Understanding market access drivers for oncology therapies in Asia – a case study in China, South Korea and Taiwan

Mrs Lin Questa
Agenda

General environment
- Burden of disease, cost drivers
- Influence in decision making
- Perception of changes in future for HTA
- Current funding and reimbursement scenario for China, South Korea and Taiwan

Case study Hepatocellular carcinoma
- Characteristics of the disease and treatment
- New drugs coming into the market

Pricing and reimbursement for HCC products
- Funding and reimbursement for HCC treatment
- Funding and reimbursement for HCC new drugs

Market access targets and strategies
- Main stakeholders to be targeted by country
- Potential market access strategies per country
- Conclusions
General environment
Asia is a strong oncology market, accounting for nearly half of all new cancer cases in the world.

Challenges
- Affordability
- Price control
- Lack of intellectual protection
- Centralised and regional decision makers
- Health Technology Assessment processes
Cancer in China
- 2nd cause of death after CVD
- Incidence rates rising

Cancer Treatment in China
- Oncology treatment covered mostly by patients
- Many Chinese can not afford drugs not covered by insurance
- Wealthier Chinese will opt for branded products

Price setting at national level needs to be addressed for expensive oncology drugs so that more Chinese cancer patients have access to these treatments.
Cancer Treatment in South Korea

- 5% co-payment is typical
- HCC have 52.5%
- About half of all cancer patients have private insurance

The National Health Insurance Corporation

- Sets prices for new drugs
- Providing evidence of the treatment value to (HIRA) is also key for reimbursement.

Even with insurance, with only partial reimbursement, affordability could be an issue when assessing uptake.
Cancer in Taiwan

- Cancer continues to be the leading cause of mortality
- Highest mortality rates for lung and liver cancer rates, with Incidence across all forms of cancer rising

Cancer Treatment in Taiwan

- New oncology treatment covered mostly by payers
- 99% of the population have health insurance through the National Health Insurance Program
- Pharmacoeconomic studies are increasingly utilized when setting reimbursement prices.

Access relies heavily on strong local clinical and economic data, a robust value dossier, coupled with a good relationship with the Department of Health & Center of Drug Evaluation.
Case study
Hepatocellular carcinoma
New products need to demonstrate overall survival rates and how using at an earlier stage can affect outcomes.

Prevalence - high
Current surgical and radiology treatments – reimbursed
Drugs available at late stages - Yes

Payers perceptions of sorafenib
- No clinical benefit in most patients
- Decreased efficacy, higher toxicity in Asian populations
- Overall survival: 8.8 months/mPFS 2.8

Reimbursement of sorafenib
- Full
- Partial
- None
- Clinical benefit not seen as relevant

China: None
South Korea: Partial
Taiwan: Full

www.ephmra.org
Case study: Hepatocellular carcinoma

Reimbursement of sorafenib

Payers perceptions of sorafenib

- No clinical benefit in most patients
- Decreased efficacy in Asian populations
- Overall survival: 8.8 months/mPFS 2.8 months

Reimbursement of sorafenib

- Not reimbursed
- Clinical benefit not seen as relevant
- Partial reimbursement
- Payers perceive that it is not effective
- Full reimbursement

Prevalence - high

Current surgical and radiology treatments drug treatment – ablation, TACE and RAF procedures reimbursed

Drugs available at late stages - Yes

China

South Korea

Taiwan
Several products for late stage but not available for initial stages of the disease

Failed to show clinical benefits compared to sorafenib

EVEROLIMUS

CAPECITABINE + OXALIPLATIN

BRIVANIB ALINATE

ERLOTINIB

MEDI-573

VARGATEF

JX-594

TIGATUZUMAB

BAY 86-9766

DOVITINIB

E7050

Pricing and reimbursement for HCC products
It is important to understand key pricing and funding mechanisms to develop market access strategies

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<th>Market</th>
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**Price setting**

- In China, prices for imported drugs are registered at NDRC.
- Prices for innovative drugs gradually adopt pharmaceutical economic evaluation methods.
- In South Korea, the price will be set by the National Health Insurance Corporation and decided based on a system of reference pricing.
- The Bureau of National Health Insurance (BNHI) is the health authority to announce the reimbursed price. Most prices are benchmarked with the price of current existing products. Only a few drugs recognized as breakthrough drugs can be listed in Advanced 10 (A10) median price.

**Decision makers for reimbursement**

- National stakeholders (MOHRSS) and regional stakeholders (BOHRSS) are key decision makers for inclusion in NRDL and PRDL for reimbursement.
- Special considerations for public officials and military forces.

**Regional and national stakeholders key in China and national key in S. Korea & Taiwan – fragmentation in China leads to more reimbursement opportunities but with more intensive use of resources**

**Prices controlled by governments – need to manage reference pricing across the regions**
It is important to understand key pricing and funding mechanisms to develop market access strategies.

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<tr>
<td>Reimbursement coverage</td>
<td>New products for HCC would not likely be included in the NRDL; potential for inclusion in some PDRL. New products will follow the path for sorafenib with partial reimbursement and coverage by private insurance. Nexavar is the only one target therapy for HCC received reimbursed price (Aug 1, 2012). But only allowed to be prescribed in late stage HCC patients. BNHI is not easy to expend the treatment provision since liver disease is top disease in Taiwan.</td>
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<td>HTA to support inclusion</td>
<td>Not currently used for formulary inclusion but potential use for 2015; models need to be populated with local data. Constant changes in the political environment makes difficult to predict criteria that would be used for HCC products but most likely follow current criteria. All new drugs are compulsory to prepare HTA dossier when submitted for reimburse. 5-year budget impact model and UK, Australia and Canada HTA report translated in Chinese are necessary. The cost effectiveness analysis can help to negotiate with government. Different reimbursement situations for drugs across the countries – market access strategy needs to adapt to individual countries.</td>
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HTA will become more important – need to plan for internal capabilities.
Market access targets and strategies
What are the implications for new HCC products for China from Market Access perspective?

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<td>Price for new HCC products might have to consider economic factors following uncertain criteria</td>
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<td>Need to follow the agreement with NICE and how the criteria and process are developed in order to address new economic requirements by NDRC</td>
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<td>New HCC products likely not to be included in the NDRL</td>
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<td>Target affluent population developing patient access schemes in order to encourage the affordability of patients to new access schemes</td>
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<td>Potential for regional inclusion in PRDL and target population like military forces or public officials</td>
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<td>Identify the regions and organisations with higher possibilities of obtaining reimbursement for HCC products and provide support for formulary inclusion</td>
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What are the implications for new HCC products for South Korea from Market Access perspective?

1. Price for new HCC products will be based on price referencing for other countries
   - Optimise launch sequence so that price referencing is not affected by lower price countries

2. New HCC products likely to be partially reimbursed
   - Target affluent population developing patient access schemes in order to encourage the affordability of patients to new access schemes

3. Coverage by private insurance of some costs will be influential for product uptake
   - Understand current coverage in order to support patients for the use of new products
What are the implications for new HCC products for Taiwan from Market Access perspective?

1. Price for new HCC products will be based on price referencing for other countries
   - Optimise launch sequence so that price referencing is not affected by lower price countries

2. New HCC products likely to be reimbursed – some delay between marketing approval and reimbursement
   - Develop patient access schemes in order to encourage the initial uptake of the product

3. Central drug evaluation will be evaluating the product based on clinical benefits and HTA
   - Develop a solid data package and support the evaluation process at Central Drug evaluation to obtain a favourable outcome