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

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VBP in the USA of ~US$3900, based on its health–economic analyses.
~<6% of eligible patients are tested


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

Drug Reimbursement
- Based on clinical Outcomes & “Value”
  - Incremental efficacy, improved therapeutic pathway, effectiveness, efficiency, safety, or overall health or economic outcomes for individuals or groups of individuals
- Based on standardized procedures and framework
- Post market performance monitoring
- Framework for drug-diagnostic co-products

Diagnostic Reimbursement
- Based on type of test procedure
- Rarely connected to their impact on health
- Highly decentralized

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

Two Examples

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

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- 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

- Monogram markets test
  - ~US$1500 / test
  - Trofile companion test received nearly 100% of payer coverage within 12 months of launch

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The EPAS is not linked to the predicted response and the real outcome.

The EPAS does not include the cost of the patient eligibility selection diagnostic.

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

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)
- Payback by manufacturer (credit note)

Manufacturer has 1 month to evaluate data and object.

Diagnostic is condition – but not part of the ‘deal’.
Patients with colon cancer

- With expression of EGF-Receptor
- With wild type KRAS

Inscribed into the registry

Value Based

Not Value Based

50% Reimbursement

Respons e Test

Treatment failure = disease progression, relapse or intolerability

To be paid back

2 months to analyze patient data and object to pay-back

http://antineoplastici.agenziafarmaco.it/Procedure_Gestione_Rimborsi_ERBITUX_colon_re

Value Generation

Current ‘Value Norm’
(Total cost, cost per patient, cost per outcome, NNT)

Higher Value Population
(Improved outcome in smaller segment, less AEs, less waste)

Enabling Focus on High-Value-Population:
Identify and treat ‘high chance responders’
- Total cost in sub-population
- Cost per patient of sub-population
- Cost / Outcome in sub-population
- NNT in sub-population

What are current incentives to develop PM elements in Europe?
- Pharma: Better access to patients, better value proposition, higher price
- Diagnostics: ???

Levels of Value based pricing

non-small-cell lung cancer (NSCLC)

We pay € xx’xxx for each additional life year gained in this patient group. You have to see how you divide the money up.

We pay the test only for treatment responders
Or
We pay the test only for the non-responders identified
1. Only patients with mutant EGFR can receive drug (identified by test).
2. WE pay the test only for treatment responders
3. WE pay a maximum of € xx’xxx per e.g. life year gained by a responder
4. You pay the test for the responders to your drug (like google clicks)

Data Quality Assurance & Reliability

Burden of ADMINISTRATION

Need for dedicated Registries coupled to reimbursement

Complicated Payback Mechanisms

Multiple Levels of Risk for Litigation

Trust / Partnership ADMINISTRATION and Quality Control
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**