Patient Access Schemes in the New NHS

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14:15 – 15:15
What is a Patient Access Scheme (PAS)?

Patient Access Schemes (PAS) are designed to ensure patients can gain access to medicines which are likely to have a high cost and might not be deemed cost-effective by payers.

Payers face budgetary constraints

Manufacturers have commercial objectives

Source: Dima Yagnyuk and Benjamin H Byron, from The Noun Project
PAS are not a “new” concept

Outcomes-Based

MS Risk-Sharing Scheme
2002

Velcade® Risk-Sharing Scheme
2007

Financially-Based

Renal Cell Carcinoma Discount Scheme
2009

Financially Based
Easy to administer
The essence of PAS – reducing uncertainty at launch

**Part A** – 12.5% Discount on list price

Reduces financial uncertainty at time of appraisal

**Part B** – Possible future rebate linked to outcome of head-to-head trial against gold standard competitor

Provides payer with long-term “guarantee” on clinical effectiveness

Two Part Patient Access Scheme
## List of approved medicines with a PAS

<table>
<thead>
<tr>
<th>TA Ref</th>
<th>Treatment</th>
<th>Indication</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA 129</td>
<td>Bortezomib (Velcade)</td>
<td>Multiple myeloma</td>
<td>Janssen-Cilag</td>
</tr>
<tr>
<td>TA 155</td>
<td>Ranibizumab (Lucentis)</td>
<td>Macular degeneration (Acute wet AMD)</td>
<td>Novartis</td>
</tr>
<tr>
<td>TA 162</td>
<td>Erlotinib (Tarceva)</td>
<td>Non-small cell lung cancer</td>
<td>Roche</td>
</tr>
<tr>
<td>TA 169</td>
<td>Sunitinib (Sutent)</td>
<td>Renal cell carcinoma</td>
<td>Pfizer</td>
</tr>
<tr>
<td>TA 171</td>
<td>Lenalidomide (Revlimid)</td>
<td>Multiple myeloma</td>
<td>Celgene</td>
</tr>
<tr>
<td>TA 176</td>
<td>Cetuximab (Erbitux)</td>
<td>Metastatic colorectal cancer (first line)</td>
<td>Merck Serono</td>
</tr>
<tr>
<td>TA 179</td>
<td>Sunitinib (Sutent)</td>
<td>Gastrointestinal stromal tumour</td>
<td>Pfizer</td>
</tr>
<tr>
<td>TA 180</td>
<td>Ustekinumab (Stelera)</td>
<td>Moderate to severe psoriasis</td>
<td>J&amp;J / Janssen-Cilag</td>
</tr>
<tr>
<td>TA 185</td>
<td>Trabectedin (Yondelis)</td>
<td>Advanced soft tissue sarcoma</td>
<td>PharmaMar</td>
</tr>
<tr>
<td>TA 186</td>
<td>Certolizumab pegol (Cimzia)</td>
<td>Rheumatoid arthritis</td>
<td>UCB</td>
</tr>
<tr>
<td>TA 192</td>
<td>Gefitinib (Iressa)</td>
<td>Non-small cell lung cancer</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>TA 215</td>
<td>Pazopanib (Votrient)</td>
<td>Advanced renal cell carcinoma</td>
<td>GSK</td>
</tr>
</tbody>
</table>

Source: NICE website [www.nice.org.uk](http://www.nice.org.uk) – Accessed 22nd October 2012
**List of approved medicines with a PAS (cont.)**

<table>
<thead>
<tr>
<th>TA Ref</th>
<th>Treatment</th>
<th>Indication</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA 218</td>
<td>Azacitidine (Vidaza)</td>
<td>Myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia</td>
<td>Celgene</td>
</tr>
<tr>
<td>TA 220</td>
<td>Golimumab (Simponi)</td>
<td>Psoriatic arthritis</td>
<td>Merck Sharp &amp; Dohme</td>
</tr>
<tr>
<td>TA 221</td>
<td>Romiplostim (Nplate)</td>
<td>Chronic idiopathic (immune) thrombocytopenic purpura</td>
<td>Amgen</td>
</tr>
<tr>
<td>TA 225</td>
<td>Golimumab (Simponi)</td>
<td>Rheumatoid arthritis</td>
<td>Merck Sharp &amp; Dohme</td>
</tr>
<tr>
<td>TA 233</td>
<td>Golimumab (Simponi)</td>
<td>Ankylosing spondylitis</td>
<td>Merck Sharp &amp; Dohme</td>
</tr>
<tr>
<td>TA 235</td>
<td>Mifamurtide (Mepact)</td>
<td>High grade resectable non-metastatic osteosarcoma</td>
<td>Takeda</td>
</tr>
<tr>
<td>TA 238</td>
<td>Tocilizumab (RoActemra)</td>
<td>Systemic juvenile idiopathic arthritis</td>
<td>Roche</td>
</tr>
<tr>
<td>TA 241</td>
<td>Nilotinib (Tasigna)</td>
<td>Imatinib-resistant chronic myeloid leukaemia</td>
<td>Novartis</td>
</tr>
<tr>
<td>TA 247</td>
<td>Tocilizumab (RoActemra)</td>
<td>Rheumatoid arthritis</td>
<td>Roche</td>
</tr>
<tr>
<td>TA 251</td>
<td>Nilotinib (Tasinga)</td>
<td>First-line treatment of chronic myeloid leukaemia</td>
<td>Novartis</td>
</tr>
<tr>
<td>TA 254</td>
<td>Fingolimod (Gilenya)</td>
<td>Highly active relapsing-remitting multiple sclerosis</td>
<td>Novartis</td>
</tr>
<tr>
<td>TA 258</td>
<td>Erlotinib (Tarceva)</td>
<td>First-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer</td>
<td>Roche</td>
</tr>
<tr>
<td>TA 259</td>
<td>Abiraterone (Zytiga)</td>
<td>Castration-resistant metastatic prostate cancer previously treated with a docetaxel containing regimen</td>
<td>Janssen-Cilag</td>
</tr>
</tbody>
</table>

Source: NICE website [www.nice.org.uk](http://www.nice.org.uk) – Accessed 22nd October 2012
When can a manufacturer submit a PAS?

1. **Upfront**
   - Include a PAS as part of the original submission

2. **In response to ACD**
   - Submit a PAS in response to negative draft guidance

3. **Post-FAD and Rapid Review**
   - Submit a PAS in response to negative final guidance and seek a rapid review

ACD = Appraisal Consultation Document
FAD = Final Appraisal Determination
PAS timing has a number of implications

- Faster reimbursement via “fast-track” process
- Shows willing to engage with NICE
- Design PAS based upon feedback
- More manoeuvrability
- Design PAS with hindsight of a full appraisal
- Positive guidance - then optimal position established

- Less room for manoeuvrability
- PAS will be solely designed on manufacturers estimates of cost-effectiveness
- No guarantee PAS will result in product being deemed cost-effective
- Inevitable delay of appraisal timelines
- Could have negative commercial impact
- Fixed timeline to agree rapid review

ACD = Appraisal Consultation Document
FAD = Final Appraisal Determination
Manufacturer of DRUG A does not submit a PAS in its initial dossier to NICE

Manufacturer of DRUG A does not submit a PAS in its initial dossier to NICE

Manufacturer decides that discount required to attain cost-effectiveness is too high

Manufacturer does not submit a PAS

Manufacturer does not submit a PAS

Manufacturer decides that discount required to attain cost-effectiveness is too high

Manufacturer does not submit a PAS

Manufacturer reimburses for DRUG A via the CDF

DRUG A Rejected by NICE

DRUG A Rejected by NICE

DRUG A Rejected by NICE

DRUG A Funded via CDF
The need for stability (and clarity)

The UK needs:

- a stable operating environment for pharmaceuticals
- clarity on what will happen to PAS going forward
- long-term solution for access to new and innovative medicines
Conclusions

- PAS have become an integral part of the UK pharmaceutical environment

- PAS have shifted from outcomes-based schemes to financially-based discounts. Bureaucratic schemes which are hard to administer are not welcomed by the NHS

- Integrating PAS and value propositions into pharmaceutical strategy as early as possible is crucial

- The CDF may act as a potential disincentive for manufacturers to engage with PAS

- The key to the long-term future of effective value propositions such as PAS is to provide a stable pricing environment in the UK