

2010 PE & HTA 華夏論壇

台北，四月2~3日

Pay for Expensive New Drugs - Risk Sharing Schemes

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演講大綱

- 一些新藥的治療價格
- 為何使用 risk-sharing?
- Risk-sharing schemes 的種類
- 一些例子

Tracleer (bosentan) 62.5 mg, 125 mg

- **Indication:** Pulmonary arterial hypertension
- **Unit price:** NT\$1,892/**tab** (both the same cost)
- **用法療程：**初始劑量為每天兩次，每次62.5 mg，口服，治療四週；維持劑量為每天兩次，每次125 mg
- **每人一年藥費：**NT\$ 1,381,160

Velcade (bortezomib) 3.5 mg/vial

- **Indication:** Multiple myeloma
- **Unit price:** NT\$ 41,512/vial
- **用法療程：**建議劑量為 $1.3\text{mg}/\text{m}^2/\text{dose}$ ，每週兩次，持續兩週，於第1,4,8,11天給藥，之後休息10天(至第21天)。每次使用以8個療程為限。
- **每人一年藥費：**NT\$ 2,878,165
[以平均成人體表面積 1.73 m^2 計算，每次注射需使用 2.25mg (1 vial)]

Sutent (sunitinib) 25mg, 50mg Cap

- **Indication:** 目前本藥健保給付於腸胃道基質腫瘤，RCC並未給付
- **Unit price:** 25mg: NT\$2,622，50mg: NT\$4,719
- **用法療程：**一般劑量：50mg/天，服藥4週+停藥2週。
- **每人一年藥費：**NT\$ 1,145,144

Erbix (cetuximab) 2 mg/ml/50 ml

- **Indication:** Metastatic colorectal cancer
- **Unit price:** NT\$ 7,982
- **用法療程：**初始劑量 $400\text{mg}/\text{m}^2$ ，維持劑量 $250\text{mg}/\text{m}^2$ ，一週一次，一個療程共計八次輸注。使用總療程以18週為上限。
- **每人一年藥費：**NT\$ 590,668

(以平均成人體表面積 1.73 m^2 計算，第一次治療使用量約 600mg ，維持治療輸注量約 400mg ，最高輸注次數為八次，故每個病人一個療程約花費 $7982*6+7982*4*7=271,388$ 元)

Enbrel (etanercept) 25 mg/ml

- **Indication:** Rheumatoid Arthritis
- **Unit price:** NT\$ 4,275/vial
- **用法療程：**建議使用劑量為25 mg，每週二次，以皮下注射方式給予。健保規定使用半年後，每三個月需重新申請。
- **每人一年藥費：**NT\$ 444,600

標靶治療藥品之估計藥費

適應症	藥品	單價	費用
肺癌	Iressa (健保二線用藥)	1,599/tab/day	一年約60萬
	Tarceva (健保二線用藥)	2,143/tab/day	一年約78萬
乳癌	Herceptin(健保二線用藥)	61,192/dose	一年約75萬
	Tykerb		自費11萬/月
肝癌	Nexavar (非適應症用藥)	1,500/tab, #4/d	自費約18萬/月
大腸結腸癌	Erbitux (健保晚期使用)	7,982/dose	一療程約29萬
	Avastin		自費100萬/年
慢性骨髓性 白血病	Glivec (健保一線用藥)	626/Tab #4/d	約7萬/月
	Tasigna (健保二線用藥)	1,252/tab #4/d	約15萬/月
	Sprycel (健保二線用藥)	1,614/tab #2/d	約8.7萬/月
非何杰金氏 淋巴瘤	MabThera	38,887/dose	6療程約25萬 ⁸

Why use risk-sharing?

- 廠商創新藥品，尤其是生物製劑：單價昂貴，適用之病患群較少，臨床療效具不確定性
- 健保單位：財務負擔過大(financial uncertainty)
- 病患：有未滿足之醫療需求，希早日治療

如何創造三贏的局面？

1. 新藥須符合成本效益；
2. 廠商承擔治療失敗風險，而能讓新藥早日被給付

Identifies a 'shared' outcome resulting from treatment

- **Clinical** outcome
- **Humanistic/Quality of Life** outcome
- **Resource** outcome – impact on healthcare resource use
- **Financial** outcome – impact on healthcare budgets
- **Economic** outcome – a cost-effectiveness threshold

Value-Based Pricing

Threshold of ICER

- **USA: US \$25,000 ~ \$50,000 ~ \$100,000/QALY**
- **Canada: US \$17,600 ~ US \$87,800/QALY**
- **Australia: US \$28,200 ~ US \$51,000/LYG**
- **NICE: £20,000–30,000 (\$37,104–55,655) /QALY**

- **WHO, 2002: <3 GDP/capita/DALY averted**
- **Australia PBAC: 1.26 ~ 2.29 GDP/capita/life-year gained**
- **England NICE: 1.4~2.1 GDP/capita/QALY**

***Risk** is based on uncertainty in the **efficient** use of **finite** healthcare resources*

- **Financial (Utilization) concern**

- Uncertainty around **dosage/dose frequency**
- Uncertainty around **overall usage**
- Uncertainty around **use of health care resources**

- **Product Performance concern**

- Uncertainty of **clinical impact** in certain patient groups
- Uncertainty of performance versus **comparator or certain outcomes**
- Uncertainty of **long term clinical trial results**

風險分攤協議(risk-sharing agreement)

- 是一種特別形式的狀況下治療給付 (conditional therapeutic coverage)
- 製藥廠商與健保單位雙方的同意契約，基於一個保證治療能達到某程度治療結果，不管那是臨床上、財務上或成本效益上的指標條件。
- 若能達到那治療結果，健保單位就付錢；若沒達到，則製藥廠商將藥物治療成本回饋給健保單位。

三種風險分攤協議的類型

1. **臨床風險分攤**：分攤一個產品在治療表現上的風險。如果一個藥物治療沒達到原先同意的臨床療效程度，健保組織可收到廠商的回饋金額 (No cure, no pay; refund)。
2. **固定預算/單價及數量的協議**：針對某新藥先規劃出雙方同意一年所使用的最大數量或金額，然後依據超出price caps的部份，廠商回饋事先同意的額度。此種財務為基礎的合約可提供最大的風險與獎勵給廠商，因為其協議基礎就是花費金額 (**台灣的三年價量協商**)。
3. **成本效益風險分攤**：建立一個藥品的成本效益目標，若沒有達到此閾值，則健保組織可要求降低單價。

Varieties of Risk Share

- Denmark: “**No cure-No pay**” programs for **valsartan, vardenafil, nicotine gum**
- EU: **GSK** have engaged with two European governments to review drug prices following completion of Phase IV studies (**CWED**)
 - Where drugs are more effective than initially thought, prices will increase
 - Where drugs are less effective than initially thought, prices will decrease
- Alberta, Canada: 3-year **financial cap with payback** for **Effexor XR**
- Italy: Financial utilization agreement in place for oncology, **Sutent and Nexavar** whereby **50% discount for first 2/3 months.**

Tracleer (bosentan)

- Actelion's Tracleer (bosentan) is a vasoconstrictor used for the treatment of **pulmonary arterial hypertension (PAH)**, which has shown to improve symptoms, quality of life, and delay clinical worsening
- Tracleer was approved in Australia in March 2004, however, recommendations to include the drug on the national formulary—the PBS—were **based on improvements in life expectancy**, even though these had not been confirmed in long-term controlled clinical studies
- Actelion proposed a clinical risk-sharing agreement¹⁶

Bosentan Patient Registry

- The **future price** of Tracleer would be in **proportion to the mortality** of patients treated with the drug under the PBS; in this way, clinical evidence was gathered to support its claimed effectiveness.
- The proposal includes the **establishment of a registry to collect survival outcome data** of Tracleer patients, through a collaboration between Australia's government, Actelion and a steering committee comprised of clinicians involved in treating PAH patients.
- The registry is **maintained by** an independent party—the Centre of Clinical Research Excellence in Therapeutics (CCRE Therapeutics) at Monash University in Melbourne, in order to maintain impartiality.

Bosentan Patient Registry

- Although Tracleer is now reimbursed in Australia, prescribing guidelines are **very restrictive**.
- The **prescription** of Tracleer is limited to specialist clinicians from hospitals approved by the Department of Health.
- In order to access subsidized Tracleer, the **PAH patient** must initially complete a written form including results of a right heart catheter, echocardiogram, and results from a 6-minute walk test, which is required to be updated every 6 months.
- Like other pay-for-performance risk-sharing agreements, the subsidized treatment of Tracleer will cease if the physician determines that the patient has not demonstrated improvement or stability with the treatment.

Velcade (bortezomib)

- Janssen-Cilag's **multiple myeloma** drug received negative guidance from the UK's NICE in October 2006
- the drug had statistically significant improved survival compared high-dose dexamethasone
- Cost of £3,000 (\$5,566) per cycle of treatment
- the ICER ranged from £33,000 (\$61,221) to £38,000 (\$70,497) per QALY
- Janssen-Cilag and NICE agreed on a **clinical risk-sharing scheme** in July 2007

Velcade Response Scheme

- The scheme proposed that the NHS only pay for Velcade in patients who benefit from the drug, while the company would refund the money spent on patients whose tumors did not shrink sufficiently after four cycles of treatment.
- NICE proposed at least a **50% reduction** (a “partial response”) **in serum M-protein**, which would result in a cost per QALY of approximately £20,700 (\$38,402)
- Final: the company would reimburse the NHS with the full cost of treatment for those patients whose tumor did not shrink (less than 50% reduction) and treatment would stop. On the other hand, the NHS would continue to pay four more cycles of treatment for those patients with a reduction of 50% or more.

台灣的可能第一個案例

抗癌藥之預防止吐用藥

- P藥止吐只需注射一劑，維持五天。
- 其他止吐劑需每天用藥。
- 廠商:P藥一劑給付藥價 = 其他用藥五天價格
- 但有20~30%病人在第四天需要第二劑治療
- 健保給付價策略:
 - 一劑價格等於其他用藥五天價格
 - 二劑價格等於其他用藥五天價格

Risk Sharing: 健保只付一劑，廠商回饋第二劑₁

Thank you for your attention!

