




**Do Existing Examples  
of Personalized  
Medicines Reflect  
“Ideal” Principles of  
Value-based  
Reimbursement?**


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**Two Examples**



- VBP in the USA of ~US\$3900, based on its health-economic analyses.
- ~ 50% of eligible patients are tested



- Mostly no reimbursement
- Very low adoption
- <6% of eligible patients are tested


Miller et al. 2011. Market access challenges in the EU for high medical value diagnostic tests. Personalized Medicine (2011) 8(2), 137–148




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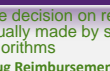

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- Monogram markets test
  - ~US\$1500 / test
  - Trofile companion test received nearly 100% of payer coverage within 12 months of launch
- Pfizer leads reimbursement initiatives for both the drug and the test ex-USA
  - Pfizer pays Monogram for the Trofile test in Europe and other ex-US markets



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**Europe: Reimbursement of Companion Dx**

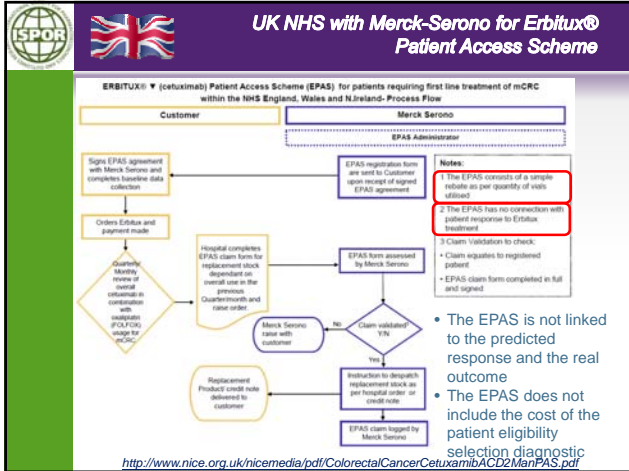
The decision on reimbursement of diagnostics (Dx) or drugs (Rx) is usually made by separate entities and does not follow the same algorithms

<p><b>Drug Reimbursement</b></p> <ul style="list-style-type: none"> <li>• Based on clinical Outcomes &amp; ‘Value’             <ul style="list-style-type: none"> <li>• Incremental efficacy, improved therapeutic pathway, effectiveness, efficiency, safety, or overall health or economic outcomes for individuals or groups of individuals</li> </ul> </li> <li>• Based on standardized procedures and framework</li> </ul>	<p><b>Diagnostics Reimbursement</b></p> <ul style="list-style-type: none"> <li>• Based on type of test procedure</li> <li>• Rarely connected to their impact on health</li> <li>• Highly decentralized</li> </ul>
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**Missing Links on the Diagnostic Side**

- Standard validation procedure guiding the generation of relevant & robust premarket evidence for tests.
- Assessment of clinical utility of tests or guidance on how to assess it.
- Assessment of cost-effectiveness of tests or guidance on how to assess it.
- Post market performance monitoring.
- Framework for drug-diagnostic co-products.

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- UK NHS – Irassa (Gefitinib)**
- Cost / pack (30 tablets / pack) is £2167.71
  - The manufacturer has agreed with the Department of Health a patient access scheme
    - gefitinib for first-line treatment of NSCLC will be available at a single fixed cost of £12,200 per patient **irrespective of the duration of treatment.**
    - The manufacturer will not invoice the NHS until the third monthly pack of gefitinib is supplied. This means that **patients who need less than 3 months of treatment will not incur a charge.**
    - The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.
- Fixed cost per responder: £12'200 (~ 5.6 months)**
- No cost for non-responders**
- ⇒ Cost of test not included in PAS ⇐
- <http://www.nice.org.uk/nicemedia/live/12185/48834/48834.pdf>

**AIFA / Italy: Herceptin Reimbursement Management Procedure 'Payment by Result'**

**AIFA**  
Agenzia Italiana del Farmaco

**Appuntamento**

**Efficacia 2013**

Procedura di Gestione Reimborsi (Pagata by result)

Si informano gli utenti del Registro Farmaci Oncologici sottoposti a Monitoraggio che **e' disponibile la procedura di gestione telematica dei rimborsi previsti secondo gli accordi negoziati per la specialita' medicinale HERCEPTIN® (Roche) esclusivamente per l'indicazione:**

"Herceptin in associazione a capecitabina o 5-fluorouracile e cisplatino e' indicato nel trattamento di pazienti con adenocarcinoma metastatico dello stomaco o della giunzione gastroesofagea HER2-positivo, che non siano stati precedentemente sottoposti a trattamento antitumorale per la malattia metastatica. Herceptin deve essere somministrato soltanto a pazienti con carcinoma gastrico metastatico i cui tumori presentano iperespressione di HER2, definita come un risultato IHC2+ e confermata da un risultato SISH o FISH, o definita come un risultato IHC3+.

Devono essere utilizzati metodi di determinazione accurati e convalidati."

[http://antineoplastici.agenziafarmaco.it/info\\_generali.htm](http://antineoplastici.agenziafarmaco.it/info_generali.htm)

- AIFA / Italy: Herceptin Reimbursement Management Procedure 'Payment by Result'**
- Reimbursement agreement for Herceptin used for metastatic gastric adenocarcinoma, which are HER2 positive
  - Patients need to be eligible and registered in the central Registry
  - Treatment Failure within the first 3 cycles (2 months) (= disease progression within first 2 months or non-tolerability)
    - ⇒ Payback by manufacturer (credit note)
  - Manufacturer has 1 month to evaluate data and object
  - Diagnostic is condition – but not part of the 'deal'
- [http://antineoplastici.agenziafarmaco.it/info\\_generali.htm](http://antineoplastici.agenziafarmaco.it/info_generali.htm)

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INFORMAZIONI GENERALI  
 Aggiornamenti

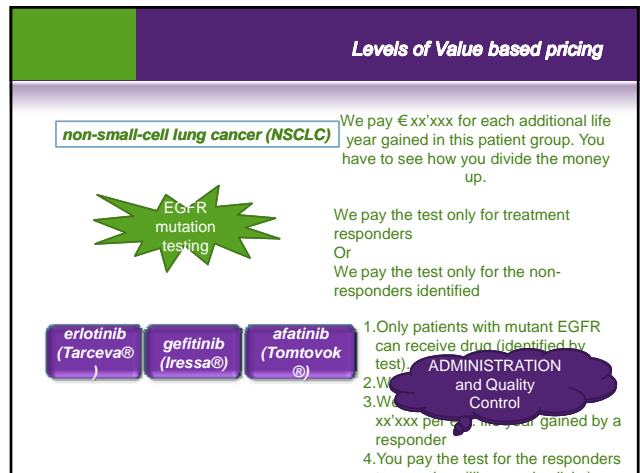
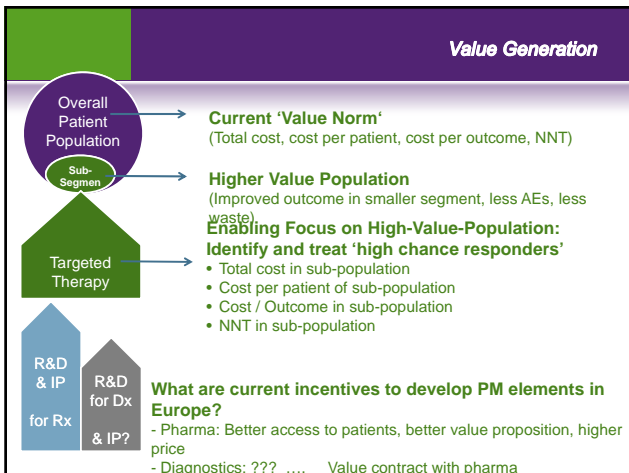
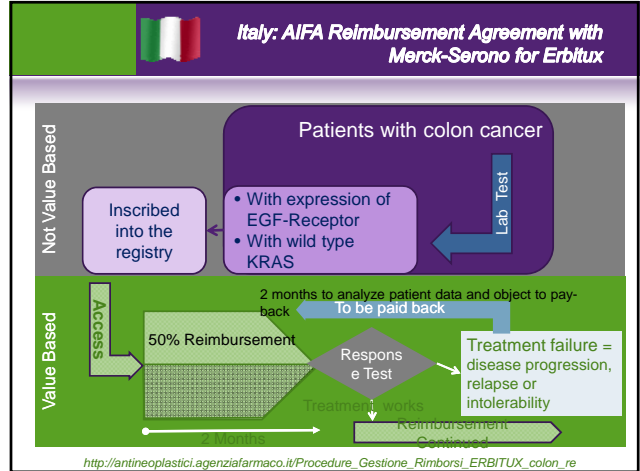
04 agosto 2011

**Procedura di Gestione Rimborsi Risk-Sharing**  
 Si informano gli utenti del Registro Farmaci Oncologici sottoposti a Monitoraggio che e' disponibile la procedura di gestione telematica dei rimborsi previsti secondo gli accordi negoziati per la specialita' oncologica ERBITUX (Erlotinib, Seroquel) e ERBITUX (Erlotinib, Seroquel) in relazione al trattamento di pazienti affetti da carcinoma metastatico del colon-retto. Per informazioni sul regolamento e base di rimborso e sui POPUPATI, si rimanda al documento allegato. Per ulteriori dettagli, consultare il documento allegato.

04 agosto 2011

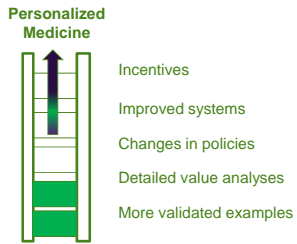
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**What is missing to support effective reward and use of Personalized Medicine?**

*We have begun to climb the ladder to Personalized Medicine but more is needed to realize its full potential . . .*



***PM solutions will have to prove their value in healthcare to become broadly accepted – But Healthcare needs to be ready to pay for proven value***