IDENTIFYING THE KEY CHALLENGES IN EVALUATION AND PRICING OF ONCOLOGY COMBINATION THERAPIES AND FUTURE POLICY CHANGES USING A WEB-BASED PORTAL TO ENGAGE PAYERS

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MAT|RPR RAPID PAYER RESPONSE

INTRODUCTION

Combinations of two or more branded oncology drugs have improved patient outcomes in several cancers, but are associated with high costs, pose challenges for payers and have faced access barriers.

This research was completed by payers in UK, France, Germany, Italy, Spain, USA and Japan to understand:

- The key challenges associated with evaluation of high cost combination oncology regimens
- The level of discounting expected for the price of combination
- The future policy changes that will impact how payers manage the high cost of combination regimens

METHODOLOGY

A web-based survey was administered through the Rapid Payer Response™ online portal (RPR®) to 40 payers with experience in HTA and reimbursement decision-making for oncology products in the USA (10) and 5 payers per country in France, Germany, Italy, Spain, UK and Japan. Payer profiles included former members of NICE and NHS England in the UK, ex-CEPS and ex-TC payers in France, ex-GBA and SHI payers in Germany and both national and regional level payers in Italy and Spain, Commercial and Medicare payers in the USA and ex-MOH members in Japan. Responses were collected through the RPR® interactive platform in 5 days allowing opportunity to ask clarifying and follow up questions to triangulate insights.

RESULTS

P & R approaches and expectations on discounting for combination oncology therapies

Whilst most scope countries negotiate the national list price of each drug separately, there is a variation in use of additional tools that impact the net price such as budget caps, price-volume agreements, or additional regional or local-level discounts. Most combinations launched to date included an in-market product and a new molecule, with only the new product subjected to price negotiation in most instances. While payers in France and Spain expect pricing discounts on combination regardless of the manufacturer base; in Germany, Italy, UK, USA and Japan greater discounts are expected mostly when products in the combination are from the same manufacturer.

Country	Price negotiation approach	Reference of global price to influence price setting	Pricing approach	Reimbursement and access
FR	Separately if manufactured by different companies or if at least one product is currently on market As combination if manufactured by the same company	✓	1 + 1 = up to 1.5	Additional negotiations on discounts required by CEPS after initial pricing, price-volume and budget ceiling agreement for each molecule
DE	Separately	✗	1 + 1 = 1.2 - 1.6	Calculations based on ex-factory price of the comparator; premium expected only with 'added benefit rating' depends on variety of factors for in-market component
ES, IT	Separately if manufactured by different companies or if at least one product is currently on market As combination if manufactured by the same company	✓	Clinical benefit and budget impact based evaluation	Pricing is proportionate to the clinical benefit offered by the combination therapy, price-volume agreements or regional/local discounts may be negotiated
JP	Separately	✗	Clinical benefit and nascent use of cost - effectiveness	Pricing would be proportionate to the clinical benefit offered by the combination therapy
UK	The combination is evaluated as one therapy but price negotiation is typically done separately for individual components if from a different manufacturer	✗	Cost-effectiveness based approach	Negotiation based on NHS set price of the comparator and incremental cost
US	Separately	✗	1 + 1 = 2 (adding individual component cost)	Cost of complications, overall cost of care also included by some plans. Formulary listing dependent on FDA approval and NCCN recommendation, and not on product cost

Figure 1. Pricing and reimbursement processes for combinations of two or more branded oncology products

Challenges in the evaluation and price negotiation of high-cost combination therapies

Lack of robustness of evidence supporting the value of combination was the key challenge for the majority payers in the reimbursement evaluation and price negotiation of high-cost combination therapies. Value attribution to individual components of the combination and inability to negotiate price with more than one manufacturer are also noted as challenging, but effective management of the overall budget impact remains one of their key payer priorities.

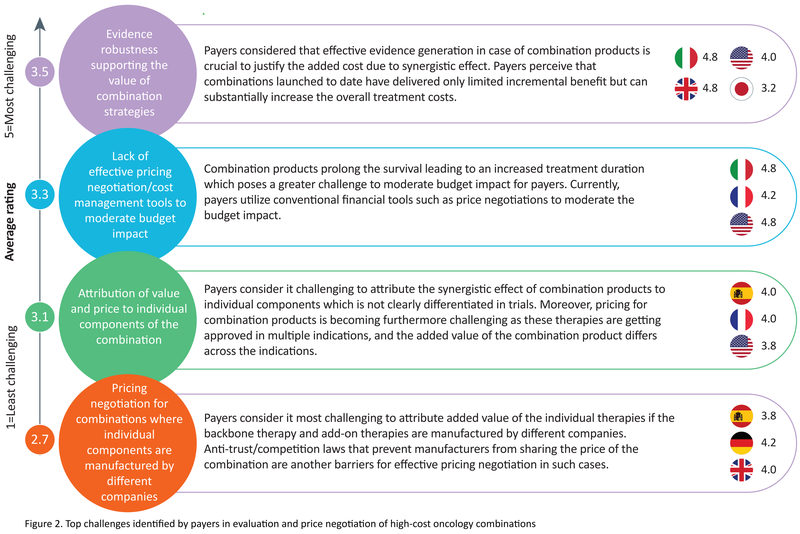

Figure 2. Top challenges identified by payers in evaluation and price negotiation of high-cost oncology combinations

Future policy changes and strategies to manage pricing and reimbursement of oncology combinations

Payers consider that current HTA processes are sufficiently robust to evaluate combination therapies, but expect such treatment strategies to face increased scrutiny in the future due to concerns over rising costs. Most payers see the use of existing cost containment tools such price volume agreements as continuing to play a key role in budget impact management, although introduction of evaluation and pricing frameworks specific for combinations are considered in some markets. Use of indication specific pricing could be an appropriate approach only in specific circumstances, while outcome-based risk sharing agreements are seen as a more likely solution across all markets except the US and Japan. Policy changes facilitating price negotiations with multiple manufacturers have been discussed in the UK and France, but the majority of payers do not expect any major near term changes to the current situation.

Cost containment strategies	DE	ES	FR	IT	UK	US	JP
Increased use of price volume agreements	Possible but low payer interest to apply	Most likely at regional and local level	Used now and likely to increase	Used now and likely to increase	Only for high cost, High impact Tx,	Used in highly competitive classes; can increase	Very limited use currently
Increased use of outcome - based agreements	Only for high cost, high impact Tx, with immature data	Used in some regions already (e.g Andalucia and Catalunia)	For Tx included in registries	Potential increase for drug on registries	Only for high cost, high impact Tx, with immature data	Possible in theory but difficult to implement	Not considered at the moment
Indication specific pricing	Possible but no payer interest to apply	Some regions might consider	For Tx included in registries	Only for high cost, high impact Tx, with immature data	Possible but no payer interest to apply	Possible but no payer interest to apply	Strong payer opposition
Ability to negotiate with both MNFs (if diffrent) and both drug price regardless of label update	Evaluation/pricing framework specific for combination could be introduced	No plan at national level; regions could implement	Not considered at the moment	Not considered at the moment	Changes have been proposed but not progressed, some negotiation is possible via NHS England as an intermediary	No ability to negotiate prices as oncology is a protected therapy area	Not considered at the moment
Other	Elimination of some orphan designation privileges	Use of cost effectiveness methods	Changes to the Accord Cadre with specific provisions for pricing of combinations	Use of subpopulation restrictions	Use of RWE to confirm efficacy	Compliance to NCCN, ASCO and/or ICER guidelines	Use of CE methods (system recently implemented); Compliance with guidelines

Figure 3. Likelihood of future policy changes and use of cost-containment tools impacting pricing and negotiations of high cost oncology combinations

Unlikely	Very unlikely	Niether likely or unlikely	Likely	Very likely

Tx= treatment(s); RWE= Real World Evidence; CE= cost-effectiveness; NCCN= National Comprehensive Cancer Network; ASCO= American Society of Clinical Oncology; ICER= Institute for Clinical and Economic Review

CONCLUSIONS

Manufacturers of products used in combination must consider the nuances of each country's approach in their pricing strategies. While use of indication-specific pricing may be feasible in specific circumstances in Italy, most payers prefer discounting and use of existing financial tools to moderate budget impact. Consequently, manufacturers will also need to actively engage with payers as they develop new policies for pricing of combinations to ensure their products are not undervalued especially when combination components are marketed by different companies.

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