Is Oncology Market Access Indeed Special?

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In September 2016, the Evidera and PPD team consulted the Pricing and Reimbursement Policy Council (PRPC) composed of one current or former payer each from Italy, Spain, England, France and Germany and two current or former payers from the U.S. The council is consulted by Evidera on a regular basis to obtain updates on current policy trends in market access and to debate how manufacturers can best address changing environments and payer demands.

At the September meeting, our interest was to gain the council's perspective on how oncology medicines will be handled by payer organizations in future years. Some countries, such as Germany, assess oncology medicines with the same methodology and thresholds as any other, with oncology orphan medicines also following the same route as other orphans. Other markets have historically given orphan oncology medicines a degree of special status. England's National Health Service (NHS) instituted a specific Cancer Drugs Fund (CDF) for those medicines found not to be cost-effective by the National Institute for Health and Care Excellence (NICE). U.S. payers have found it challenging to value medicines in this sensitive area, and many states mandate coverage for virtually all oncology medicines. Our key question to the PRPC, therefore, was will past trends continue in those countries that treat oncology medicines as a 'special case' (i.e., will they continue to be less subject to health technology assessment (HTA) and price pressures)? If not, how do council members foresee the way in which the balance between high need, innovation, and budget impact will be handled?

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Some clear trends and commonalities emerged from the PRPC, suggesting that payers are increasingly aware of the cost impact of oncology medicines and the difficulty demonstrating additional clinical value as opposed to innovation. Those consulted all indicated that considerations were being given to how this could be better managed.

Quote from a U.S. payer: **"We have concerns and beliefs that many of the new agents offer only small improvements over existing treatments, and not enough to justify the huge cost increases."**

As a clear example of a shift in payer perspective, England's CDF was revised in July 2016, introducing a managed entry period, with the expectation that positive guidance will only be available if final cost-effectiveness figures are within the conventional £20-30K per QALY range. Previously, this range was not applied. This is a highly material change.

Equally in Germany, where oncology treatments never enjoyed a 'special status,' the latest proposed changes to the law to strengthen the supply with medications (Entwurf eines Gesetzes zur Stärkung der Arzneimittelversorgung in der GKV, July 2016, BMG) may

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challenge the access of oncology treatments by objecting to the reimbursement of populations that have not demonstrated an incremental benefit.

Quote from the Spanish PRPC council member: **"I guess part of the contracting will go down DRG type of reimbursement."**

Quote from a U.S. payer: **"In crowded specialty categories like rheumatoid arthritis and multiple sclerosis, we contract for preferred agents and this type of approach could cross over into oncology."**

The fact that some segments of the oncology market are becoming relatively competitive (i.e., with choices now available) gives leverage to payers in many countries when discussing reimbursement prices. In these busier segments, payers are beginning to move into contracting discussions in a similar manner to other therapy areas, without significant hurdles.

Most PRPC council members commented on the imminent and expected arrival of biosimilars into the oncology market, and their expectation that these will enter the market at significantly lower prices, exerting broad downward pressure on prices within the relevant market segment. Pharmaceutical companies need to be aware of this expectation and manage it appropriately to ensure there is no mismatch in expectations. Are the differences between generic products and biosimilars fully understood?

Again learning from past experience in other therapy areas, there is a clear move in most countries towards introducing clearer value frameworks within oncology contracting. Payers from many countries (Italy, U.S., England, France) all mentioned the potential for some type of financial and/or outcome-based risk sharing agreements, and in many countries these agreements are already in place. Italy has had such schemes in place since 2006, and NICE in England and the Scottish Medicines Consortium (SMC) in Scotland have been expecting and accepting such proposals for several years, primarily since they were included as an option within the 2009 UK Pharmaceutical Price Regulation Scheme (PPRS). It appears that the U.S. is also looking at this option.

Quote from a U.S. council member: **"Value-based contracts are in early development, but I think it is unlikely that we will see meaningful value-based contracts with oncology drug manufacturers in the next two to three years due to the complexities of implementing these types of contracts. However, we are seeing the growth of full or partial risk sharing by physician groups."**

The challenges in managing outcome-based schemes are very real (i.e., tracking the relevant outcome over time and over multiple healthcare providers), and ensuring that the consequence if the target outcome is not attained triggers the relevant action is not simple, especially if there are multiple such schemes. If a rebate is then due, ensuring that it can be provided to the relevant payer is also often not simple. Most healthcare systems are not designed to track information in this way, in particular if the patient can move between providers. Consequently, most payers prefer financial-based schemes such as an upfront discount (generally confidential, to maintain the list price) or a price-volume discount arrangement.

With the proposed latest changes in Germany, the ultimate end to free pricing in Germany will be assured. If the proposed change to the law is accepted by the Parliament, companies will face the need for very tough price calculations in the first year of being on the market, and with having to accept the agreed price from the month the revenue will exceed €250M. Equally, the ability to evaluate treatments launched before AMNOG (Arzneimittelmarkt-Neuordnungsgesetz - The Act on the Reform of the Market for Medical Products) in 2014 permanently excluded from any G-BA (Gemeinsamer Bundesausschuss – Federal Joint Committee) evaluations, may be evaluated henceforth if these treatments seek an extension into another indication or line of treatment. This is likely to hit oncology treatments hard.

Pharmaceutical companies need to be aware of these payer considerations and adapt to global and local trends as they develop their launch or lifecycle strategy for each market.

And looking further ahead, payers expressed some concerns regarding the impact of EU adaptive pathways on the ability to maintain any value-based frameworks.

Quote from the Italian payer: **"Adaptive licensing could give a blow to evidence-based medicine."**

Maybe a topic for a future discussion!

Years ago oncology was a uniquely attractive therapy area for drug development. There is still high need, therefore it is still attractive, but it needs significant management.

Historically, oncology has been viewed as a health priority with an elevated social importance that is widely acknowledged by payers and reflected in political initiatives including National Cancer Plans and development research facilities.

Payers have been apprehensive to place downward pressure on prices of oncology drugs to manage budgets, so the strategy has generally been to focus on market access.

Source: www.who.int; www.nhs.gov.uk; www.e-cancer.fr

Given evolving payer trends in oncology and the robustness of manufacturers' oncology pipelines, it is essential for manufacturers to incorporate market access implications into its development and commercialization strategies.

By incorporating the payer perspective into commercialization strategies, manufacturers will be able to help shape future outcomes for pipeline products and achieve optimal pricing and market access (P&MA) opportunities.

The trend that payers across the U.S. and EU5 are creating an increasingly restrictive environment for oncologics will continue and will present a challenge which must be managed proactively, in portfolio and lifecycle management.

"COPD and heart disease are worse ways to die but these don't get a look compared to cancer!"
*– UK payer, 2010**

"Cancer is a priority in France. Our President has said that it is a priority."
*– French payer, 2010**

"Oncology is an area to do with life threatening illnesses affecting all ages, so it will always have a special status."
*– German payer, 2010**

"It's very, very unlikely that cancer will lose its protected status."
– UK KOL, 2010#*

*Entwurf eines Gesetzes zur Stärkung der Arzneimittelversorgung in der GKV, July 2016, BMG

Evidera Payer Research 2010

Table 1: Pricing and Reimbursement Council Feedback on Evolving Trends in Market Access – September 2016

Evolving Landscape		Oncology Management				
		Contracting in oncology	New pricing strategies	Adjusting assessment frameworks	New funding and pricing schemes (i.e. DRG pricing or indication pricing)	Biosimilar preference
U.S.	Hoping that value frameworks will supply the means to manage oncology products better	✓		✓	✓	
ENG	Working within the newly defined Cancer Drug Fund, including a Managed Entry scheme if relevant	✓	*F*	*F*	✓	*F*
GER	Free pricing to be abolished for drugs that exceed €250MEuros in any months during the first 12 months and excluding sub- populations from reimbursement rated "no incremental benefit"*	✓	*F*	*F*	*F*	
FR	The pricing committee considers since March 2016 contracting as a substantial part of pricing	✓	*F*	*F*	*F*	*F*
IT	AIFA pushes for Biosimilar use and encourages the investigation into switching	✓	*F*		*F*	✓
SP	Consideration to pricing aligned to DRG coding	✓	✓	✓	*F*	

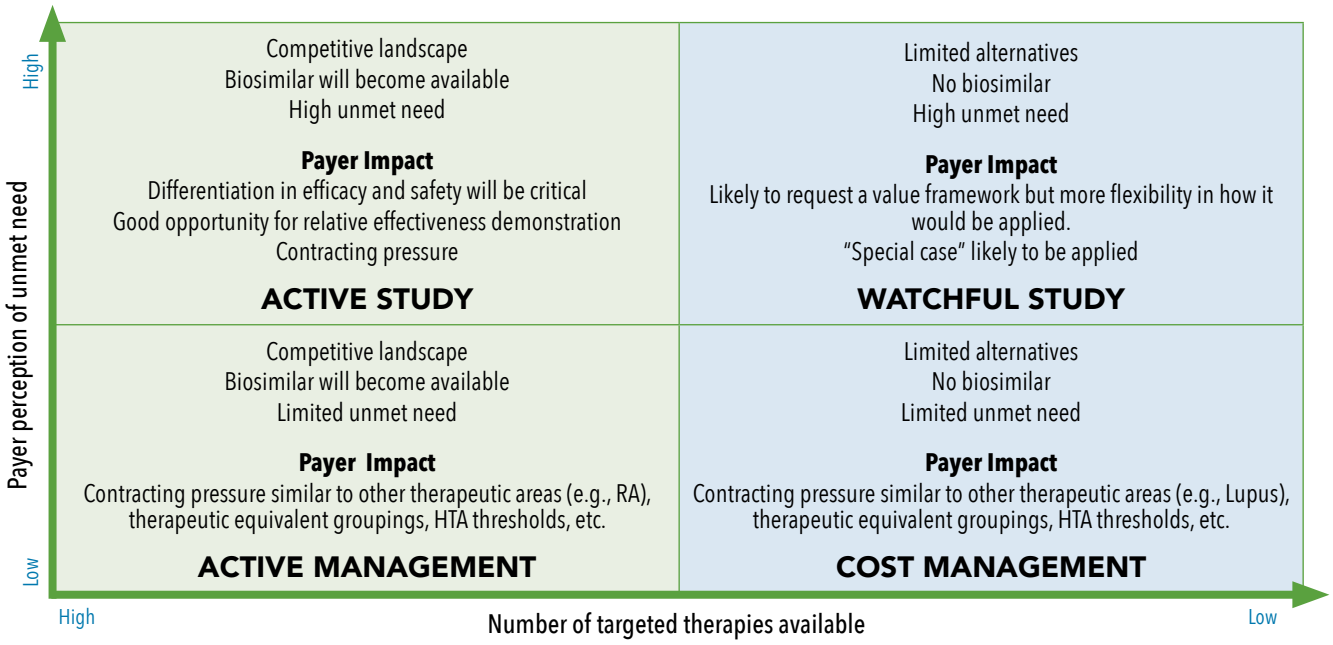
✓ - In place *F* – Likely future consideration

Contracting: financial, volume, target or clinical outcome schemes agreed with funding or pricing agencies valid over a defined period or time or until value review of the molecule.

Biosimilar preference: Preference in treatment initiation or switching to biosimilar use. Italy: http://www.agenziafarmaco.gov.it/sites/default/files/Secondo_Concept_Paper_AIFA_BIOSIMILARI.pdf

*Entwurf eines Gesetzes zur Stärkung der Arzneimittelversorgung in der GKV, July 2016, BMG

Oncology should not be viewed as one environment: Understanding payer views by tumor and specific indication gives insight into their approach to pricing and management



Limited unmet need according to payer perception – current treatments have achieved benefits

Table 2: Concluding Key Trends in the Evolving P&MA Oncology Landscape

Issue	Key Trends
Evolving P&MA Trends	1. Specific oncology indications may remain for the time being "special" to payers (i.e., less focus on price and HTA assessment) depending on the need in the specific indication given current treatments and achieved survival benefits versus economic considerations such as price of competitors, number of alternative treatments, and biosimilar availability. 2. We are already seeing downward pressure on price levels achievable for new oncology agents. Payers will assess their ability to pursue contracting, optimize biosimilar availability and uptake, and improve their means to assess value. 3. New pricing and funding schemes at national/regional and local levels are likely to evolve over the next five to seven years and may hit oncology.
Client Learnings	1. By fully understanding how payers view a specific tumour/indication, manufacturers can develop more successful strategies. • Can a high-need sub-group be identified (e.g., with biomarkers)? • Has the most appropriate comparator in pre- or post-authorization trials been ensured? • What clinical data and real-world evidence (RWE) package is required for contracting? • How can any contracting agreement be operationalized to the uptake management by payers and how will contracting and operationalization be monitored? 2.Transfer learnings from other indications. • Payers are likely to use control and management solutions which have worked well in other high-tech disease areas. 3. Prepare to address funding early in clinical development and when preparing for HTA submission. 4. Be prepared for new stakeholders in price determination – such as on regional and local levels.

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