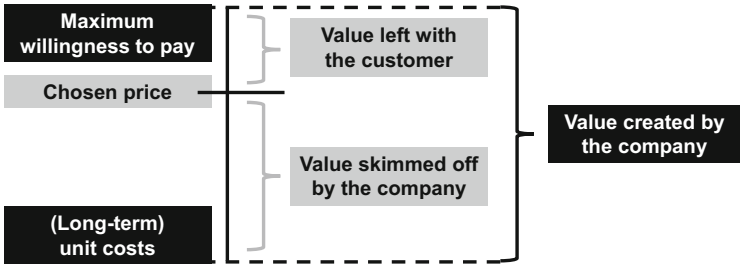


**Fig. 1** Exemplary representation of consumer and producer surplus


**Fig. 2** Graphical representation of a negotiated solution. Source: Own representation based on Gregson et al. (2005)

the case of a market with little demand (e.g. in the case of individually created products or services), this is expressed in negotiations with different buyer and seller price expectations. Price negotiations therefore move within a bandwidth, the upper end of which represents the customers' maximum willingness to pay. The lower end is represented by the company's long-term unit costs (a service can only be provided if the price is higher than the costs) as well as, if applicable, the financing conditions and different market conditions (competition, influence on other markets, etc.). The negotiated price is in the area of tension between the internal requirements for a return on investment (ROI) and prices that can be achieved on the market (Fig. 2).

Value-based pricing is often associated with the attempt to differentiate buyers according to their willingness to pay. This would mean that the same (or a very similar) product can be sold at higher prices to customers with a higher willingness to pay. Ideally (from the manufacturer's point of view), prices can be negotiated individually with customers. However, in the German DiGA context a company would likely need to decide beforehand whether they want to focus on the SHI or the patient individual market.

## *1.3 Strategic Considerations in Pricing*

Regardless of the size of the added value, further strategic considerations should be taken into account with respect to pricing. For the dynamic perspective, for example, a distinction can be made between so-called skimming and "penetration". In a skimming strategy, an attempt is made to skim off the high willingness to pay, which can lead to a quick amortisation of development costs and an entrenchment in the premium segment. In the medium term, there is the possibility of using consumer discrimination to serve the willingness to pay below the premium price. Examples would be new, more powerful memory cards or processors initially very expensive on the market but whose prices fall. A disadvantage of this strategy is lower sales volumes at market launch and associated higher unit costs. In the digital healthcare market, the skimming strategy could be considered in the context of patient individualized health apps with add-on features.

A penetration strategy tends to be used to quickly gain market share in a highly competitive market with the lowest possible price for the market launch, on the one hand, and to set the highest possible market entry barrier for possible new competitors on the other. The penetration strategy can also be combined in a slightly modified form with various possibilities for price differentiation (e.g. via discounts to end customers such as hospitals, sale of product bundles, etc.). A fundamental disadvantage of the penetration strategy is the risk to one's own brand, as it may be associated as a "cheap product" with poor quality.

## *1.4 Privately Paid (Premium) Price*

The individual willingness to pay is also decisive for the purchase decision for some of the "classic" health services according to the delimitation of the health expenditure account. Thus, some services, especially in the outpatient sector, are generally not reimbursable or have been excluded from the benefits catalogue. Digital health applications have mainly been sold in the privately paid market before the introduction of the so-called DiGA law in 2020.

In addition, willingness to pay also plays a role in the demand for digital services with co-payments and for prices above the so-called reference prices.

From the point of view of a digital health company, a fundamental advantage of the strategy of positioning a new service to patients directly, is that such a market offer can be implemented comparatively quickly and that potentially high premium prices can also be achieved. However, it must be taken into account that in this area only very low sales volumes are generally achieved in Germany. This is mainly due to the fundamentally low willingness to pay of patients in Germany, who consider healthcare goods to be goods that the insurance system has to finance.

## *1.5 Pricing in the SHI and Economic Evaluation*

In analogy to pricing in the secondary healthcare market, four categories can also be distinguished to price a new service in statutory health insurance in Germany:

- Cost-based surcharge when setting new reimbursement rates
- No extra charge: savings in existing supply
- Value-based surcharge for new digital health solutions according to the DiGA law
- Strategic considerations in pricing

However, since it is a matter of using scarce resources for public tasks, criteria other than individual willingness to pay in connection with the interplay of supply and demand on markets are decisive. This is also expressed, among other things, in the application of methods of health economic evaluation in the price determination for new services in the healthcare system.

## *1.6 Cost-Based Surcharge*

In principle, the SHI is oriented towards cost-based pricing: new services that meet the criteria of positive reimbursement decisions are to be reimbursed for the amount of their costs incurred in the healthcare operation. Based on this understanding, willingness to pay is not differentiated from the costs of the service from the perspective of the service provider in the SHI, which also includes the costs of the new digital health service.

The costs of a medical service are understood to be the value of all resources consumed in the production of the service. The business calculation of the total costs of a service unit (socalled full cost accounting in contrast to "partial cost accounting", which only takes selected costs into account) is usually divided into three stages (Cf. Frod 2011, p. 55ff; Keun and Prott 2009, p. 158ff):

- Cost-type accounting answers the question of which costs have been incurred. All costs are initially taken from the accounting system and recorded according to their type. This includes in particular, capital commitment costs, costs for insurance and contributions (e.g. contributions to the medical association, medical liability insurance), storage costs (e.g. costs for storing medical consumables), costs for administrative and laboratory supplies (e.g. medicines, treatment materials, laboratory materials), general operating costs (e.g. costs for the medical service). Medicines, treatment materials, laboratory materials), general operating costs (e.g. telephone, waiting room equipment), personnel costs (e.g. salaries, training allowances), room costs (e.g. rent, cleaning, maintenance), travel and further training costs (e.g. further training materials, accommodation costs) and equipment costs (e.g. acquisition and maintenance of medical equipment).
- Cost centre accounting answers the question of where the costs were incurred. These costs are assigned to the organizational areas in which they were incurred or in which they can most likely be influenced. These can be departments of a hospital, for example. Not all costs can be assigned directly. These so-called overhead costs (e.g. rent or property tax for the entire building complex) must be allocated to the cost centres with suitable distribution keys (e.g. area of the respective units).
- Cost unit accounting determines which costs have been incurred for what and by what amount. The costs incurred are finally allocated to the units of service provided to be able to compare the costs of service provision with the price achieved. Cost units can be individual services rendered; for inpatient care, DRG-reimbursed cases represent central cost units. Whereas direct costs can be directly allocated to cost units, overhead costs are usually allocated using the distribution keys developed in cost centre accounting.

How exactly the costs of services are collected and transformed into a remuneration level differs between outpatient and inpatient care in the same way as for reimbursement and for the assumption of services. Basically, both reimbursement schemes are oriented towards full cost accounting, whereby in the inpatient sector, due to the responsibility of the Länder for investments, only current care costs are mapped.

## *1.7 No Extra Charge: Savings in Existing Supply*

In many cases, the development of a new remuneration figure with a cost-based surcharge that includes the additional costs of the good offered by one's own company is either not possible for companies or cannot be implemented within a time horizon acceptable for the company. The question then arises whether the costs for the new digital health good can be compensated by savings elsewhere, so that the company's business case can be based on cost-neutral additional benefits or even added value in the form of additional benefits and savings.

It is important to include the issue of perspective when considering costs—costs of a health service can be incurred by very different actors in the health system in different amounts, and accordingly looking at costs from the perspective of only one service provider can give a very incomplete picture. For example, a GP might spend more time on thorough digital respiratory education as part of an improved care process for the care of a COPD patient. This subsequently reduces the number of costly exacerbations, so that the additional costs at the GP are partially offset or even result in overall savings. Such cost effects are not included in the consideration solely from the perspective of individual service providers.

Perspective is an important aspect of health economic cost analyses. A distinction can be made between costs from the perspective of individual service providers or the SHI system as a whole; costs from the perspective of other sectors (e.g. care costs borne by long-term care insurance), costs from the perspective of the patient and his family (e.g. travel costs to the doctor) and costs from the societal perspective, which also includes so-called indirect costs (Cf. Drummond 2005, p. 18ff) productivity losses due to incapacity to work, disability and premature death.

According to these different perspectives, a company can verify with whom savings are most likely to be expected and who is accordingly most likely to be willing to pay as a customer for the new health good—which is not always the service provider itself (for example, in the example of the digital care process for COPD patients mentioned above).

There are three steps to be taken when determining costs in health economic evaluations (Cf. Krauth et al. 2005):

1. Identification of the required use of resources,
2. Quantity recording of resource consumption and
3. Evaluation of the resources used.

An analysis of the added value of medical innovations solely on the basis of associated cost savings bears the name of cost-minimisation analysis in the health economic evaluation literature. In this, it is assumed that the benefits of the different alternatives are equal, so that analysis of the benefits can focus on costs alone. In this form of analysis, therefore, all care costs with the intervention under study are calculated and compared with the costs of relevant comparative interventions (in particular, current treatment practice without the innovation). It is important to include all relevant resources and their valuation in the analysis.

The SHI pricing procedure currently completely refrains from offsetting cost savings elsewhere in the healthcare system with additional costs of another (digital) health solution. In any case, it is important to include all relevant costs from the decision-maker's point of view, which is also recommended by IQWiG.

Although there are very differentiated methods of health economic evaluation and cost accounting, an estimate of the saved costs, determined as the difference of clinical events and multiplied by their care costs from the perspective of health insurance funds (i.e. reimbursement rates), can be used as a pragmatic approximation. This cost difference can represent a possible price ceiling for a savings-based value proposition at the level of health insurance funds (e.g. for a new digital care programme). Similarly, comparisons between DRG revenues and actual costs with and without innovation at the level of individual service providers can enable an approximate estimate of possible savings. This can give an indication of how high a possible surcharge could be and whether savings-based pricing could lead to a convincing business case for the entrepreneur.

## *1.8 Value-Based Reimbursement*

From an economic perspective, added value is also the central reference for pricing in the healthcare system, and health economic evaluation is a method for quantifying added value. However, how added value for decisions on health services can be determined in terms of content in accordance with legal framework conditions in Germany is an issue that has not yet been solved by consensus among all relevant experts and interest groups. Whereas with cost measurement at the level of individual service providers and the implementation of simple cost-minimisation analyses from the perspective of health insurance funds, a sub-area of health economic evaluation methodology is very relevant and widespread in the assessment of medical innovations. The methodology of complete health economic evaluations for SHI decision-making and thus associated with launch activities in Germany has so far been more of a theoretical reference model than a practical decision-making aid (which is often different internationally, e.g. with regard to the United Kingdom).

The price of an additional unit of health benefit associated with a new service might also be expressed in its incremental cost-effectiveness ratio (ICER). It is often represented graphically with the help of a cost-benefit diagram (Fig. 3). It has become common practice to plot benefits on the abscissa and costs on the ordinate, so that a higher slope expresses a higher price per additional health gained. However, this is convention and IQWiG suggests plotting benefits on the ordinate and costs on the abscissa, so that a flattening of the curve can be interpreted as decreasing efficiency.

One first distinguishes between four quadrants: A new intervention can have a higher benefit and be more cost-effective compared to a standard treatment S. Then it would dominate the current standard treatment S and should be introduced in any case (south-east quadrant). The opposite case of a less effective and at the same time

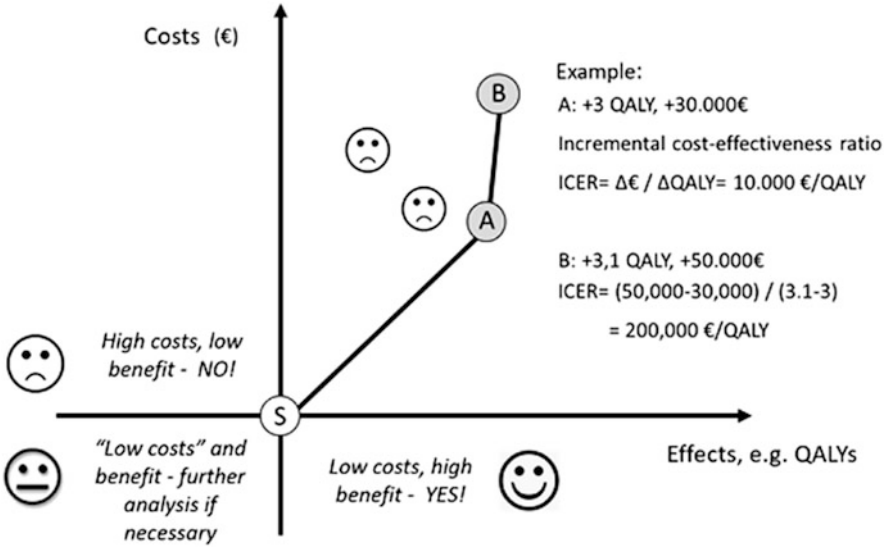


**Fig. 3** Cost—benefit quadrants. Source: own representation based on Rogowski (2016, p. 224)

more expensive intervention (North-West quadrant) means that the new intervention is dominated by the standard treatment and should not be adopted. The decision becomes more complex in the two remaining fields, whereby innovations in the South-West quadrant are hardly addressed in the health economic literature. Most innovations that have succeeded in entering the market also fall into the north-east quadrant, i.e. they offer additional benefits at higher costs.

In the first paragraph of this chapter it was said that full economic evaluations in Germany are currently primarily a theoretical reference model (although it should be added that they are central to decision makers such as NICE in the UK). However, this does not limit the usefulness of economic evaluation for structuring a pricing rationale in digital health care, which also applies to Germany.

Decision analytic modelling can provide a quantitative synthesis of the value proposition in healthcare or help to optimize the value proposition (Cf. Briggs et al. 2006). Important elements of decision analytic modelling include:

1. Adequate definition of the relevant goal for the decision-maker (e.g. health measured in QALYs instead of individual customer benefit).
2. Appropriate mapping of the health problem, for which clinical experts are consulted.
3. Correct representation of the structure of the decision problem, which ideally includes the inclusion of all available alternatives—Fig. 3 illustrates that cost-effectiveness is very much dependent on comparator therapies—without an alternative A, the ICER for option B would be €16,129/QALY (€50,000/3.1 QALYs). Thus, all services applicable to the target group should be included or the exclusion of relevant services should at least be well justified.

4. Identification, measurement and evaluation of health outcomes according to the specifications of the decision-makers (this typically includes HTA to incorporate existing clinical studies).
5. Identification, measurement and evaluation of all relevant costs, which strongly depend on the perspective of the decision maker; often a SHI perspective can be taken and costs can be included in the reimbursement amount.
6. Methodologically transparent presentation of results—especially for discussions with the SHI system and use in formal reimbursement processes. The transparent presentation of the method and how a result was calculated is as relevant as the result itself.
7. Appropriate analysis of uncertainty—whereas current health economic methodological standards require so-called probabilistic analyses in which parameter uncertainty is taken into account with model simulations. In the context of the early evaluation, similar to the business plan, it is primarily important to understand the impact of individual parameter changes (such as effectiveness) on the results.

The empirical estimate of a ratio of additional costs and benefits alone does not provide an answer as to whether an innovation offers "added value" at a given price. On the one hand, there are various theoretical answers to this question in the literature. Representatives of the English NICE often argue that there should be a cost-effectiveness threshold that reflects the cost-effectiveness of services that can no longer be financed in view of scarce resources. If the cost-effectiveness is less favourable than this threshold, further benefit is lost from a health system perspective than is generated by the new service, and the price must be reduced or the service excluded from provision. In English decision-making practice, a politically established threshold value range of approximately £20–30,000/QALY is used for this purpose, which is somewhat higher than a currently empirically estimated threshold value of about £13,000/QALY. It should be noted that the empirical estimate is not free of limitations (Cf. Martin et al. 2008) and the (utilitarian) principle of achieving a population-related maximum gain in lifetime and health-related quality of life with the given means is in contradiction to formative legal and ethics principles in Germany. An alternative approach is to estimate an average willingness to pay per QALY in representative surveys, although this is associated with the problem that the estimation results are very heterogeneous and an ubiquitous willingness to pay per QALY can hardly be determined (Cf. Pennington et al. 2015). Finally, IQWiG proposes under the name "efficiency frontier concept" to use the incremental cost-effectiveness of the previously reimbursed service with the greatest health benefit as orientation, which corresponds to the intuition "for 50% more service I am willing to pay 50% more". However, this approach has also been criticized, for example because it attributes a higher value to a certain additional benefit the higher the costs of care in an indication area.

In addition to the extra costs and effects, however measured, other legal, medical and ethics aspects flow into the value judgement as to whether a new health service actually offers "added value" from the point of view of the system. In addition to

content-related considerations (e.g. severity of illnesses), procedural requirements (e.g. transparency, participation) also play an important role (Cf. Marckmann 2008).

In German decision-making practice, value-based pricing is currently limited as a formal procedure to new digital health application in the outpatient setting. In this context, a new digital healthcare product is subject to a benefit assessment within the framework with the BfArM (Chapter "Digital Health Applications: DiGAs—Pathway to Reimbursement"). If the BfArM makes a final positive decision on the additional benefit and hence includes the digital health application in the DiGA registry, negotiations on discounts on the list price of the new digital product take place between the DiGA company and the Head association of the statutory health insurance fund (GKV Spitzenverband) based on the benefit assessment (reference). In contrast to the transparent benefit assessment, there are no explicitly predefined criteria for the price negotiation, but rather confidential negotiations. Potentially relevant criteria in the negotiation are the following points according to the framework agreement on price negotiation:

- The BfArM decision on the permanent benefit assessment with the findings made therein, in particular on the additional benefit in relation to the appropriate comparator therapy and the number of patients.
- The benefit assessment of the BfArM to be published on the internet, which forms the basis of the commenting procedure following the publication, and the submitted clinical evidence prepared by the DiGA company.
- The actual selling prices in other European countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Netherlands, Portugal, Slovakia, Spain, Sweden, United Kingdom).
- The annual therapy costs of comparable medicinal products suitability is derived from the international standards of evidence-based medicine.

The benefit assessment and information on costs and prices are interpreted by the decision-making body of the GKV Spitzenverband and a decision is made based on this. As of early 2021 there was no negotiation that took place after a BfArM decision. However, it is expected that in addition to the negotiation criteria already mentioned, the severity of the disease as well as the availability of alternatives and the degree of innovation of a new digital solution could also have an influence. Furthermore, the importance of a disease in the public perception (e.g. breast carcinoma) can have an influence on the decision. In addition, political aspects (e.g. innovation promotion/industrial policy) including the political influence of physicians and patient representatives as well as a possible press repercussion can play a role.

In order to optimally plan new digital therapies in the pricing decision environment, companies are recommended to seek contact with decision-makers. These can usually be contacted formally through official consultations or sometimes informally by means of workshops. Furthermore, completed benefit assessments should be evaluated and the current willingness-to-pay and prices of potential comparator therapies relevant for price determination (so-called "price anchors") should be analysed.

## 1.9 *Innovative Pricing Agreements for Digital Health Applications*

In order to be able to determine a value-based price, all information regarding the value of the product should be available during the price negotiations between the manufacturer and the head association of statutory health insurance funds (GKV-SV). This is however, not always the case. To some extent the parties involved in the price negotiations need to deal with uncertainties, e.g. with respect to clinical outcomes, epidemiology, and cost impact.

In order to address these uncertainties, innovative pricing agreements could be negotiated to share the risks. The main concepts are summarized in Fig. 4. Based on the uncertainties to be addressed, different innovative pricing arrangements can be delineated. In general, outcomes-based agreements are separated from non-outcomes based agreements (also known as financial-based risk-sharing agreements) (Cf. Urbinati et al. 2017; Carlson et al. 2010; Navarria et al. 2015; Garrison et al. 2013).

Non-outcomes-based agreements can further be separated on population level agreements and patient level agreements. An example for a population level agreement is a price-volume agreement. For this agreement type, the manufacturer allows for price discrimination based on different sales volumes. A utilization cap agreement follows the same mechanism, however is based on patient level (Cf. Garrison et al. 2013).

Outcomes-based agreements link the coverage to clinical outcomes instead of utilization measurements. They can be further separated in Coverage with Evidence Development (CED) and outcomes-based risk-sharing agreements. CED amplify that new medical interventions are only covered for a certain period of time, which

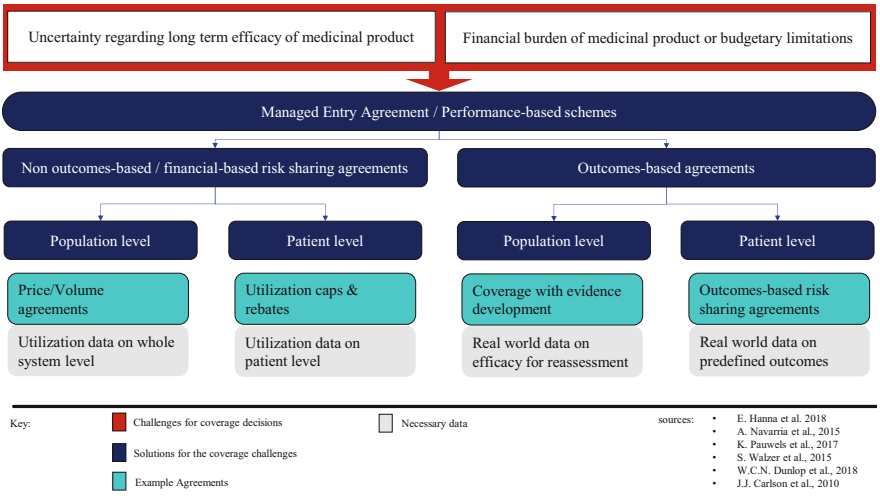


**Fig. 4** Excerpt of terminology and concepts on innovative pricing agreements

was agreed on by the payer and manufacturer. During this time, additional data on the long-term effects of the intervention are collected and used for a reassessment of the coverage decision (Cf. Hutton et al. 2007). Outcomes-based risk sharing agreements hold the promise to negotiate truly value based prices. The parties involved in the design of this agreement define outcomes that will be measured once the product is launched to the market. The pricing is directly linked to these outcomes. If a digital health application holds the promise to increase a defined clinical outcome parameter (e.g. overall survival), this parameter could be anchored to an outcomes-based risk-share agreement. Such an approach could primarily be applied to all clinical outcomes that are easily, continuously and consistently measurable. Since some digital health applications are continuously generating data regarding health outcomes of patients, these information could be used as a basis for an innovative price agreement.

Out of the box: Learning from innovative pricing agreements for advanced therapy medicinal products.

A central point of discussion within the field of drug pricing are reimbursement agreements for advanced therapy medicinal products (ATMPs) which include gene therapies, somatic cell therapies and tissue engineered medicinal products (Cf. Jönsson et al. 2019).

Six out of nine ATMPs were granted a non-quantifiable additional benefit by the G-BA. The assessment of Zynteglo® resulted in a hint for a non-quantifiable additional benefit (Cf. Gemeinsamer Bundesausschuss 2020). For Imlygic® no additional benefit could be proven (Cf. Gemeinsamer Bundesausschuss 2016). The potential value of Luxturna® was classified as a hint for a major additional benefit (Cf. Gemeinsamer Bundesausschuss 2019).

The reimbursement decisions for ATMPs with transformative effects incorporate innovative, outcomes-based reimbursement agreements (Cf. Jorgensen et al. 2020). The agreements are negotiated between cooperation of insurances and the marketing authorization holders. For Alofisel®, Yescarta®, Kymriah®, Zynteglo® and Zolgensma® outcomes-based risk-sharing agreements with individual payers have been negotiated (Cf. Walzer et al. 2019). These agreements are based on a full upfront payment by the payer with confidential discounts. The marketing authorization holder partially or fully refunds the payer, if the therapy does not result in the anticipated treatment success (Cf. Jorgensen et al. 2020).

## *1.10 Strategic Consideration in Digital Healthcare Pricing*

A strategic aspect of product positioning—and thus also of price determination—has already become clear from the consideration of the ICER: added value is defined by the comparative intervention. This can be partly influenced by the manufacturer's product strategy: innovative services can often be applied in different indication areas (and thus possibly, for example, in disease areas with or without existing treatment options) or at different points in the treatment pathway (e.g. first, second or

third line treatment in the case of a digital health service). In the development process, the company can focus early on a niche in which comparatively higher prices can be achieved. In addition, companies can try to position their services in a high-price niche first and then successively expand the area of application. However, it should be borne in mind that, from the point of view of the SHI, the cost-effectiveness in the patient group in which the cost-effectiveness ratio is the least favourable is basically decisive for pricing (Cf. Claxton et al. 2011).

In response to this, this is also at the same time a strategic opportunity for product positioning for both DiGA companies and the SHI: if another, high-priced intervention or, for example, a low-cost DiGA were used alone as the comparator product in the process of reimbursement decision and price negotiation, significant influence could be exerted on the outcome even before the cost-benefit assessment.

Closely related to this is the expected number of (patient) cases. Even if a therapy is considered cost-effective on the basis of economic evaluation (i.e. its cost-benefit ratio is below a threshold value accepted in a health system), this assumption means an additional expenditure for the budget. Therefore, many countries, e.g. Belgium and Germany, include a budget impact analysis to verify not only the "suitability" of the reimbursement but also the "reasonability" for the system, to refer to the terms mentioned in the SGB V. The more cases and hence the higher the budget impact, the lower, ceteris paribus, the willingness to pay for high prices would be.

Finally, a third aspect of major importance is the orientation of decision-makers to prices in other countries ("external price referencing"). This external price referencing can be applied in different ways. Some countries only accept the lowest price from a defined group of countries as their own price, others take an average from several countries as the price determination and still others use foreign prices informally as a further argument for discounting possible entry prices from the industry. As a consequence, this leads companies to strategically market entry planning in different health systems to bring about a price-maximising "launch sequencing"—strategically determined sequence of the introduction of new digital products.

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