



Definitions of payment models to address market access and affordability of innovative medicinal products

MSc Science & Business Management

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Plain Language Summary

Innovative therapies can treat conditions and diseases that were previously considered incurable. There is a class of biopharmaceuticals, called Advanced Therapy Medicinal Products (ATMPs), that include somatic cell therapies, gene therapies and tissue-engineered products. ATMPs offer potentially life-changing cures for patients, as well as therapeutic alternatives for conditions with limited clinical options. Despite this, pricing and reimbursement authorities are confronted with extremely high prices and significant clinical uncertainty, rendering their reimbursement particularly challenging.

ATMP development is expensive due to the many years of research and development required, accompanied by a complicated production process. Manufacturers are unable to recoup production costs with lower prices due to a limited patient population, in the case of rare diseases. Manufacturers also take advantage of the higher willingness to pay for innovative therapies targeting diseases with no current treatment options. Clinical uncertainty is expected because the ability to conduct clinical trials is limited by a small patient population. ATMPs are often supported by single-arm clinical trials, and no long-term data.

In response to reimbursement issues, managed entry agreements (MEAs) have been proposed and implemented. MEAs are defined as ‘any agreement beyond a yes/no decision on reimbursement between the marketing authorization holder (hereafter called manufacturer) of a therapy and a payer’. MEAs are typically categorised either as financial-based agreements (FBAs) or outcome-based agreements (OBAs). FBAs aim to contain costs and make a product more affordable. OBAs aim to reduce uncertainties surrounding the effectiveness of a product by holding manufacturers accountable for their outcomes in the real world.

There is increased discussion in the literature surrounding MEAs, in order to facilitate the reimbursement of the growing number of ATMPs in the drug development pipeline. There are however several barriers impeding their widespread application. Among these, is the necessity of a standardised negotiation framework, which is further complicated by the lack of a consensus-based MEA taxonomy and definitions. Thus, this work aims to create a taxonomy of the payment models described in the literature, and the definitions used. This will accommodate further research, design, assessment, and implementation of these models in health care systems.

A literature review of articles published in PubMed, Medline, and Embase between 2010-2023 was conducted. Articles containing MEAs and their definitions related to ATMP reimbursement were selected. The availability of full texts was required and the articles had to be written in English. The search queries retrieved 3442 results. Removal of duplicates, followed by title and abstract screening, and full-text screening yielded a final selection of 64 articles to be included in the Microsoft Excel datasheet.

In total, 255 MEAs and definitions were identified. A comprehensive table of MEA types and their definitions was created. Categorisation of MEA types was displayed in both a clustered table, and in a unique taxonomy tree. A lack of consensus regarding MEA taxonomy and definitions is evident. A common language between payers and manufacturers is needed to facilitate effective reimbursement negotiations. To conclude, a call to action for the establishment of a standardised negotiation framework, accompanied by consensus-based MEA terminology is made.

Abstract

Background: Advanced therapy medicinal products (ATMPs) are innovative therapies launched with high upfront costs and limited short-term clinical data. Payers struggle to provide patient access to ATMPs due to uncertainty regarding their real-world value and the short-term budget impact. Managed entry agreements (MEAs) are schemes that aim to address the challenges linked to ATMP reimbursement, by decreasing the financial burden or the clinical uncertainty.

Objective: To identify and define the MEAs implemented or proposed for ATMP reimbursement in the literature. To then compile a comprehensive table of MEA types and their definitions, followed by the construction of a unique taxonomy tree.

Methods: We conducted a literature review of articles published in PubMed, Medline, and Embase between 2010-2023. Articles containing MEAs and their definitions related to ATMP reimbursement were selected. Availability of full texts was required and the articles had to be written in English.

Results: The search queries retrieved 3442 results. Removal of duplicates, followed by title and abstract screening, and full-text screening yielded a final selection of 64 articles to be included in the Microsoft Excel datasheet. In total, 255 MEAs and definitions were identified. A comprehensive table of the MEAs and their definitions was created. Categorisation of MEA types was displayed in both a clustered table, and in a unique taxonomy tree.

Conclusions: A lack of consensus regarding MEA taxonomy and definitions is evident. A common language between payers and manufacturers is needed to facilitate effective reimbursement negotiations. A call to action for the establishment of a standardised negotiation framework, accompanied by consensus-based MEA terminology is made.

Key Words: Healthcare financing; Drug costs; Reimbursement; Innovative therapies

Introduction

Innovative therapies have emerged to treat conditions and diseases that were previously considered incurable. Among innovative therapies, there is a class of biopharmaceuticals, called Advanced Therapy Medicinal Products (ATMPs), that include somatic cell therapies, gene therapies and tissue-engineered products (1). ATMPs offer potentially life-changing cures for patients, as well as therapeutic alternatives for conditions with limited clinical options. Despite this, pricing and reimbursement authorities and payers are confronted with extremely high prices and significant clinical uncertainty, rendering their reimbursement challenging (2).

The high prices are attributable to several aspects of ATMP development. Many years of research are required, before the expensive production process even takes place. Manufacturers need to recoup costs and are unable to do so with lower prices due to a limited patient population (16, 59). Manufacturers also take advantage of the higher willingness to pay for innovative therapies targeting orphan indications (16). Clinical uncertainty is expected because the ability to conduct clinical trials is limited by the patient population. ATMPs are often supported by single-arm clinical trials, and no long-term data (16, 36). As a result, determining the cost-effectiveness of an ATMP is extremely challenging.

In response to reimbursement issues, managed entry agreements (MEAs), also referred to as risk-sharing agreements, or patient access schemes have been proposed and implemented. MEAs are defined as ‘any agreement beyond a yes/no decision on reimbursement between the marketing authorization holder (hereafter called manufacturer) of a therapy and a payer’ (3). MEAs are typically

categorised either as financial-based agreements (FBAs) or outcome-based agreements (OBAs). FBAs aim to contain costs and facilitate the affordability of a product on the market. OBAs aim to reduce uncertainties surrounding the effectiveness of a product by holding manufacturers accountable for their outcomes in the real world post approval (4).

To date, FBAs have been implemented more frequently than OBAs due to their simplicity, especially in low to middle income countries (5). Conversely, OBAs require expensive infrastructure for patient registries as well as extensive monitoring which has been reported to be too burdensome (6). Nevertheless, OBAs are still an attractive option for payers, as they tie the price of a therapy to its performance, mitigating the risk posed by clinical uncertainty. A survey of US and EU payers carried out by Nazareth et. al., indicates a positive trend in OBA activity in the future (7).

Similarly, interest in MEAs has increased, in order to facilitate the reimbursement of the growing number of ATMPs in the drug development pipeline. There are however several barriers impeding their application (8). Among these, is the necessity of a standardised negotiation framework, which is further complicated by a lack of a consensus-based MEA taxonomy and definitions (9). The divergent use of language and lack of accepted definitions hampers the research, application, and development of alternative payment models.

Thus, this work aims to create a taxonomy of the payment models described in the literature, and the definitions used. This will accommodate further research, design, assessment, and implementation of these models in health care systems.

Methods

The literature review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (10). The protocol was registered on PROSPERO under registration number CRD42024496136.

a. Search Strategy:

The search was conducted in PubMed, Medline and Embase. A search query containing relevant keywords and synonyms was used, refining the search to [Title/Abstract]. The search query contained two elements. The first element was related to payment models, reimbursements and other key synonyms. The second element defined that it had to be related to patient access or a healthcare system. The search queries used are included in the appendix (Figures 7 and 8).

b. Selection Criteria

The search was restricted to the years 2010-2023 in order to select the most relevant payment models and related developments for current decision makers. To be included, articles were required to be written in English, the full text had to be accessible, and articles needed to mention a payment model and its definition. The latter has been fundamental to avoiding payment model misclassification in a taxonomy. To ensure that all new payment methods were included, both implemented payment models and proposed theoretical models were considered. A human filter was also applied to filter out articles related to animals.

c. Data Collection

In order to perform and operationalise data collection, Rayyan.ai was used (11). When resolving duplicates in Rayyan.ai, an n-1 action was taken to ensure that not all records were

deleted. Title and abstract screening was first performed by (SW). This was followed by independent title and abstract screening performed by (AG). (AG) screened the full dataset of articles.

Following this, full text screening was performed by (SW) to ensure that the articles selected met the full inclusion criteria. (AG) also performed full text screening, fulfilling the chosen threshold of 10% in this step. Disagreements were resolved through discussion until a consensus was reached. If necessary, a third researcher, (RtH) could be consulted for guidance.

d. Displaying Data

A PRISMA Flow Diagram was used to display how the selection criteria were implemented, leading to the final number of articles included in the literature review.

e. Analysis and Synthesis

The payment models and their respective definitions mentioned in the included articles were transferred to a data extraction spreadsheet in Microsoft Excel. A database outlining payment model types, definitions, geographical context, as well as their implementation was created. It was based on the ECLIPSE (Expectation, Client Group, Location, Impact, Professionals and Service) model which is used in searches related to health policy/management (12).

Results:

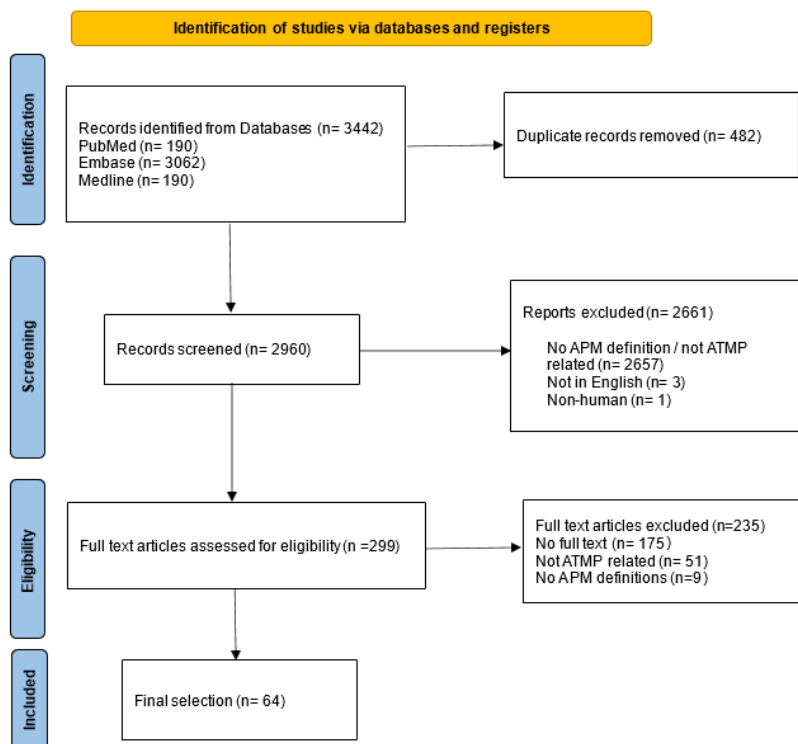


Figure 1: PRISMA Flow Diagram outlining the screening of 3442 articles down to the final selection of 64 articles.

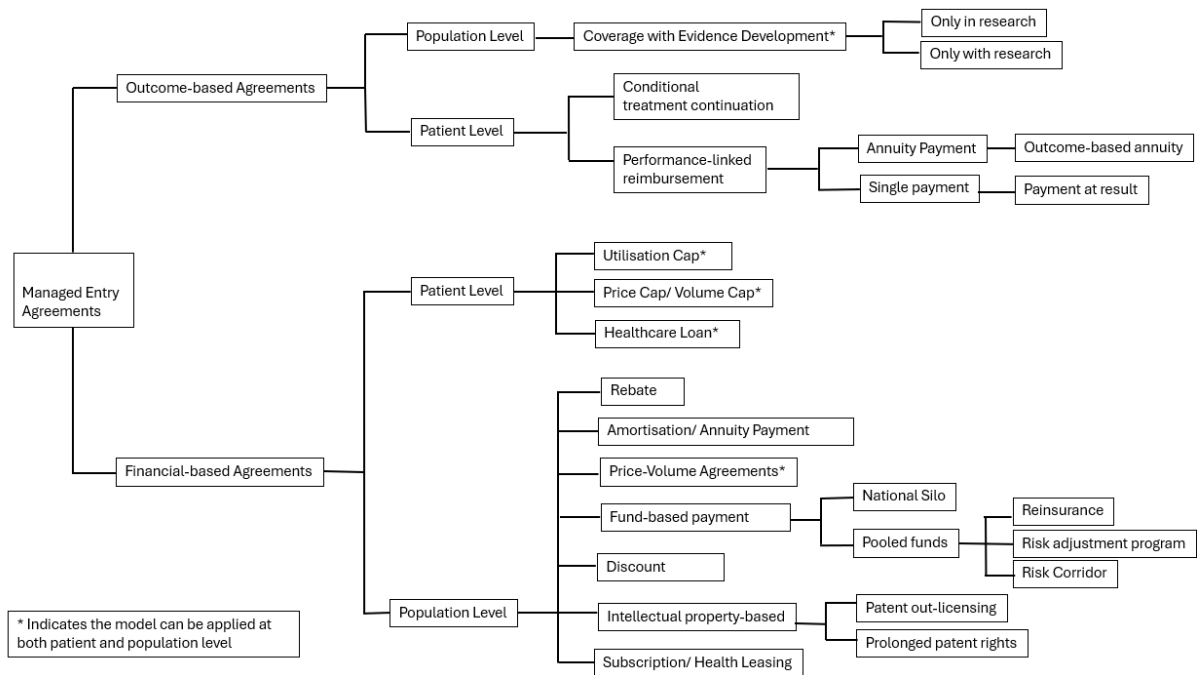


Figure 2: Taxonomy of Managed Entry Agreements

Taxonomy

The first step in creating the taxonomy tree shown in Figure 2 was to compile a comprehensive table of all the payment model types from the Excel database, which is included in the appendix (S1). To begin the categorisation process, payment models with different names but the same definitions were clustered. Existing taxonomies constructed by Carlson et al, Hanna et al, and Dabbous et al (13, 2, 4) were consulted to assist in structuring this updated taxonomy. The MEAs are separated into population and patient level agreements, a feature that is conserved amongst several taxonomy trees in the literature (2, 4, 8, 50, 51, 53, 71)

An asterisk is used to denote agreements that can be applied on both a population and a patient level. Taking price/volume caps as examples, patient level agreements aim to cap the annual cost or the number of treatments for an individual patient per year. In contrast, population level agreements aim to cap the annual expenditure on a patient population via a budget threshold or a cap on the volume purchased from the manufacturer (2, 3, 56). A further subcategorization of OBAs based on the payment mechanism was necessary due to the difficulty in distinguishing OBA types based on their definitions. The rationale behind this subcategorization decision is explained further in the next section.

Divergent Terminology

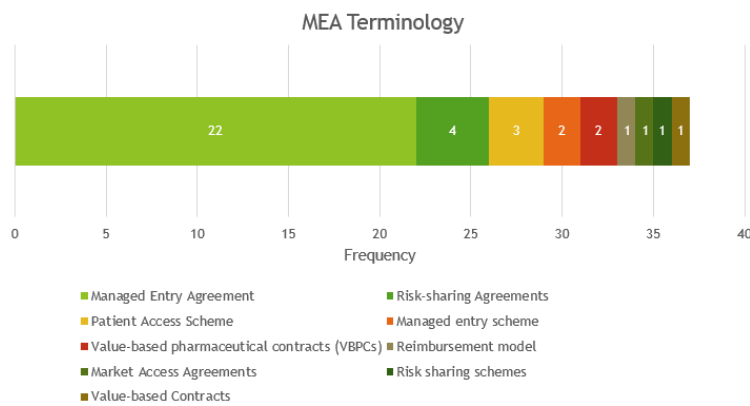


Figure 3: Graph displaying the number of MEA synonyms identified.

It is crucial that a clear and consensus-based definition of a managed entry agreement (MEA) exists because the entire taxonomy of alternative payment models stems from this point. Figure 3 shows that various other terms such as patient access scheme and risk-sharing agreement (RSA) are used interchangeably with MEA in the literature (14, 15, 16, 17). Inconsistent use of RSA in particular was a prominent issue in the literature. RSA is used to refer to both MEAs and outcome-based agreements (OBAs) blurring the lines between MEAs and one of the two major subtypes of MEAs, OBAs.

Similarly, inconsistent use of MEA terms made it difficult to distinguish between OBAs and performance-based agreements (PBAs). OBA and PBA are often used interchangeably in the literature (14, 56). This conflicts with taxonomy trees displaying PBAs as a subcategory of OBAs alongside evidence generation schemes (2, 50, 53). Consequently, this lack of distinction between OBAs and PBAs made the categorisation of OBA types a far more complex task. Therefore, it was necessary to categorize OBA types based on their payment structure, namely annuity style payments or single payments, taking inspiration from Hanna et al (2).

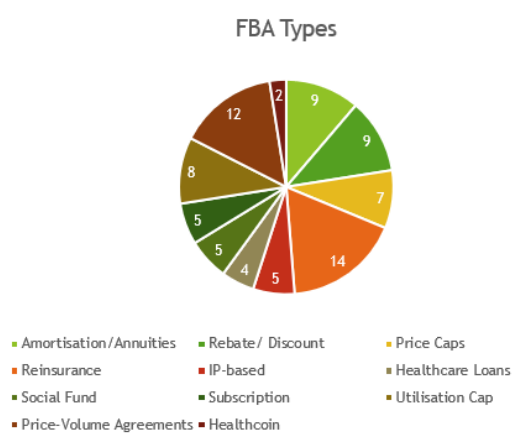


Figure 4: Graph displaying the various FBA agreements identified.

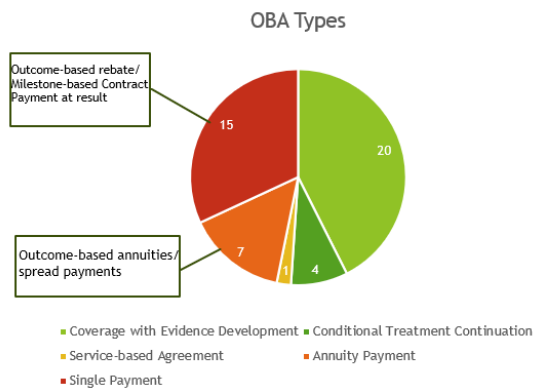


Figure 5: Graph displaying the various OBA agreements identified.

A third example of inconsistency is warranty payment models being categorized as both OBAs and FBAs in the literature (1, 15, 32). Warranties are used across many major industries to reimburse the payer if the product does not fulfil its performance targets. Hence, a warranty covering an ATMP could logically be categorized as an OBA.

MEA Trends

As part of the data analysis and synthesis, the identification of geographical and annual trends related to MEA types was attempted. It must be noted that the geographic information in the datasheet originates from the countries in which the articles were published. Therefore, the data does not accurately represent the countries in which the MEAs were implemented. This shortcoming did not apply to articles that discussed the MEA landscape in a particular country. It was however a prevalent issue associated with systematic reviews which listed different MEA types but neglected to provide the country of implementation.

The datasheet indicates that there are regional trends related to the use of certain payment model terminology. For instance, articles discussing the reimbursement of ATMPs by The National Institute for Health and Care Excellence (NICE) in the UK predominantly use patient access scheme as opposed to MEA (1, 14). Managed entry scheme is the preferred term in Australia, whereas MEA and RSA are used worldwide without a clear trend (34, 9)

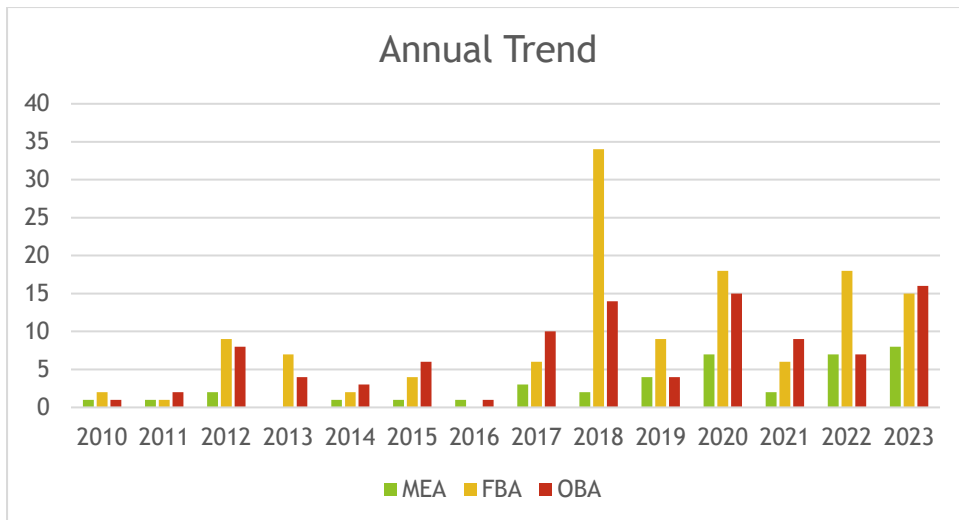


Figure 6: Graph displaying the increasing frequency of MEA definitions available in the literature.

The datasheet shows an increasing trend of MEA, OBA, and FBA discussion in the literature, which is supported by several other systematic reviews (1, 2). However, the trend results are not indicative of MEA implementation over the 2010-2023 period. The publishing years of the articles in the datasheet were used because the implementation dates of MEAs were not readily provided in the literature. For instance, Figure 6 shows a notable decrease in MEA frequency in 2016, but this is a result of only one article from that year being present in the datasheet.

There are articles in the datasheet indicating that simple FBAs such as discounts are preferred to OBAs in lower middle income countries (LMIC) (5, 22). Countries in the Middle East and North African (MENA) region in particular, opt for discounts to avoid the added complexity and expense of patient monitoring and the infrastructure required (18, 35, 24). Israel and Saudi Arabia are the exceptions to this rule, having successfully implemented several OBAs (29,35). Another trend identified shows that reinsurance models are predominantly implemented in the United States, a country with a multi-payer system (41).

A multi-payer system is characterised by several payers including both public and private healthcare providers deciding upon reimbursement. The purpose of reinsurance models is to compensate payers that incur unusually high costs when covering expensive therapies such as ATMPs (1, 2, 23) . The multi-payer system also has the effect of reducing the adoption of long-term OBAs by payers. In a system where patients can switch coverage plans, the future rebates may be transferred to a different payer (41). In response to this issue, a tradeable currency called Healthcoin has been proposed to incentivise payers to invest in ATMPs. Healthcoin converts the incremental outcomes produced by ATMPs into a common currency that can be converted into US dollars (23, 2).

Discussion:

MEAs have been adopted by payers worldwide in order to mitigate the risks associated with reimbursing high-cost ATMPs with limited clinical evidence. These agreements provide the more flexible coverage options needed to facilitate positive reimbursement of ATMPs, compared to traditional fee-for-service models. Currently, reimbursement negotiations are not approached in a systematic way, leading to inconsistencies when assessing the value of an ATMP, prioritizing risks associated with clinical uncertainty, as well as the feasibility of the selected MEA (9, 16, 28).

Structured negotiation frameworks have been described in the literature with the purpose of providing a systematic approach to identifying concerns related to affordability, or clinical uncertainty (9, 70). As a result, negotiation time and the implementation burden are minimised. In the case of OBAs, horizon scanning has been shown to be crucial in anticipating the most suitable contracts and conditions for innovative products (26, 71). Payers need to take a proactive, rather than reactive approach to reimbursement negotiations.

In order for this research to have the maximum impact on MEA implementation, a call for action is necessary. It is evident that a lack of consensus regarding MEA terminology and trust leads to ineffective communication between payers and manufacturers. Consequently, MEA implementation is delayed or reduced, which is detrimental to patient access to life-changing ATMPs (9, 26, 70). A consensus based MEA taxonomy as part of a negotiation framework would speed up the negotiation process, potentially improving patient outcomes. It would also reduce the costs associated with inefficient implementation and outcomes (4).

This research contributes to the literature by providing a comprehensive description of all MEAs and their definitions described between 2010 to 2023 (S1). Categorisation of MEA types was based on the alignment of their definitions, shown in the clustered table (S2). MEA categories are displayed in our unique taxonomy tree (Figure 2). The purpose of the tree is to offer a visual representation of payment model types, and their positions in the MEA environment. Our table illustrates the sheer variation and redundancy of MEA terminology in the literature, where several different names referring to a specific payment model type is commonplace, budget threshold being an example (S2).

Therefore, the issue of producing a consensus-based MEA taxonomy and definitions must be of high priority for HTA groups and healthcare providers worldwide. An international joint task group aimed at creating consensus-based MEA definitions, needs to be assembled. A joint task group was established in 2018 to develop a new and internationally accepted definition of HTA (69). A set of guiding principles were first developed, that encompassed translatability to other languages, and minimal use of jargon. This achievement shows how the international HTA community can collaborate on an important common goal. Their approach and learnings can be used to best guide a working group developing consensus-based MEA definitions.

Conclusion:

ATMPs offer potentially life-long cures to cancers and rare-diseases with one administration. Efforts to accommodate their high prices and to reduce their clinical uncertainty have yielded mixed results. Barriers to implementation include a lack of a negotiation framework, governance structures, and confidentiality agreements. This review focuses on the MEA taxonomy and definitions issue. Compiling a comprehensive list of MEAs and their definitions, followed by categorisation, and visualization with a taxonomy tree, will accommodate the future research and implementation of these agreements. A call to action is necessary to generate the most attention to this issue, maximising the potential impact. With more ATMPs entering the drug development pipeline, urgent action is needed.

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Appendix:

```
(("alternative payment model"[Title/Abstract] OR "amortization"[Title/Abstract] OR "annual
payment model"[Title/Abstract] OR "annuity based reimbursement"[Title/Abstract] OR "annuity
payment"[Title/Abstract] OR "annuity-based payment over time"[Title/Abstract] OR "block
contract"[Title/Abstract] OR "budget cap"[Title/Abstract] OR "bundle payment"[Title/Abstract]
OR "episode of care"[Title/Abstract] OR "bundled payment"[Title/Abstract] OR
"capitation"[Title/Abstract] OR "coinsurance"[Title/Abstract] OR "conditional treatment
continuation"[Title/Abstract] OR "cost sharing"[Title/Abstract] OR "cost-offset"[Title/Abstract] OR
"cost-plus price"[Title/Abstract] OR "coverage with evidence development"[Title/Abstract] OR
"discount"[Title/Abstract] OR "fee for service"[Title/Abstract] OR "financial-based
reimbursement"[Title/Abstract] OR "full cost offset"[Title/Abstract] OR "fund-based
payment"[Title/Abstract] OR "health coin"[Title/Abstract] OR "health leasing"[Title/Abstract] OR
"subscription"[Title/Abstract] OR "healthcare loan"[Title/Abstract] OR "indication-based
price"[Title/Abstract] OR "indication-specific price"[Title/Abstract] OR "innovative-pricing
mechanism"[Title/Abstract] OR "intellectual property-based"[Title/Abstract] OR "leased
payment"[Title/Abstract] OR "life cycle cost"[Title/Abstract] OR "managed entry"[Title/Abstract]
OR "managed entry agreement"[Title/Abstract] OR "milestone based"[Title/Abstract] OR "multi-
indication price"[Title/Abstract] OR "national rebate"[Title/Abstract] OR "Netflix
model"[Title/Abstract] OR "outcome based rebate contract"[Title/Abstract] OR "outcome-based
payment"[Title/Abstract] OR "outcomes-based reimbursement"[Title/Abstract] OR "over-time
payment"[Title/Abstract] OR "P4P"[Title/Abstract] OR "pay at outcomes achieved"[Title/Abstract]
OR "pay-for-outcome with outcome guarantees"[Title/Abstract] OR "pay-for-
performance"[Title/Abstract] OR "payment-by-result"[Title/Abstract] OR "performance-
based"[Title/Abstract] OR "performance-based payment"[Title/Abstract] OR "performance-based
reimbursement"[Title/Abstract] OR "performance-based risk-sharing"[Title/Abstract] OR
"performance-linked"[Title/Abstract] OR "price cap"[Title/Abstract] OR "price-volume
agreement"[Title/Abstract] OR "profit-maximising uniform price"[Title/Abstract] OR "prospective
payment"[Title/Abstract] OR "rate of return pricing"[Title/Abstract] OR "rebate"[Title/Abstract]
OR "reinsurance market"[Title/Abstract] OR "risk adjustment"[Title/Abstract] OR "risk
based"[Title/Abstract] OR "risk corridor"[Title/Abstract] OR "risk sharing"[Title/Abstract] OR "risk-
sharing"[Title/Abstract] OR "shared saving"[Title/Abstract] OR "simple price
discount"[Title/Abstract] OR "single price"[Title/Abstract] OR "staggered
payment"[Title/Abstract] OR "total cost of care"[Title/Abstract] OR "upfront
payment"[Title/Abstract] OR "value based program"[Title/Abstract] OR "value based
purchasing"[Title/Abstract] OR "value-based contract"[Title/Abstract] OR "value-based
financing"[Title/Abstract] OR "value-based insurance design"[Title/Abstract] OR "value-based
payment"[Title/Abstract] OR "value-based price"[Title/Abstract] OR "value-based
reimbursement"[Title/Abstract] OR "volume cap"[Title/Abstract] OR "warranty"[Title/Abstract])
AND
(("healthcare system"[Title/Abstract] OR "medicinal product"[Title/Abstract] OR
"pharmaceutical"[Title/Abstract] OR "healthcare provider"[Title/Abstract] OR "patient
access"[Title/Abstract]))
```

Figure 7: Search query used for PubMed and Medline databases.

```
('alternative payment model':ab,ti,kw OR 'amortization':ab,ti,kw OR 'annual payment
model':ab,ti,kw OR 'annuity based reimbursement':ab,ti,kw OR 'annuity payment':ab,ti,kw OR
'annuity-based payment over time':ab,ti,kw OR 'block contract':ab,ti,kw OR 'budget cap':ab,ti,kw
OR 'bundle payment':ab,ti,kw OR 'episode of care':ab,ti,kw OR 'bundled payment':ab,ti,kw OR
'capitation':ab,ti,kw OR 'coinsurance':ab,ti,kw OR 'conditional treatment continuation':ab,ti,kw OR
'cost sharing':ab,ti,kw OR 'cost-offset':ab,ti,kw OR 'cost-plus price':ab,ti,kw OR 'coverage with
evidence development':ab,ti,kw OR 'discount':ab,ti,kw OR 'fee for service':ab,ti,kw OR 'financial-
based reimbursement':ab,ti,kw OR 'full cost offset':ab,ti,kw OR 'fund-based payment':ab,ti,kw OR
'health coin':ab,ti,kw OR 'health leasing':ab,ti,kw OR 'subscription':ab,ti,kw OR 'healthcare
loan':ab,ti,kw OR 'indication-based price':ab,ti,kw OR 'indication-specific price':ab,ti,kw OR
'innovative-pricing mechanism':ab,ti,kw OR 'intellectual property-based':ab,ti,kw OR 'leased
payment':ab,ti,kw OR 'life cycle cost':ab,ti,kw OR 'managed entry':ab,ti,kw OR 'managed entry
agreement':ab,ti,kw OR 'milestone based':ab,ti,kw OR 'multi-indication price':ab,ti,kw OR
'national rebate':ab,ti,kw OR 'netflix model':ab,ti,kw OR 'outcome based rebate
contract':ab,ti,kw OR 'outcome-based payment':ab,ti,kw OR 'outcomes-based
reimbursement':ab,ti,kw OR 'over-time payment':ab,ti,kw OR 'p4p':ab,ti,kw OR 'pay at
outcomes achieved':ab,ti,kw OR 'pay-for-outcome with outcome guarantees':ab,ti,kw OR 'pay-for-
performance':ab,ti,kw OR 'payment-by-result':ab,ti,kw OR 'performance-based':ab,ti,kw OR
'performance-based payment':ab,ti,kw OR 'performance-based reimbursement':ab,ti,kw OR
'performance-based risk-sharing':ab,ti,kw OR 'performance-linked':ab,ti,kw OR 'price
cap':ab,ti,kw OR 'price-volume agreement':ab,ti,kw OR 'profit-maximising uniform
price':ab,ti,kw OR 'prospective payment':ab,ti,kw OR 'rate of return pricing':ab,ti,kw OR
'rebate':ab,ti,kw OR 'reinsurance market':ab,ti,kw OR 'risk adjustment':ab,ti,kw OR 'risk
based':ab,ti,kw OR 'risk corridor':ab,ti,kw OR 'risk sharing':ab,ti,kw OR 'risk-sharing':ab,ti,kw OR
'shared saving':ab,ti,kw OR 'simple price discount':ab,ti,kw OR 'single price':ab,ti,kw OR
'staggered payment':ab,ti,kw OR 'total cost of care':ab,ti,kw OR 'upfront payment':ab,ti,kw OR
'value based program':ab,ti,kw OR 'value based purchasing':ab,ti,kw OR 'value-based
contract':ab,ti,kw OR 'value-based financing':ab,ti,kw OR 'value-based insurance design':ab,ti,kw
OR 'value-based payment':ab,ti,kw OR 'value-based price':ab,ti,kw OR 'value-based
reimbursement':ab,ti,kw OR 'volume cap':ab,ti,kw OR 'warranty':ab,ti,kw)
AND
('healthcare system':ab,ti,kw OR 'medicinal product':ab,ti,kw OR 'pharmaceutical':ab,ti,kw OR
'healthcare provider':ab,ti,kw OR 'patient access':ab,ti,kw)
```

Figure 8: Search query used for Embase database.

S1: Comprehensive Table

Payment Model	Definition
Managed Entry Agreement	<ol style="list-style-type: none"> 1. An arrangement between a pharmaceutical manufacturer and a payer/provider that enables access to (coverage or reimbursement of) a health technology subject to specific conditions. (18) 2. A mechanism to share risks associated with the introduction of new products of which there is uncertainty around budgetary impact, cost-effectiveness or other factors (such as safety). (19) 3. Allow coverage or reimbursement of medicines subject to specific conditions and address uncertainty regarding the likely efficacy of these medicines. (20) 4. Arrangements between drug manufacturers and CAPR (competent authorities for pricing and reimbursement) that ensure access to coverage or reimbursement of a drug under specified conditions” (21) 5. Any agreement beyond a yes/no decision on reimbursement between the manufacturer of a therapy and a healthcare payer. (22) 6. A type of formal institutional arrangement between pharmaceutical companies and payers for sharing the risk with respect to the introduction of new pharmaceutical technologies. (5) 7. MEAs are generally contractual agreements between manufacturers and payers addressing either the high cost or the uncertainties surrounding the effectiveness of highly priced health therapies. (23) 8. Agreements determining specific conditions for reimbursement, usually in a confidential manner. (1) 9. Manage uncertainty related to the impact of a drug, including its effectiveness and tolerance profile, the duration of treatment and the size of the eligible population.

	<p>10. An arrangement between a manufacturer and payer that enables access to new technologies in health care. These arrangements can exist in a variety of forms, such as outcome--based agreements or financial-based agreements as well as a combination of both agreements. (24)</p> <p>11. Enable access to high-cost treatments with substantial uncertainty. (25)</p> <p>12. An arrangement between a [pharmaceutical] manufacturer and payer/provider that enables access to (coverage or reimbursement of) a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use or limit their budget impact. (26)</p> <p>13. A policy tool utilized when reimbursement decisions cannot be made due to uncertainties about clinical evidence, financial impacts or CE. (7)</p> <p>14. A formal institutional agreement between pharmaceutical companies and payers to share the associated risks deriving from the administration of innovative pharmaceutical technologies. (27)</p> <p>15. A formal confidential arrangement between payers and manufacturers typically divided into financial or outcome/performance-based schemes. (28)</p> <p>16. An arrangement between a manufacturer and payer/provider that enables coverage or reimbursement of a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use or limit their budget impact. (29)</p>
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	<p>17. Any agreement beyond a yes/no decision on reimbursement between the marketing authorization holder (hereafter called manufacturer) of a therapy and a payer can be called a managed entry agreement. (30)</p> <p>18. Arrangements between manufacturers and payers that allow for reimbursement of new medicines while managing uncertainty around their financial or clinical impact. (8)</p> <p>19. An arrangement between a company and a payer/provider that enables access to (reimbursement of) a product subject to specific conditions to manage budget impact, optimize performance, or address uncertainty relating to clinical and/or cost-effectiveness. These schemes can range from simple discounts to the price that is applied to all patients, through to complex real-world research studies where data is collected to address uncertainties and inform a reappraisal or renegotiation of price. (31)</p>
Managed-Entry Agreement	<p>1. Contractual arrangements between pharmaceutical companies and third-party payers that foresee either simple discounts under specific circumstances or more complex reimbursement schemes, with the aim of enabling the coverage of new medicines under uncertainty around their effectiveness or budget impact in real contexts. (32)</p> <p>2. To grant access to new, often high-cost medicines with limited evidence. (33)</p>
Managed Entry Scheme	<p>1. An update to the MEA, a submission would be considered for a MES when there was 'a high clinical need for the proposed drug in the indication requested by the sponsor', and that 'new clinical data would resolve the issues of uncertainty in relation to the extent or value of the clinical effect which would have otherwise prevented an initial positive recommendation'. This includes the possibility of a randomised controlled trial (RCT)-based managed entry scheme with a</p>

	<p>trial protocol available at the time of the original submission. (34)</p> <ol style="list-style-type: none"> 2. A product will be listed at a price commensurate with it being cost-effective based on the evidence existing at launch. Thereafter, the price of the product will be adjusted (upward or downward) on the basis of cost-effectiveness estimates arising from the generation of further randomized clinical trial (RCT) evidence (postlaunch). (9)
Patient Access Scheme	<ol style="list-style-type: none"> 1. Typically involve either free drug or discounts for an agreed period to enhance the value of new medicines and improve the possibility of their funding/reimbursement. Patient access schemes also include price-capping schemes, which focus on controlling the financial impact but from an individual patient perspective. (14) 2. Alternative market access agreements, typically between payers and manufacturers, to enable provisional or conditional coverage of promising health technologies. (15) 3. Agreements between payers and pharmaceutical/medical device companies are implemented to address financial and clinical uncertainties. (16)
Risk-sharing Agreement	<ol style="list-style-type: none"> 1. Risk-sharing agreements (RSAs) are set between pharmaceutical companies and payers to enable rapid access of patients to new health technologies that have uncertain value. (35) 2. Link coverage and reimbursement levels to real-world performance or utilization of medical products. (36) 3. An agreement between the producer/manufacture and the payer/provider that allows access (coverage/reimbursement) of a health technology under certain conditions. These agreements may use a variety of mechanisms to address uncertainty about technology performance or to manage technology adoption in order to maximise their effective use or to limit their budgetary impact'. (17)

	<ol style="list-style-type: none"> 4. Pharmaceutical companies and insurance payers mutually agree to share the financial burdens or uncertainties regarding clinical outcomes. (37) 5. Enable access to treatments where traditional appraisal processes would not lead to their use/reimbursement. (38)
Risk Sharing Scheme	Agreements concluded by payers and pharmaceutical companies to diminish the impact on the payer's budget of new and existing medicines brought about by either the uncertainty of the value of the medicine and/or the need to work within finite budgets. (14)
Risk Sharing Contract	Manufacturer charges less for the cost of therapy for patients or populations with suboptimal results or missed health outcomes. (39)
Value-based Contracts	<ol style="list-style-type: none"> 1. A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures. (4) 2. Innovative payment models to link reimbursement to a treatment's real-world performance. VBCs between Medicaid and the manufacturer are a way to spread costs over time based on the therapy's performance, thus alleviating potential budget shocks and ensuring financial risk is shared between Medicaid and the manufacturer. (40)
Value-based Pharmaceutical Contracts	<ol style="list-style-type: none"> 1. Performance-based reimbursement agreements typically between health care payers and medical product manufacturers in which the price, quantity, or nature of reimbursement are tied to clinical, intermediate, or economic endpoints. (41) 2. Performance-based reimbursement agreements between payers and pharmaceutical manufacturers in which the price, quantity, and nature of reimbursement are tied to clinical, intermediate, or economic endpoints. (42)

Value-based Purchasing	Agreement where providers are paid fee-for-service with payment adjustments up or down based on value metrics, a structure also known as pay-for-performance. (43)
Value-based Purchasing Arrangement	Outcomes-based contracts where payment is tied to reaching pre-determined goals – sometimes clinical, but not necessarily – and reducing payer risks. (44)
Value-based Pricing	A drug’s price is based on its cost-effectiveness, calculated by the relative cost per unit of benefit—whether measured in quality-adjusted life-years (QALYs), future healthcare costs avoided, budgetary impact, or other metrics. (45)
Combination Managed Entry Agreement	Rely on both financial and performance considerations to address different issues at the same time, for example, budget impact and use, and access and cost-effectiveness. (18)
Enlightened Risk Sharing	An agreement based on enlightened capitalistic decisions from the part of the pharmaceutical companies to maximize profits by procuring a wide consumer base through broad access to their drugs, and on a cooperative model of financial risk sharing among the main stakeholders. The cost of making pharmaceuticals accessible is distributed between the three parties, so that no single party is left facing a disproportionate share of the costs. (66)
Reimbursement Model	Arranged into purely financial (e.g., discounts) and outcome-based agreements (e.g., pay-for-performance). (22)
Payment Model	Payment models can be broken down into upfront payments or delayed payment models (e.g., annuity payment and payment at outcomes achieved). (22)
Population (indication) specific Managed Entry Agreement	Population (indication) specific arrangements limit the financing to a subpopulation of patients, e.g., per indication, or by a defined severity level. (46)
Outcome Based Agreement	Agreements based on defined outcomes (generally clinical) or agreements based on the development of new evidence. This includes patient risk sharing agreement (price decided based on

	<p>patient subtypes with respect to probability of benefits of treatment. (6)</p>
Outcome-based Agreement	<ol style="list-style-type: none"> 1. Where reimbursement/ price depends on the post-marketing impact of a medicine on health (e.g., coverage with evidence development and performance-linked reimbursement. (47) 2. Provide access to therapies with uncertain clinical benefits by adapting the amount or level of reimbursement based on achieved health outcomes. (26) 3. Address uncertainty regarding the clinical and/or cost-effectiveness of new medicines. In addition, they play a significant role in managing budget impact and utilization. (48) 4. Schemes between healthcare payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life. (34)
Outcomes-based Agreement	<ol style="list-style-type: none"> 1. Links the reimbursement of the medicine to clinical outcomes, measured with regard to patient quality or quantity of life. (20) 2. These agreements, established between manufacturers and payers, allow for market access of therapies under specific pre-determined, agreed upon conditions directly tied to outcomes these therapies intend to deliver to patients. (23) 3. A subset of what has been called performance-based risk-sharing arrangements. (67) 4. Link the level of payment to defined therapeutic outcomes of the technology, therefore focusing on product performance and potentially enforcing real-world evidence (RWE) collection. (9)
Outcome-based Managed Entry Agreement	<p>Outcome-based managed entry agreements with spread payments in the context of addressing the high budget</p>

	impact and clinical uncertainties associated with advanced therapies. (28)
Outcomes-based Managed Entry Agreement	A MEA that can help determine/check the real-world effectiveness of OMPs within the healthcare setting. (38)
Outcomes-based Risk-Sharing Agreement	<ol style="list-style-type: none"> 1. The manufacturer provides or agrees to rebates, refunds, or price adjustments if their product fails to meet agreed-upon clinical outcome targets. (49) 2. Agreements based on clinical results, i.e., associated with the performance of the medicinal product in real clinical practice. In this type of RSA, there is an agreement between the payer/provider and the pharmaceutical company for the collection of real-world data and the payment is based on the observed results. (50)
Outcomes-based Scheme	<ol style="list-style-type: none"> 1. Agreements where the cost of the drug depends on the outcomes of treatment, as determined after launch in the “real world” clinical setting. (51) 2. The price, level, or nature of reimbursement are tied to clinical or intermediate endpoints measured in the future and ultimately related to patients’ quality or quantity of life. (24)
Outcomes-based Contract	A type of risk-sharing arrangement (RSA), that has emerged as a promising avenue for payers to engage with manufacturers in linking value-based payments (i.e., reimbursement and rebates) with real-world outcomes. (53)
Value-based payment/ outcomes-based arrangements	Spread the cost of therapies over time or tie reimbursement to outcomes. (52)
Outcomes Guarantees	<ol style="list-style-type: none"> 1. Payer only supports costs of patients not reaching a predetermined response are fully or partially paid back by the pharmaceutical company. (50) 2. An agreement where the manufacturer provides rebates, refunds or price adjustments if the product fails to meet the agreed outcome target. (33)
Pay-for-outcome/ outcome guarantees	The price level and/or revenue received is related to the future performance of the product in either a research or real-world environment. Therapy costs are eliminated or reduced by the manufacturer if outcomes are not achieved. (3)

Outcomes-based payments	Outcomes-based agreements or contracts adjust the effective price of a treatment for individual patients. Financial adjustments can be either prospective or retrospective; the payer can make payments only if the treatment works or can receive refunds if the treatment does not work. (1)
Population Outcomes-based Agreement	Payer adjusts price for all patients based on proportion achieving treatment outcomes. (1)
Outcomes-based Reimbursement	Tying the payment mechanism to patient outcomes achieved in the real world. (47)
Outcomes-based Annuity	Payer pays a fixed price with payments spread over many instalments but only if the drug continues to meet certain prespecified outcomes. Payer and manufacturer share risk. (15)
Performance-based annuities	A type of performance-based contract in which payments for a cell or gene therapy are spread over multiple years and linked to therapy performance. If a therapy fails to deliver an agreed outcome, no further payments are made. (32)
Outcome-based spread payments	Paying for gene therapies with instalments over multiple years corrected for real-world outcomes of the treatment. (26)
Outcome-based Pricing	A drug manufacturer might sell the drug at a given price, but owe the rebate to the drug's purchaser if it failed to confer a benefit. It's like a money-back guarantee. Alternatively, the purchaser could pay a base rate for the drug, with the obligation to make further payments only if patients meet particular health milestones (e.g., remission for a cancer drug). It's like getting a bonus for performing a job especially well. (27)
Outcome-based Coverage Agreement	Link the price paid for a technology to an agreed measure of clinical outcome. (29)
Outcome-guarantee Scheme	Patient level OBAs that include rebates or reimbursement if the medicine fails to achieve the expected results, or conditional continuation schemes. (34)
Health-outcome-based Scheme	The final price of a product is linked to health outcomes observed in real life. (33)
Outcome-based Coverage Decision	Link the effective price paid for a technology to some measure of clinical outcome and, therefore, operate at the

	level of the individual patient (although these can be aggregated and so operate at the population level). (8)
Price linked to Outcome Scheme	Involve the price being directly linked to a specified outcome for each patient. These schemes share similarities with money-back guarantees, although the risk is still shared because the better a patient's outcome the higher the price. (8)
Money-back Guarantee	These involve a refund to the health service if a patient does not achieve a specified target. These schemes can be considered "risk shifts," where the risk of a patient not achieving the outcome, and therefore having a negative NHB if the list price was paid, is shifted from the purchaser to the manufacturer. (8)
Individual Outcome-based Managed Entry Agreement	Ensuring appropriate use and assessment of outcomes for each patient (paying only if response achieved or refund if response not achieved, continuation of treatment according to certain responses). (38)
Population Outcome-based Managed Entry Agreement	Collection of data to aggregate for reappraisal. (38)
Performance-based Managed Entry Agreement	<ol style="list-style-type: none"> 1. Link the reimbursement level to well-defined clinical outcomes in the real world and include different forms such as money-back guarantees and conditional treatment continuation. (18) 2. An agreement with the objectives of progressively reducing uncertainties about a drug's performance, mitigating healthcare payers' financial risk, and managing budget impact. (39) 3. Link drug reimbursement to a drug's performance or patient outcomes. (54)
Performance-based Agreement	<ol style="list-style-type: none"> 1. Address the uncertainty with respect to evidence on clinical outcomes or eligibility of patient populations. Instruments of performance-based agreements include outcome guarantees, patient eligibility requirements/registries, and coverage with evidence development. (5) 2. PBAs seek to reduce uncertainties surrounding the effectiveness of a product by holding manufacturers accountable for their outcomes in the real world post approval. (4)

Performance-based Contract	Link payment to the clinical performance of a therapy over time, which allows manufacturers to share in the risk related to uncertainty around clinical outcomes. (56)
Performance-based Risk-sharing Arrangement	<ol style="list-style-type: none"> 1. MEAs that measure health outcomes in characterising performance. (53) 2. Health insurers have implemented various contracts and arrangements with drug manufacturers in response to uncertainty around clinical outcomes for specific drugs. Such arrangements include, but are not limited to, value-based contracts, outcomes-based contracts, risk-sharing agreements, coverage with evidence development (CED), and managed entry schemes. (40)
Performance-based Risk-sharing Agreement	<ol style="list-style-type: none"> 1. If the medication fails to meet a clinically defined outcome or specific cost-effectiveness threshold, the payer typically receives a reimbursement from the manufacturer. (35) 2. Contracts between a health care payer and manufacturer, in which both parties share risk for the performance of a product in a defined patient population, tying payment to outcomes achieved. (49)
Performance-based Model	Schemes whereby companies refund agreed monies or provide free drug if the desired outcomes are not reached. Alternatively, a price reduction if the new drug fails to deliver the desired health gain in practice. (14)
Performance-linked Payment Scheme	The financing is linked to a measure of clinical outcomes. (17)
Performance-linked Reimbursement Scheme	Aim to manage utilisation and guarantee the cost-effectiveness of a new health technology in the real-world by linking performance at the individual patient level to payment or reimbursement of a new technology. (53)
Performance-linked Reimbursement Arrangement	The reimbursement level of the drug is linked to the measure of clinical outcomes. (7)
Pay-for-Performance Scheme (Fully Penalized)	Fully penalizes the firm (i.e., firms must pay back the whole price of the drug to the healthcare system) when the treatment does not work. In such cases, the firm has to return the payments

	made for such treatments to the health authorities. (57)
Pay-for-performance (P4P)	An agreement between payer and manufacturer where “the price level and/or revenue received is related to the future performance of the product in either a research or a real-world environment. (2)
Payment for Performance Agreement	P4P is set to pay only for patients who achieve a pre-specified response to a drug. While P4P must involve defining individual patient's response, it does not have the potential to deliver high-quality data on drug's actual (cost-) effectiveness and does not lead to a more evidence-based reimbursement decision or HTA recommendation.
Pay-for-failure Scheme	Manufacturers offer rebates or discounts to payers for treatment failure. (42)
Pay-for-success Scheme	Manufacturers offer rebates or discounts to payers for treatment success. (42)
Pay at outcomes achieved	Paying treatment costs only after results have been achieved. (3)
Payment by result	Extends the modalities of RS by providing 100% reimbursement by the MAH to NHS for non-responders. It consists of a months-based payback model. (38)
Payment at result	Exploits the SF paradigm: the hospital pays the MAH only if the treatment is successful (outcomes-based) after starting with a free supply or upfront payment. It involves an annual payment model. (38)
Pay-over-time Scheme	An outcome-based, pay-over-time option for a maximum of 5 years, with payment stoppage in case of no observed therapeutic effect. (65)
Success Fee	It is based on the definition of the responder: the hospital/pharmacy pays the MAH only if the treatment is successful after starting with a free supply. (38)
Flexible Pricing Model	Payer and manufacturer would agree on a list price and conditions under which a discount would be modulated as pre-set outcomes would be met. (6)
Service-based Agreements	Services funded by manufacturers dedicated to facilitate patient management from several perspectives (patients, healthcare professionals, healthcare providers) ensuring better use and better outcomes of expensive therapies. (4)

Shared Accountability Model	Incorporates services that support a patient throughout their care transitions that aim to optimize their outcomes. (39)
Cross-Company Deal	Funding a new medicine at an agreed price in a defined patient population in exchange for the manufacturer lowering the cost of their other listed medicines. (68)
Market Access Agreement	Finding a compromise between health care payers and the industry on the drug's price and reimbursement status, HTA recommendation (for specific populations of patients) and/or formulary listing. (64)
Commercial Agreement	Permanent agreements in a sense that they do not assume a future final reimbursement decision in light of new data on pre-specified health outcomes from a well-designed study. (Error! Reference source not found.)
Improved Value-based pricing reimbursement	Payment for pharmaceuticals is split between county council and state. The county councils pay the marginal cost of production while the state pays for the innovation. (62)
Financed-based Agreement	Aim to contain costs and facilitate the affordability of a product on the market by also including the manufacturer on the financing of a product. (4)
Financial Based Agreement	Agreements between manufacturer and payers based on observable financial performance. This includes price agreement based on manufacturer's market share, price-volume agreements, pricing by channel (discounts on certain products/channels), capitation (discounts for specific patients), free in initiation (patient/ dose dependent discount), portfolio agreement (discounts based on manufacturer's portfolio. (6)
Financial-based Agreement	<ol style="list-style-type: none"> 1. Require company contributions to the cost of the particular pharmaceutical product i.e. through discounts, rebates, cost-capping, price-volume agreements or utilisation caps. (20) 2. Reimbursement / price depends on the post-marketing impact of a medicine on the payers' budget (e.g., price-volume agreements, spending cap on medicines). (47)

	<ol style="list-style-type: none"> 3. Address cost-sharing efforts, facilitate manufacturer contributions to the cost of a new health drug, product, or technology (e.g., discounts or rebates, price-volume agreements, utilization caps) for a particular patient or population without linking reimbursement to health outcomes. (67) 4. Controlling and managing budget impact based on financial metrics (e.g., total sales) or real-world utilization are the main objectives of these agreements. (48)
Financial-based Arrangement	Aim to address concerns over the budgetary impact associated with the introduction of a new health technology. (53)
Financial-based Managed Entry Agreement	<ol style="list-style-type: none"> 1. Use financial considerations to determine the price and nature of reimbursement, regardless of the drug's performance, such as price/volume, discounts, patient/dose-dependent discount, or price capping. (18) 2. These schemes are not linked to health outcomes and may include patient spending caps, stopping rules, among others. (17) 3. Indirectly lower drug prices through simple discounts, price-volume agreements, or rebates. (54) 4. Represent a route to manage uncertainty around the budget impact of a new technology by setting and tracking usage or financial parameters. (9)
Financial-based Risk-sharing Agreements	<ol style="list-style-type: none"> 1. These agreements specify the cost-containment process such as simple price discount/caps, utilization caps, and budget caps, or discounts based on data from real-world (clinical) effectiveness. (35) 2. Reimbursement is tied to financial measures (e.g., total sales) or to utilization. (49) 3. Cost containment is defined merely on the basis of the price of the medicinal product or the cost of the treatment. (50)
Financial Scheme	Financial schemes focus on targeting the financial impact of new drugs to patients and/or health systems and

	leverage instruments such as discounts, price/volume agreements, patient/dose-dependent discounts, and utilization-based price capping. (5)
Financially-based Scheme	Negotiate company contributions to the cost of a product (e.g., discounts or rebates, price-volume agreements, utilization caps) for a particular patient or population without linking reimbursement to health outcomes. (24)
Non-outcome-based Coverage Agreement	Non-outcome based, or financial-based agreements are usually implemented to reduce the budget impact uncertainty (e.g., due to unknown number of patients) associated with the use of a technology. These agreements which can be implemented both at a patient (e.g., duration of treatment) or a population level are used to limit the expense on a treatment without limiting the number of patients that benefit from it. (29)
Non-outcome based Agreement	Usually financial in nature and aim to contain the costs without taking into consideration health outcomes. They may include price-volume agreements, discounts, price-capping schemes or dose-capping schemes. (34)
Non-health-outcome-based Scheme	Agreements such as simple confidential discounts and price-volume agreements. (34)
Patient-level non-outcome-based coverage decision	Different effective prices for a given technology for different patients, but this is not achieved by linking prices to measures of outcome; rather, prices are linked to other factors associated with treatment. (8)
Population-level non-outcome-based coverage decision	Characterized by the effective price being determined at the level of the health care system rather than the individual patient. (8)
Coverage with Evidence Development MEA	Permit the early adoption of pharmaceuticals for a limited time under the explicit requirement of gathering additional evidence. (18)
Coverage with Evidence Development	1. Allows access to the drug while evidence is generated; reimbursement continuation, including price and reimbursement conditions, may be dependent on additional data gathering and presentation. (50)

	<ol style="list-style-type: none"> 2. A conditional reimbursement linked to the collection of post-launch real world data. (2) 3. Payer adjusts price for all patients based on re-evaluation of drug cost-effectiveness. (1) 4. Agreement that involves purchasing the medicine and running a health outcomes study on a cohort of patients. CED always leads to a scheduled reassessment of the drug's (cost-) effectiveness, price revision and to regular reimbursement status. (Error! Reference source not found.) 5. A positive coverage decision is based on the collection of additional evidence (only with research or only in research), might result in continued, expanded, or withdrawn coverage. (67) 6. Coverage decision is conditioned upon the collection of additional population-level evidence. (53) 7. Population level OBA defined as 'any policy mechanism that links financial support for medical technologies or treatments to a requirement for systematic data collection and analysis with the intent of using that data to modify health policy or clinical decision - making'. (34) 8. Reimbursement where additional data gathered in the context of clinical care would further clarify the impact of the medicines, and patient eligibility linked to patient registries to measure post-marketing clinical outcomes. (33) 9. Provisional reimbursement of promising technologies with limited clinical evidence. Temporary reimbursement is granted with an obligation for the manufacturer to obtain and provide additional data. Can be organized either with patients only having access when included in the study (only in research) or with an obligation to generate data and unrestricted access (only with research). (3)
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	10. Involves an agreement by a health insurer to provide broader coverage for a promising treatment despite evidence gaps and is contingent on the facilitation of additional collection of data. (40)
Conditional Coverage Agreement	Coverage is granted only on the basis of a program of further data collection. (51)
Conditional Coverage Scheme	Coverage is granted conditionally upon the generation of RWE from clinical practice. Once additional evidence is gathered, prices and reimbursement may be re-negotiated. Conditional coverage schemes are divided into two categories, coverage with evidence development at the population, or at the individual level. (17)
Conditional Coverage Arrangement	Coverage is granted conditionally on the initiation of a program of data collection that informs the use of the drug in the payer population. (7)
CED Only in Research	Coverage of a technology is available only to patients involved in research. This option may involve the purchaser paying for the research, requiring some influence over research decisions (i.e., being able to contract for the research to be conducted). Alternatively, it may involve the purchaser rejecting the technology and simply recommending research, with the research being paid for by another party (e.g., the manufacturer or another stakeholder), which would not require the purchaser to be able to ensure the research was conducted. (3)
CED Only with Research	A positive coverage decision is conditioned upon the collection of additional evidence to support continued, expanded, or withdrawal of coverage. So, the technology is covered for relevant patients, but further research is also required. This research may be funded by the purchaser, the manufacturer, or another stakeholder, but such a decision would require that the purchaser is able to enforce that the research is actually conducted, and so it will be treated here as an available option only when the purchaser can ensure the research is conducted. (8)
Evidence Generation Agreement	Utilised where a positive reimbursement decision is dependent upon the

	collection of additional evidence for the respective pharmaceutical. (20)
Evidence Generation Scheme	A positive coverage decision is conditioned upon the collection of additional evidence through clinical studies, which might result in continued, expanded, or withdrawn coverage. (24)
Coverage with Evidence Generation	Manufacturer is financially liable or upside may be based on real-world evidence outcomes (e.g., from registries, active surveillance, claims). (39)
Temporary Authorization for Use	Allows reimbursed access before marketing authorization approval, to therapies that hold particular therapeutic promise and are not currently available through clinical trials in France. Under the ATU program (and until the HTA and pricing negotiations have been completed with national authorities), the manufacturer can set the price freely, subject to an annual spending cap and the potential for postlaunch paybacks. (41)
Conditional Treatment Continuation	<ol style="list-style-type: none"> 1. Only patients achieving a previously defined level of response are eligible for reimbursement. (50) 2. This involves the health system paying for the continued use of a technology only in those patients who have achieved a target clinical effect. (8) 3. Based on individual patient's response after treatment. If the response meets the predefined treatment goal, the drug continues to be reimbursed by the payer, the National Health Insurance Service (NHIS). Otherwise, the company should refund the full drug costs to the NHIS. (55) 4. Continuation of coverage for individual patients is conditioned upon meeting short-term treatment goals. (3)
Patient Assistance Program	Pharmaceutical companies donate anticancer drugs to patients who cannot afford them for low or no cost. (54)
Milestone-based Contract	<ol style="list-style-type: none"> 1. A type of performance-based contract in which a manufacturer guarantees to refund the cost of therapy (partially or fully) to the payers if an agreed outcome is not achieved. (15)

	<ol style="list-style-type: none"> 2. A type of performance-based contract in which a pharmaceutical company guarantees to refund the cost of therapy (partially or fully) to the payer if an agreed outcome is not achieved. (32)
Amortization	<ol style="list-style-type: none"> 1. Amortization is an accounting concept applied to intangible assets that allows for spreading the cost an intangible asset over time, allowing for repayment to occur via interest and principal payments sufficient to repay the intangible asset in full by its maturity. This allows to avoid the cost of the asset being concentrated on the year of acquisition. (23) 2. The concept of amortization introduces the principle that the payments for a high-cost product should be spread over a period of time during which the benefits of the health technology may be accrued, while at the same time, payments and costs of the disease are continuously reduced as time goes on. (4) 3. Payer enters into an agreement with a drug manufacturer, with terms that enable the payer to allocate the costs of the treatment in prescribed milestones, while the manufacturer allocates revenue on the same schedule or based on agreed-upon financing measures. (59)
Annuity/Amortization Model	Spread a fixed cost over time, as opposed to paying the full cost of a one-time treatment up front, may help to solve the challenges associated with a high initial cost. (15)
Amortisation (Installment payments)	Payer makes fixed payments, dividing total cost of drug over multiple years. (60)
Annuity payments	<ol style="list-style-type: none"> 1. Annuity or Installment payments allow for payers to pay for the costs of a GRT on an installment plan, which could be annually or based on another agreed upon schedule between manufacturer and payer. (23) 2. An agreement between manufacturers and payers aiming to replace the high upfront cost with a stream of payments

	<p>triggered, at patient level, by the achievement of clinical milestones. (2)</p> <ol style="list-style-type: none"> 3. A specific form of spread payments, are paid once every year instead of every few months. This reimbursement method combines an OBA with spread payments over time which may solve the immediate unaffordable budget impact caused by the high upfront treatment price while the inclusion of an OBA foresees the correction of payments for real-world performance solving both short- and long-term clinical uncertainties. (26) 4. Spreading payments over multiple years, with an agreement upon amount of treatment or outcomes delivered. (3)
Drug Mortgage	<p>Spread out payments over time, enabling patients (or, more likely, their insurers) to avoid a large one-time payment for a drug that confers a lifetime of benefits. Drug mortgages make a great deal of sense for cures and other drugs that require only a short course of treatment but offer substantial health gains. (27)</p>
Reinsurance	<ol style="list-style-type: none"> 1. Reinsurance occurs when payers insure themselves in the case of large, unpredictable, emergent payouts. Reinsurance payments could occur annually or via an agreed upon timeline. This option rather addresses the risk of disproportional distribution of patients with highly costly therapies among insurers. (23) 2. An insurance policy that insurers buy to protect against excess financial risk. (2) 3. Payer pays premium per patient to third-party reinsurer, reinsurer reimburses payer for drug costs. The insurance is secondary insurance for insurance companies and stop-loss insurance for self-funded employers. (1) 4. An insurance policy that insurers buy to protect against excess financial risk. (61)
Reinsurance Risk Pool	<p>The high aggregate costs of drug treatment for an individual patient are borne by a risk pool of multiple payers.</p>

	This pool reimburses payers for the portion of claims incurred by high-cost patients, the same way reinsurance does now for very high-cost healthcare claimants in general. (2)
Risk Pool	Payer makes contributions to a common fund, fund reimburses payer for drug costs. (1)
Stop loss Coverage (Reinsurance)	The high aggregate costs of drug treatment for an individual patient are borne by a risk pool of multiple payers. (55)
Stop-loss/ Reinsurance	Carrier provides protection against shock claims (high-dollar, low frequency events and overall exposure) in exchange for an annual premium. (15)
Risk Adjustment Program	<ol style="list-style-type: none"> 1. All payers pay into a fund that compensates those payers that incur unusually high costs. (2) 2. All payers pay into a fund that will compensate those payers that incur unusually high costs. (61)
Risk Corridors	<ol style="list-style-type: none"> 1. U.S. Department of Health and Human Services (HHS) collects funds from plans with lower than expected claims, and makes payments to plans with higher than expected claims. Plans with actual claims less than 97% of target amounts pay into the program and plans with claims greater than 103% of target amounts receive funds. (2) 2. Limit both downside risk of losses and excess profits for health plans. (61)
Risk Carve-out Solution	Payer delegates coverage, management, and coordination for product to a third-party in exchange for a premium. (15)
Insurance Pool	Several or all health insurers in a catchment area or a country teaming up to contribute to a joint fund in order to finance specific costly projects. (23)
Orphan Reinsurer and Benefit Manager (ORBM)	A risk pooling solution to manage actuarial risk and executional challenges, including contracting, reimbursement, and care coordination. (15)
Healthcoin	<ol style="list-style-type: none"> 1. Healthcoin converts incremental outcomes produced by a GRT to a common currency. This would appeal to a multi-payer system where there is a high insurance provider turnover. (23)

	<ol style="list-style-type: none"> It converts the incremental outcomes produced by curative treatments to a common currency, such as life-year equivalents. Healthcoin can be exchanged for US dollars in the marketplace. (2)
Price-Volume Agreement	<ol style="list-style-type: none"> These focus on controlling financial expenditure with pharmaceutical companies refunding over budget situations. (14) Unitary price reduction after a certain volume is reached. (50) Agreements where drug prices are reduced based on sales volume (e.g. after every 10,000 vials sold, the price is reduced by 20% for the next vials). Alternatively, depending on the total sales volume, the price will be discounted for all vials sold, according to a predefined scheme. (2) Payer pays full price per patient, drug price decreases as more patients treated. (1)
Price Volume Agreement	<ol style="list-style-type: none"> Most common form are “weighted use” prices across different indications for the same drug and price falls/rebates if usage is beyond agreed amounts. Drug prices are progressively lowered as more patients receive the treatment. (3) Link the price paid per unit for a health care technology to the total number of units purchased. (8)
Price Volume Agreement ‘with cap’	<p>Stipulate the volume that may be sold, based on forecast sales. If the sales volume or budget is exceeded, the pharmaceutical manufacturer is penalised, usually by having the price of the drug reduced (i.e. discount) or by having to pay-back (i.e. rebate) the amount of sales above the agreed levels. (53)</p>
Price Volume Agreement ‘without cap’	<p>The unit price of a drug is linked to the expected volume sold (negotiated at product launch), so that it declines when volume increases. (53)</p>
Price Cap/ Volume Cap (patient level)	<p>Control and limit pharmaceutical prices and manufacturer revenues. At patient level, they aim, respectively, at capping</p>

	the yearly price, or the number of yearly treatment courses reimbursed. If additional courses are needed, these have to be provided by the manufacturer free of charge. (2)
Price cap/Volume cap (population level)	At population level, these strategies aim at capping the yearly expenditure or volume the manufacturer allowed to be sold. Beyond the cap, manufacturer may have to reimburse the full retail price, the full ex-factory price, or a proportion of the price, depending on the agreement. (2)
Volume-based rebate	Payer receives a rebate if the volume of patients exceeds a certain threshold. (65)
National Volume Cap	National or regional volume caps aim at limiting the volume of sales of a drug in a given geography. The rationale may be driven by either the budget constraint, epidemiology, or a combination of both. (4)
Warranty	<ol style="list-style-type: none"> 1. Payer pays full price upfront, manufacturer pays premium to third-party insurer, insurer reimburses payer for costs of treatment failure. (1) 2. A manufacturer purchases a patient-specific warranty policy that reimburses treatment-related costs for suboptimal performance to payers over an agreed time period. (15) 3. A pharmaceutical company purchases a patient-specific warranty policy that reimburses treatment-related costs for suboptimal performance to payers over an agreed time period. The value is related to covered healthcare costs and is not a refund for the cost of the treatment. (32)
Subscription	<ol style="list-style-type: none"> 1. The payer does not purchase individual units of the drug but pays the manufacturer a set price for an unlimited supply. (1) 2. A pharmaceutical company provides treatment for a set fee regardless of the number of patients treated or a set price per patient. (32)
Subscription Model	Manufacturer provides treatment for a set fee regardless of the number of patients treated or a set price per patient. (15)

Subscription Arrangement	A reimbursement model based on a fixed licensing fee for access, irrespective of the volume of medicines sold. (16)
Health leasing/ Subscription/ Netflix Model	Paying for unlimited use of a therapy during a predefined period. The annual tariff is not linked to the value the therapy provides, since use is unlimited. The tariff may nevertheless be based on an estimation of the use and the prospected benefits, and retrospectively it may be feasible to calculate whether the system as a whole has been cost effective. (3)
Capping	Agreed total budget cap, eligible patients treated for free after cap reached. (38)
Capping of Drug Expenses	Different examples of this type of agreement: maximum no. of reimbursed doses, after which the pharmaceutical company commits to supply/support the remaining doses. The reimbursed treatment duration is agreed after which the pharmaceutical company supports the additional costs required to complete the treatment. Maximum limit for the cost of treatment per patient, after which it is supported by the pharmaceutical company. (50)
Expenditure Cap	<ol style="list-style-type: none"> 1. Payer pays full price per patient until total spending cap reached, then pays nothing for additional patients. (1) 2. Sets the total annual expenditure of the drug in advance. The company pays back an agreed rate of the exceeding amount to the NHIS. (56) 3. Limit the total expenditure on a treatment without limiting the total quantity of the treatment available. (8)
Cost Capping	The maximum cumulative cost of treatment per patient is specified [for a period of time] and beyond this threshold, the pharmaceutical manufacturer provides its drug at a discount or free of charge. (53)
Budget Threshold/ Dedicated Funds	Maximum amount of spending for an individual innovative treatment (budget threshold) or therapeutic area (dedicated funds) to contain total expenditures. Translates into maximum number of patients treated per year or sharing of

	costs with the manufacturer or patients after costs have been exceeded. (3)
Rebate	<ol style="list-style-type: none"> 1. Payments refunded by the manufacturer to the payer after the transaction has occurred. (2) 2. Discounts to the list price of drugs (rendered post sale as rebates) are negotiated in exchange for preferential formulary placement, which increases sales. (54)
Outcome-based Rebate	The payer pays the full price of the drug up front but receives a rebate if the drug does not achieve prespecified outcomes. (15)
Outcomes-based Rebate/ Milestone-based Contract	Payer pays full price up front, manufacturer refunds drug costs to payer for treatment failure. (1)
Value-based Rebate	Payer receives a rebate if the drug achieves specific outcomes. (65)
High-cost drugs rebate model	Rebates by a healthcare payer or a succession of payers to patients with large cost-sharing burdens for high-cost drugs after the completion of, or milestones along, a course of treatment. (55)
100% Pass-through Rebate Model	Requires that PBMs pass 100% of rebates and associated manufacturer fees through to plan sponsors to eliminate the incentive for PBMs to develop formularies that drive utilization to highly rebated drugs despite higher net costs for payers. (62)
Point-of-sale Rebate	Passing all or a proportion of rebate savings directly to patients. This option appears to most directly address high out-of-pocket costs. (62)
Discount/ Rebate	Simple price discounts, publicly or confidentially agreed upon between the payer and manufacturer. (3)
Discount	<ol style="list-style-type: none"> 1. Price reductions granted to payers, usually confidentially, under specific conditions without affecting the drug list price. (2) 2. Therapy is provided by the pharmaceutical manufacturer at a reduced cost to the National Health Service for all eligible patients. (53)
Upfront Discount	Upfront discounts could facilitate the application of cost-effectiveness findings to the development of formularies if prices are known and can be compared at the outset. Discounts

	could be allowed to vary depending on clear and uniform criteria such as formulary placement, cost-effectiveness or expected volume. (62)
Discounted Treatment Initiation Program	Involve patients receiving a technology for a price that is different from the list price at the initiation of treatment. The price then reverts to the list price if the patient remains on the treatment after a set number of courses or period of time. (8)
Free/ Discounted Treatment Initiation	Therapy is free or discounted up to a specified number of doses or treatment cycles. (53)
Special Dedicated Government Fund	Such funds are usually established in single payer systems with their budget established as additional to and separate to the overall health insurance budget. It is an artificial way to cover therapeutics within the healthcare system without directly impacting the payer's budget. (23)
Fund-based Payment/ National Silo	National silo fund for specialist conditions (e.g. the Cancer Drugs Fund). (2)
Social Fund	Financed by private companies and/or insurers. (2)
Cancer Drugs Fund	<ol style="list-style-type: none"> 1. Drugs subsidized under the CDF are those receiving a negative recommendation from The National Institute for Health and Care Excellence (NICE) or those still in the reimbursement approval process. Drugs under the CDF will receive coverage with evidence development for two years with the chances of being delisted if further evidence shows no additional benefits or unresolved uncertainties. (54) 2. Provide patients with access to drugs that have clinically plausible potential with additional data but have not yet been appraised. (40)
Utilization Cap/ Fixed cost per patient	Designates the upper limit of utilization of the drug per patient. Further, the company covers the cost of the drug beyond pre-agreed utilization. (56)
Utilization Cap/ Individual Volume Agreement	Involve the cost of treatment of patients being reduced (often falling to zero) following an agreed length of treatment if the patient is judged still to require further treatment. (8)

Utilization Capping	The total number of doses or cycles of treatment is agreed on. Any excess beyond this limit is penalised financially. (53)
Fixed cost per patient	Involves a set price for an entire course of treatment regardless of the number of treatments received. This involves a risk share between the manufacturer and the purchaser. (8)
Episode of Care	Payment of a single sum for all the care a patient needs over the course of a defined care episode, instead of paying for each discrete service. (2)
Patient-level Cap	For an individual patient, the payer would pay up to a certain dose or cost threshold, and the manufacturer would provide any additional doses for free. (1)
Bundle Payment	An all-inclusive payment per enrollee for a defined scope of services, regardless of the quantity of care provided. (50)
Bundled Service	Manufacturers offer additional patient services with the product. (39)
Healthcare Loans for Patients	An equivalent of mortgages for large health care expenses. (2)
Consumer Loans	Consumers, the patient, are responsible for securing a loan, sometimes referred to as a healthcare loan (HCL), in order to fund their costly therapy. Such a loan could also be amortized, making it more accessible for patients to receive the costly therapy. (23)
Payer Loan	Payers may also receive loans to fund costly therapies. Payers would be expected to pay back these loans. (23)
Credit (Payer Level)	Governments facilitate better credit instruments for public payers. Credit or contracting arrangements between payers and pharmaceutical companies. (2)
Intellectual Property based Payment Model	intellectual property ownership may either be transferred, shared between the public-private partners or licensed out. (48)
Intellectual-based payment (Prizes for patents)	Public buy-out of the therapy, rewarding the manufacturer with a large sum in return for full government control over production and distribution. (2)
Patent Buyout/ Direct Funding	Acquisition of the intellectual properties protecting a therapy globally or within a jurisdiction. (3)

Out-licensing of technology rights	License out production and distribution rights to public or private payers, while the manufacturer maintains intellectual property (IP) rights. (2)
Prolonged Patent Rights	Marketing exclusivity extension, as in the case of orphan drugs. (2)
Upfront Payment	Paying treatment costs upfront at the time of delivery of treatment. Can be combined with rebates when a therapy does not achieve predefined outcomes. (3)
Cost Sharing	Application of a discount (fixed or variable, from MAH to NHS) on the cost of the treatment cycles/ months for all eligible patients. (38)
Copayment	Reimbursement is provided if a certain level of cost-effectiveness is achieved, but different copayment rates are applicable depending on the disease characteristics and patients' needs. (37)
Refund Model	The company refunds a certain percentage of the nominal price of the drug to the NHIS. (56)
Price Change	The negotiation of a price per unit of the technology between the manufacturer and the purchaser that differs from the list price. (8)

S2: Clustered Table

Model Type	Definition
Managed Entry Agreement Patient Access Scheme Risk-Sharing Agreement Market Access Agreement Value-based Contract	An arrangement between a manufacturer and payer/provider that enables access to (coverage or reimbursement of) a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use, or limit their budget impact. (26)
Financial-based Agreements Non-outcomes based Scheme Non-health outcomes Scheme	Financial schemes focus on targeting the financial impact of new drugs to patients and/or health systems and leverage instruments such as discounts, price/volume agreements, patient/dose-dependent discounts, and utilization-based price capping. (5)
Outcomes-based Agreement Value-based Pharmaceutical Contract Performance-based Agreement	Schemes between healthcare payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life. (34)
Service-based Agreement Shared Accountability Model	Services funded by manufacturers dedicated to facilitate patient management from several perspectives (patients, healthcare professionals, healthcare providers) ensuring better use and better outcomes of expensive therapies. (4)
Healthcoin	It converts the incremental outcomes produced by curative treatments to a common currency, such as life-year equivalents. Healthcoin can be exchanged for US dollars in the marketplace. (2)
Coverage with Evidence Development Conditional Coverage Scheme Evidence Generation Scheme	Coverage is granted conditionally upon the generation of RWE from clinical practice. Once additional evidence is gathered, prices and reimbursement may be re-negotiated. Conditional coverage schemes are divided into two categories, coverage with evidence development at the population, or at the individual level. (17)
Pay-for-performance Outcome-guarantee Scheme Milestone-based Agreement Market Access Agreement Performance-based Agreement	Address the uncertainty with respect to evidence on clinical outcomes or eligibility of patient populations. Instruments of performance-based agreements include outcome guarantees, patient eligibility requirements/registries, and coverage with evidence development. (5)
Conditional Treatment Continuation	Based on individual patient's response after treatment. If the response meets the predefined treatment goal, the drug continues to be reimbursed by the payer, the National Health Insurance Service (NHIS). Otherwise, the

	company should refund the full drug costs to the NHIS. (55)
Warranty	A pharmaceutical company purchases a patient-specific warranty policy that reimburses treatment-related costs for suboptimal performance to payers over an agreed time period. The value is related to covered healthcare costs and is not a refund for the cost of the treatment. (32)
Pay for success Pay at outcomes achieved Pay at result	The price level and/or revenue received is related to the future performance of the product in either a research or real-world environment. Therapy costs are eliminated or reduced by the manufacturer if outcomes are not achieved. (3)
Amortisation Instalments Annuity Payments Drug Mortgage	The concept of amortization introduces the principle that the payments for a high-cost product should be spread over a period of time during which the benefits of the health technology may be accrued, while at the same time, payments and costs of the disease are continuously reduced as time goes on. (4)
Expenditure Caps Cost Capping Dedicated funds Budget Threshold Volume Cap	Maximum amount of spending for an individual innovative treatment (budget threshold) or therapeutic area (dedicated funds) to contain total expenditures. Translates into maximum number of patients treated per year or sharing of costs with the manufacturer or patients after costs have been exceeded. (3)
Price-Volume Agreement Volume-based rebate Price cap patient-level	Agreements where drug prices are reduced based on sales volume (e.g. after every 10,000 vials sold, the price is reduced by 20% for the next vials). Alternatively, depending on the total sales volume, the price will be discounted for all vials sold, according to a predefined scheme. (2)
Discounts/Rebates Refund Model	Price reductions granted to payers, usually confidentially, under specific conditions without affecting the drug list price. (2)
Reinsurance Risk Pool Stop-loss coverage Risk Adjustment Program	Reinsurance occurs when payers insure themselves in the case of large, unpredictable, emergent payouts. Reinsurance payments could occur annually or via an agreed upon timeline. This option rather addresses the risk of disproportional distribution of patients with highly costly therapies among insurers. (23)
Risk Corridor	U.S. Department of Health and Human Services (HHS) collects funds from plans with lower than expected claims, and makes payments to plans with higher than expected claims. Plans with actual claims less than 97% of target amounts pay into the program and plans with claims greater than 103% of target amounts receive funds. (2)
Intellectual Property-based Payment Model Patent Buy-Out	Public buy-out of the therapy, rewarding the manufacturer with a large sum in return for full

	government control over production and distribution. (2)
Patent out-licensing	License out production and distribution rights to public or private payers, while the manufacturer maintains intellectual property (IP) rights. (2)
Prolonged Patent Rights	Marketing exclusivity extension, as in the case of orphan drugs. (2)
Utilisation-level Cap Fixed-cost per patient Patient-level cap Episode of care Bundle payment	The total number of doses or cycles of treatment is agreed on. Any excess beyond this limit is penalised financially. (53)
Health Leasing Netflix Model Subscription	Paying for unlimited use of a therapy during a predefined period. The annual tariff is not linked to the value the therapy provides, since use is unlimited. The tariff may nevertheless be based on an estimation of the use and the prospected benefits, and retrospectively it may be feasible to calculate whether the system as a whole has been cost effective. (3)
National Silo Social Fund	Such funds are usually established in single payer systems with their budget established as additional to and separate to the overall health insurance budget. It is an artificial way to cover therapeutics within the healthcare system without directly impacting the payer's budget. (23)
Cancer Drug Fund	Drugs subsidized under the CDF are those receiving a negative recommendation from The National Institute for Health and Care Excellence (NICE) or those still in the reimbursement approval process. Drugs under the CDF will receive coverage with evidence development for two years with the chances of being delisted if further evidence shows no additional benefits or unresolved uncertainties. (54)
Healthcare Loan Consumer Loan	Consumers, the patient, are responsible for securing a loan, sometimes referred to as a healthcare loan (HCL), in order to fund their costly therapy. Such a loan could also be amortized, making it more accessible for patients to receive the costly therapy. (23)
Payer Loan Payer Credit	Payers may also receive loans to fund costly therapies. Payers would be expected to pay back these loans. (23)