White Paper

Accelerating patient access to precision oncology in Asia Pacific

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Introduction

Precision oncology can offer a path forward, delivering more targeted treatment options that will redefine the medical paradigm for cancer patients, and reduce the economic burden of cancer care. Precision oncology is defined as an emerging approach for cancer prevention and treatment that uses molecular profiling of tumors to identify targetable alterations. Powered by Next-Generation Sequencing (NGS) technology, there has been a shift from evaluating single biomarkers to Comprehensive Genomic Profiling (CGP)[1]. Unlike conventional testing, CGP uses NGS to rapidly and broadly detect all four classes of gene alterations: DNA mutations, copy number variations, genomic signatures and gene fusions across the genome. By providing more comprehensive molecular insights, CGP enables better-informed treatment decisions.

The advent of powerful NGS technologies has led to the discovery of tumors with rare genomic signatures across diverse cancer types. This has ushered in the development and approval of treatments selected based on the specific variants identified that are agnostic to the tissue of origin, known as tumor-agnostic therapies (TAT)[2]. These therapies have transformed the outlook for several deadly cancers that harbor specific molecular alterations, including non-small cell lung cancer, renal cell carcinoma and colorectal cancer[3]. The number of approved TATs is on the rise and could become a major pillar for oncology treatment[4].

However, there are challenges to the uptake of precision oncology, including health technology assessments (HTA) and reimbursement of precision oncology, as well as clinical and data infrastructure. In Asia Pacific (APAC), HTA systems may not be designed to evaluate precision oncology.

Existing HTA evaluation frameworks are usually specific to a single drug or indication and many markets do not have specific pathways for medical technology or diagnostics test. This could create challenges for the adoption of precision oncology and become barrier for patient access.

Advances in precision oncology, including CGP and TAT, often target newly discovered causes of cancer and defy traditional treatment approaches. Hence there is a need for healthcare systems to evolve so they can accelerate patient access to these innovations and fully capture their health and economic benefits.

Bringing precision oncology to APAC

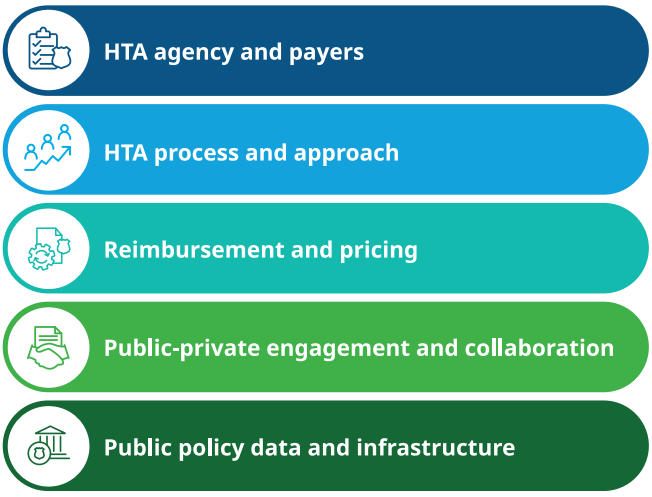
APAC is home to 60 percent of the world's population[5], which continues to be a growing and aging population. This has resulted in an increasing cancer burden, putting pressure on local healthcare infrastructure to deliver better and more cost-effective treatments.

The APAC region is highly attractive for the launch of innovative treatments, including precision oncology. However, there is a mix of mature and emerging markets, each with different political and healthcare priorities. Overall, there is an uneven uptake of precision oncology. In addition, HTA systems in APAC vary in their capabilities, assessment processes and evidence requirement. This means manufacturers will need to

take a tailored approach to engaging stakeholders in each market. To ensure successful market access, a well-prepared evidence generation strategy that supports product value is a must. In addition, continuously raising awareness for precision oncology and communicating the benefits for patients, payers, and the healthcare community will be necessary.

Archetypes and their descriptions

This article aims to assess the adoption of precision oncology in APAC, delving into CGP and TAT as prime examples of diagnostic and treatment innovations that drive the shift towards precision oncology. To understand the priorities of HTAs across APAC, a comprehensive literature review was conducted. Based on the research findings a landscape assessment framework was developed. The five domains of this framework include:



A set of interviews with external stakeholders were undertaken to validate the market evaluation and recommendations to complement the literature review. Eighteen interviews with medical oncologists and HTA/health economic experts from six markets (China, Australia, South Korea, Taiwan, Malaysia and Thailand) were conducted from July to August 2020. In applying this assessment framework, we found varied levels of access and adoption of precision oncology across APAC, particularly CGP and TAT, which we characterized into three main archetypes:

THE INITIALIZING ARCHETYPE

Markets in this archetype, for example China, are formalizing their HTA frameworks and processes for adoption of precision oncology. The HTA bodies are still in the developmental stage, and HTA processes are not yet systematically incorporated into healthcare-decision making. Evaluation of diagnostics, irrespective of the evaluation methods, is not yet put in place and is still not required for reimbursement decisions. This could intensify the access challenges to precision oncology.

There is finite political support and low financial investment in building the testing and data infrastructure necessary for precision oncology in these markets. TAT is still a very new concept in many healthcare settings and drug evaluation is still largely based on indications. Coupled with the modest awareness of CGP and TAT in these markets, limited testing capabilities leads to a limited uptake of CGP in both specialized and tertiary hospitals. However, the launch of the Precision Medicine Initiative in China in 2016 is helping to build awareness of CGP and TAT among the HTA bodies and payers. Despite this, its use is still limited to a few leading institutions, mainly for research or trials.

Currently, involvement from stakeholders in HTA and reimbursement evaluation process is low. Payers and other public stakeholders prefer an organic approach to designing and customizing systems in accordance with demand, while collaborations between the stakeholders to drive precision oncology adoption in these markets are still evolving.

THE DEFINING ARCHETYPE



Markets in this archetype, for example Malaysia, Thailand or Taiwan are in the process of defining their precision medicines strategy and have established HTA bodies. Their appetite for precision oncology is growing, but formal processes regarding access and reimbursement are not yet in place.

Due to limited utility of CGP and TAT in clinical settings, payers and HTA agencies are still building their understanding of these health technologies and their potential benefits to patients. These technologies may not be reimbursed or limited to a few disease areas or specific patient groups.

Despite collaborative efforts among research and clinical institutions to enhance development of precision oncology, competing healthcare priorities and limited availability may reduce efforts to increase adoption of CGP and TAT, or to expand testing.

Data infrastructure is established but not sufficiently extensive yet to enable robust evidence generation. The Taiwan Biobank, for example, has an established genomic database but genomic data has yet to be linked with other health and phenotypical data in the electronic medical records due to data privacy concerns. Efforts are currently being pursued to develop a governance framework to support the convergence of these databases in Taiwan[6].

THE INNOVATING ARCHETYPE


Markets in this archetype, for example Australia or South Korea, have well-established HTA agencies with official guidelines and processes, and the knowledge of precision oncology among payers and HTA agencies is higher than in the other archetypes. Health policies driving the uptake of precision medicine are in place, and well-established data and testing infrastructure are available, resulting in a higher adoption of precision oncology.

Nevertheless, these countries still face the methodological challenge of allocating the costs of CGP to one specific treatment. Genomic testing can be used to inform a multitude of management strategies. As a result, a novel therapy can be penalized for being innovative, despite spillover effects from genomic testing that informs multiple subsequent therapies.

Markets within this archetype are better poised with technological know-how to direct efforts progressively at going beyond existing methodologies and fine-tuning evaluation strategies appropriate for their healthcare landscape. They often have established formal working groups, comprising members from public and private sectors, to further and align their precision medicine initiatives.

Payers and HTA agencies acknowledge the need to explore reimbursement for precision oncology through innovative pricing models, such as risk-sharing agreements. There is also strong government support for precision oncology in these markets, and they have an expansive network of testing infrastructure available. Genomic and clinical data is typically stored within each hospital's database; and a central data repository has yet to be constructed, a crucial step to enable population health studies. For example, K-MASTER, operated by Korea University, received US$70 million funding from the South Korean government to support three key goals in precision oncology over 5 years[7].

Conclusion

The advances in molecular profiling tools coupled with developments in novel cancer therapeutics have led to the era of precision oncology, where the management of cancer is enhanced by the identification of actionable genomic alterations, and the incorporation of advanced diagnostics, such as CGP, could aid early diagnosis, treatment selection and disease surveillance monitoring, leading to improved patient outcomes and more efficient use of healthcare resources. The dynamic HTA landscape of precision oncology offers both risks and opportunities for manufacturers. By considering the nuance local environment and market archetypes, strategic initiatives can be devised to address obstacles and incorporate precision oncology into the healthcare system.
With better awareness and understanding of these archetypes, industry can better tailor their strategies and build sustainable partnership that help improve patient access to these treatments.

To learn more about the APAC archetypes and how they are evolving, download **Accelerating Patient Access to Precision Oncology in Asia Pacific**.

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Sirin heads the Real World Insight team in South East Asia. She leads a team of highly experienced senior consultants in Singapore HQ, servicing multinational pharmaceutical clients for their health technology assessment (HTA) strategy and evidence generation in APAC. Sirin has over 12 years of extensive knowledge in the pharmaceutical industry with roles in generating HEOR and Real World Evidence (RWE) to support product strategy and HTA submissions, and developing pricing& market access strategy. Sirin holds a MS in Healthcare Research from Queen Mary, University of London.

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