Individual Patient Funding Request (IPFR) and One Wales Interim Commissioning Processes

Professor Phil Routledge, Clinical Director AWTTC
NUMBER OF NEW CHEMICAL OR BIOLOGICAL ENTITIES (1994-2013)

Source: SCRIP – EFPIA calculations (according to nationality of mother company)

All Wales Medicines Strategy Group

“Getting the best outcomes from medicines for patients in Wales”

Statements of Advice

56
Non-engagement notices

• 56 Statements of advice in April 2015-March 2016

• 4 submissions subsequently received (several others expected)

• Reasons (when given): *Not launching in UK, resource constraints*,

• 17/56 submitted to the Scottish Medicines Consortium (SMC)

• 8 approved by SMC by the end of March 2016
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lenvatinib (Lenvima&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI)</td>
</tr>
<tr>
<td>Secukinumab (Cosentyx&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adults when response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate</td>
</tr>
<tr>
<td>Aflibercept (Eylea&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Treatment of patients with visual impairment due to myopic choroidal neovascularisation</td>
</tr>
<tr>
<td>Aflibercept (Eylea&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Treatment of adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)</td>
</tr>
<tr>
<td>Bevacizumab (Avastin&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>In combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix</td>
</tr>
<tr>
<td>Diamorphine hydrochloride (Ayendi&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Diamorphine hydrochloride nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring</td>
</tr>
<tr>
<td>Isavuconazole (Cresemba&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Treatment of invasive aspergillosis and mucormycosis in patients for whom amphotericin B is inappropriate</td>
</tr>
<tr>
<td>Febuxostat (Adenuric&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematological malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS)</td>
</tr>
</tbody>
</table>
MIND THE “GAPS”!

• Negative appraisal of Medicines
• Delayed appraisal of licensed medicines
• Non-appraisal of licensed medicines
• Off-label use of medicines
New medicine

Licensed for that clinical indication?

Yes*

On NICE work programme?

Yes

Await NICE guidance

No

Has company made a submission to AWMSG?

Yes

AWMSG appraisal process

Positive recommendation?

No*

Requires IPFR for individual patient

Yes

NHS Wales to fund within 3 months

No

Non-endorsement advisory notice on AWMSG Website

Requires IPFR for individual patient

No

Await company submission (within 3 months of licensing)

No submission

Requires IPFR for individual patient

⌂ Requires IPFR for individual patient

⌂ Requires IPFR for individual patient

⌂ Requires IPFR for individual patient
Methods to achieve timely access for patient groups via HTA

- Early HTA
- “Late” HTA (if medicine available in England via a commissioning route)

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Trade name</th>
<th>AWMSG Status</th>
<th>MINISTERIAL RATIFICATION</th>
<th>NICE STATUS</th>
<th>NICE APPRAISAL DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>sorafenib</td>
<td>(Nexavar®)</td>
<td>Optimised recommendation</td>
<td>05/04/2016</td>
<td>Not recommended</td>
<td>26/05/2010</td>
</tr>
<tr>
<td>aflibercept</td>
<td>(Zaltrap®)</td>
<td>Not recommended</td>
<td>08/06/2015</td>
<td>Not recommended</td>
<td>25/03/2014</td>
</tr>
<tr>
<td>eribulin mesilate</td>
<td>(Halaven®)</td>
<td>Optimised recommendation</td>
<td>29/04/2016</td>
<td>Not recommended</td>
<td>01/04/2012</td>
</tr>
<tr>
<td>pomalidomide</td>
<td>(Imnovid®)</td>
<td>Recommended</td>
<td>27/08/2015</td>
<td>Not recommended</td>
<td>26/03/2015</td>
</tr>
</tbody>
</table>
IPFR PANELS IN WALES

- 7 Health Board IPFR Panels
- 1 “national panel” (WHSSC)
What is an Individual Patient Funding Request?

• A request to a health board to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a health board has agreed to routinely provide

• This can include a request for any type of healthcare including a specific service, treatment, medicine, device or piece of equipment
Categories suitable for IPFR

- A treatment that is either new, novel, developing or unproven and is not within the health board’s routine schedule of services and treatment (e.g. A drug that has yet to be approved for use in a particular condition)
- A treatment that is provided by the health board in certain clinical circumstances but is not eligible in accordance with the clinical policy criteria for that treatment (e.g. Treatment for varicose veins)
- The patient has a rare or specialist condition that falls within the service remit of the Welsh Health Specialised Services Committee (WHSSC) but is not eligible in accordance with the clinical policy criteria (e.g. Plastic surgery)
## IPFRs conducted since 2012

<table>
<thead>
<tr>
<th>Year</th>
<th>2012-13</th>
<th></th>
<th>2013-14</th>
<th></th>
<th>2014-15</th>
<th></th>
<th>2015-16</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>IPFR (medicines)</td>
<td>406</td>
<td>60</td>
<td>437</td>
<td>59</td>
<td>348</td>
<td>67</td>
<td>309</td>
<td>45</td>
</tr>
<tr>
<td>IPFR (medicines) - approved</td>
<td>216</td>
<td>53</td>
<td>223</td>
<td>51</td>
<td>176</td>
<td>51</td>
<td>176</td>
<td>57</td>
</tr>
<tr>
<td>IPFR (treatments)</td>
<td>275</td>
<td>40</td>
<td>303</td>
<td>41</td>
<td>173</td>
<td>33</td>
<td>374</td>
<td>55</td>
</tr>
<tr>
<td>IPFR (treatments) - approved</td>
<td>131</td>
<td>48</td>
<td>160</td>
<td>53</td>
<td>86</td>
<td>50</td>
<td>226</td>
<td>60</td>
</tr>
<tr>
<td>Total IPFR</td>
<td>681</td>
<td>100</td>
<td>740</td>
<td>100</td>
<td>521</td>
<td>100</td>
<td>683</td>
<td>100</td>
</tr>
<tr>
<td>Total IPFR - approved</td>
<td>347</td>
<td>51</td>
<td>383</td>
<td>52</td>
<td>262</td>
<td>50</td>
<td>402</td>
<td>59</td>
</tr>
</tbody>
</table>

**IPFR system**

**2014 IPFR Review**

**Present Review**
“It is right that we have a process in Wales to enable access to treatments and devices which are not normally available via the NHS. Each health service in the UK has such a process, with clinical criteria to determine accessibility”

“The NHS Wales process has been improved following a review in 2013-14. A further review will now take place to ensure better consistency of decisions across Wales and make recommendations about what clinical criteria should be applied when determining eligibility”

Vaughan Gething AM
Cabinet Secretary for Health, Well-being and Sport
• Contains 27 recommendations relating to 7 important areas:
  o Commissioning
  o Exceptionality
  o Non-clinical factors
  o Consistency and the number of panels
  o Communication
  o Paperwork and the IPFR process
  o Medicines appraisal

http://gov.wales/topics/health/nhswnes/funding/?lang=en
New medicine
Licensed for that clinical indication?
Yes*  No*

On NICE work programme?
Yes  No

Requires IPFR for individual patient

Await NICE guidance
Requires IPFR for individual patient

Has company made a submission to AWMSG?
No

Company not yet ready for HTA

Has company made a submission to AWMSG?
Yes

Await company submission (within 3 months of licensing)

Non-endorsement advisory notice on AWMSG Website

Meets criteria for one Wales Interim Commissioning?
Yes

Interim Commissioning process
Positive recommendation (with ratification)?
Yes

Requires IPFR for individual patient

NHS Wales to fund

Positive recommendation?
No≠

Requires IPFR for individual patient

NHS Wales to fund within 3 months

AWMSG appraisal process

Positive recommendation?
No≠

Requires IPFR for individual patient

NHS Wales to fund

* There is the facility to appraise before NICE if directed by WG
* = Some LHBs have their own unlicensed/off-label processes
≠ There is an opportunity for re-appraisal by AWMSG in certain circumstances
ǂ Some LHBs have price threshold before conducting IPFR

“One Wales” Interim Commissioning for licensed medicines
"One Wales" Decision Tool for licensed medicines

All the conditions in the coloured boxes must be met for the One Wales Process to proceed

Has an unmet medical /clinical need for the medicine to treat a serious condition been identified

Has the Company agreed to provide appropriate evidence

Has the holder of the marketing authorisation committed to a health technology appraisal by NICE and / or AWMSG?

Is it feasible to collect data on outcomes in the period before formal HTA?

‘One Wales’ interim commissioning process to proceed

Not suitable for ‘One Wales’ interim patient cohort decision

Please note this only applies for licensed medicines. Unlicensed medicines or off-label use of a medicine will be considered on a case-by-case basis.
### “One” Wales Interim Pathway Commissioning Group (IPCG) decisions, May 2016 to date

<table>
<thead>
<tr>
<th>Medicine, indication and licensed status</th>
<th>IPCG decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Axitinib, post-pazopanib, for advanced renal cell carcinoma (off-label)</td>
<td>Use supported</td>
</tr>
<tr>
<td>2. Docetaxel in combination with hormone therapy for the treatment of metastatic prostate cancer (off-label)</td>
<td>Use supported</td>
</tr>
<tr>
<td>3. Bevacizumab (7.5 mg) for the 1st line treatment of advanced ovarian cancer in patients at high risk of disease progression (off-label)</td>
<td>Use not supported</td>
</tr>
<tr>
<td>4. Adalimumab (Humira®) for the treatment of paediatric patients with severe refractory uveitis (off-label)</td>
<td>Use supported</td>
</tr>
<tr>
<td>5. Adalimumab (Humira®) for the treatment of adult patients with severe refractory uveitis (licensed indication)</td>
<td>Use supported</td>
</tr>
<tr>
<td>6. Arsenic trioxide (TRISENOX®) for Acute promyelocytic leukaemia - 1st line therapy in patients unsuitable for anthracycline-based therapy (off label)</td>
<td>Use supported</td>
</tr>
</tbody>
</table>

Further medicine-indications for patient cohorts in Wales are being prepared for consideration by IPCG.
“One Wales” Interim Commissioning Points to note

• ‘One Wales’ interim commissioning will not apply to medicines that have been appraised by NICE/AWMSG and received a negative recommendation

• The duration of an interim commissioning decision for licensed medicines will be decided on a case by case basis

• For unlicensed medicines the ‘One Wales’ interim commissioning decision will be reviewed annually

• For unlicensed medicines to be considered there must be no suitably licensed alternative

• Patient outcomes are to be monitored following a positive decision for both licensed and unlicensed medicines
New Treatment Fund (NTF) in Wales

• A total of £12 million will be released to health boards with immediate effect, with a further £4 million being made available later to help speed up access to medicines recommended by NICE and AWMSG

• Under the new system, all health boards will be required to make a NICE or AWMSG recommended medicine available no later than two months from the date the final guidance is published, shortening the maximum amount of time before which a health board must make a treatment available by a third

• In respect of NICE recommendations, health boards will now be expected to introduce medicines recommended by NICE at the first publication of the final guidance, rather than waiting for the final Technology Appraisal guidance published after the appeal period

Acknowledgements

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• Welsh Government: Karen Eveleigh, Andrew Evans, Miranda Morton, Chris Hatton and Karan Edwards

• AWMSG, NMG and CAPIG: Stuart Linton, Saad al-Ismail, Rob Bracchi, all members of these Groups and their AWTTC support teams
Diolch yn fawr