

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



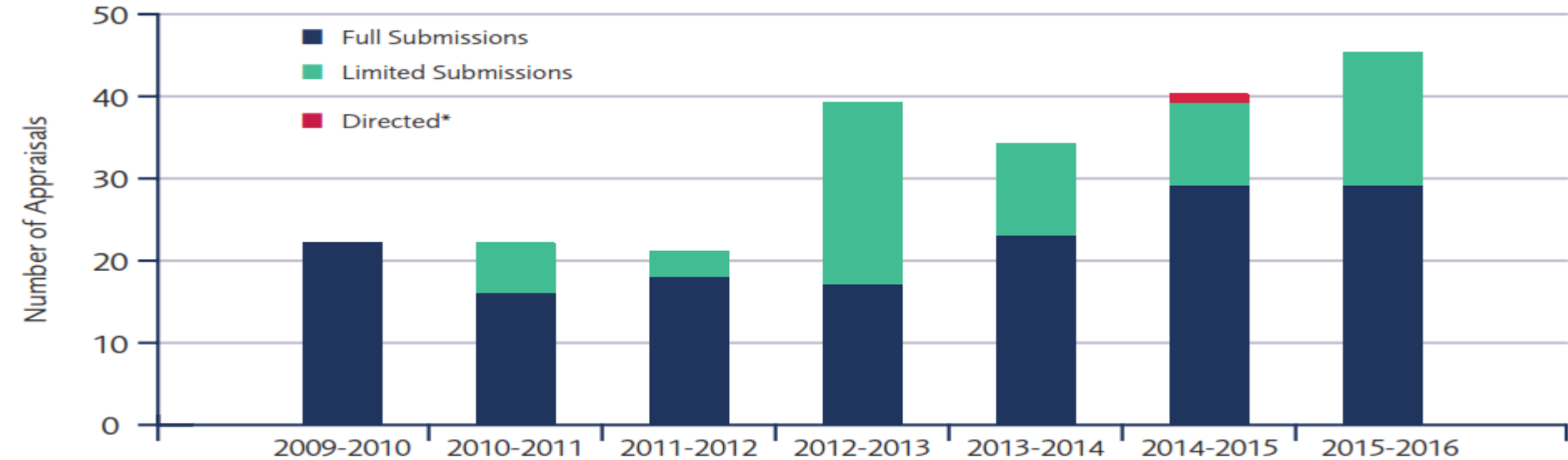
Professor Phil Routledge, Clinical Director AWTTC



AWTTC
All Wales Therapeutics
& Toxicology Centre

All Wales Medicines Strategy Group

"Getting the best outcomes from medicines for patients in Wales"



All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



Pathways to medicines access in Wales

New medicine

Licensed for that clinical indication?

- * 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
- ⬆ Some LHBs have price threshold before conducting IPFR

Yes*

No†

On NICE work programme?

⬆ Requires IPFR for individual patient

Await NICE guidance

Has company made a submission to AWMSG?

⬆ Requires IPFR for individual patient

Positive recommendation?

AWMSG appraisal process

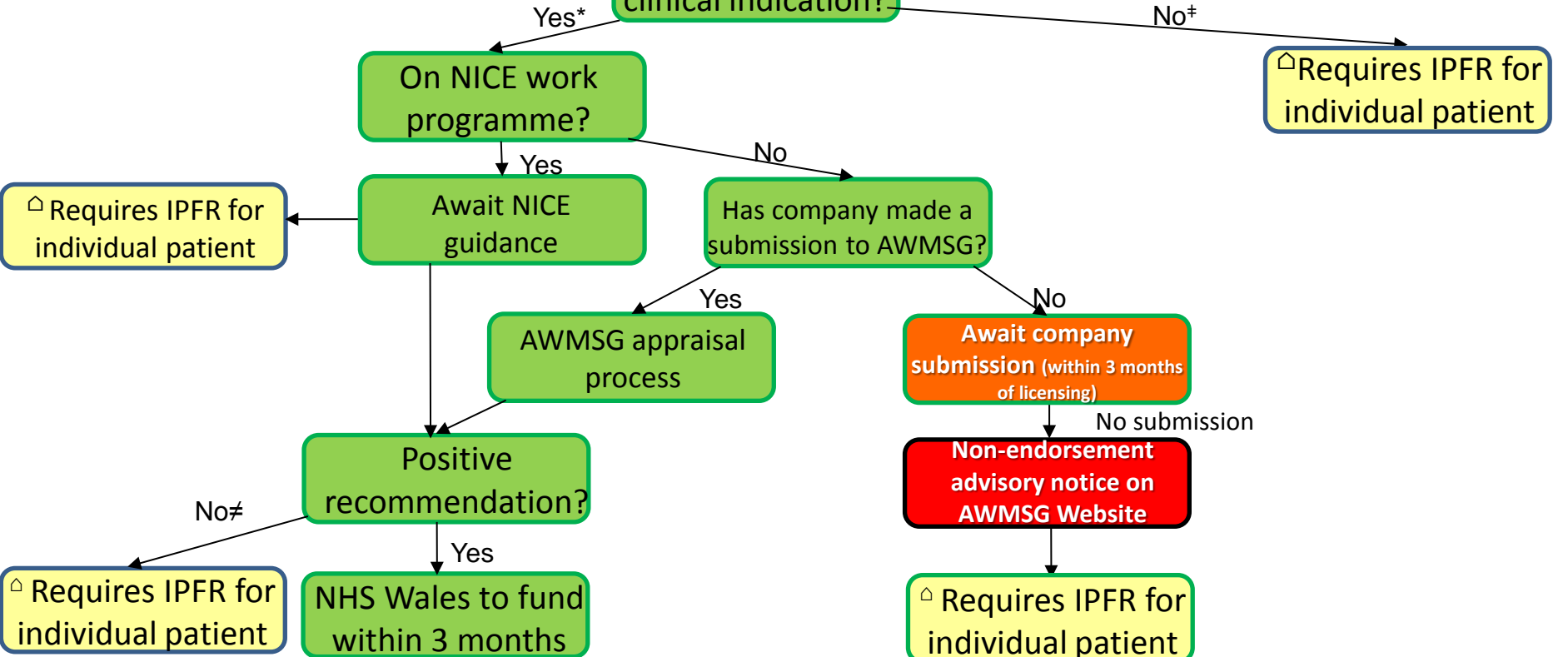
Await company submission (within 3 months of licensing)

NHS Wales to fund within 3 months

Non-endorsement advisory notice on AWMSG Website

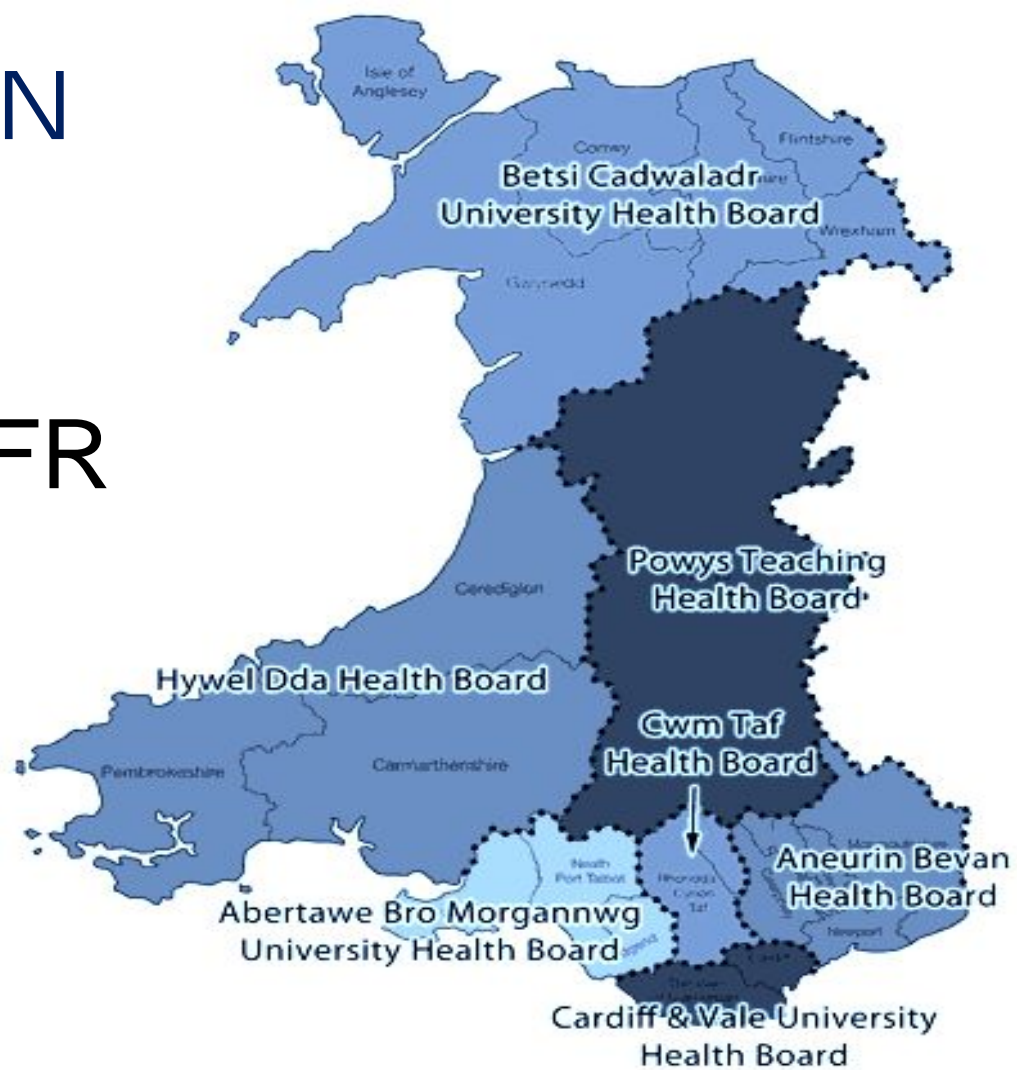
⬆ Requires IPFR for individual patient

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IPFR PANELS IN WALES

- 7 Health Board IPFR Panels
- 1 “national panel” (WHSSC)



What is an Individual Patient Funding Request?

IPFR

- 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

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)

IPFR

IPFRs conducted since 2012?

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

**IPFR
system**

**2014 IPFR
Review**

**Present
Review**

2016-17 Review of IPFR Process

“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



Methods to achieve access for patient groups

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

Generic name	Trade name	AWMSG Status	MINISTERIAL RATIFICATION	NICE STATUS	NICE APPRAISAL DATE
sorafenib	(Nexavar®)	Optimised recommendation	05/04/2016	Not recommended	26/05/2010
aflibercept	(Zaltrap®)	Not recommended	08/06/2015	Not recommended	25/03/2014
eribulin mesilate	(Halaven®)	Optimised recommendation	29/04/2016	Not recommended	01/04/2012
pomalidomide	(Imnovid®)	Recommended	27/08/2015	Not recommended	26/03/2015

"One Wales" Interim Commissioning Process for licensed medicines

New medicine

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- △ Some LHBs have price threshold before conducting IPFR

Yes*

No†

On NICE work programme?

△ Requires IPFR for individual patient

Await NICE guidance

Has company made a submission to AWMSG?

Company not yet ready for HTA

Meets criteria for one Wales Interim Commissioning?

△ Requires IPFR for individual patient

AWMSG appraisal process

Await company submission (within 3 months of licensing)

One Wales Interim Commissioning process

Positive recommendation (with ratification?)

Non-endorsement advisory notice on AWMSG Website

Positive recommendation (with ratification?)

No≠

Yes

No submission

No

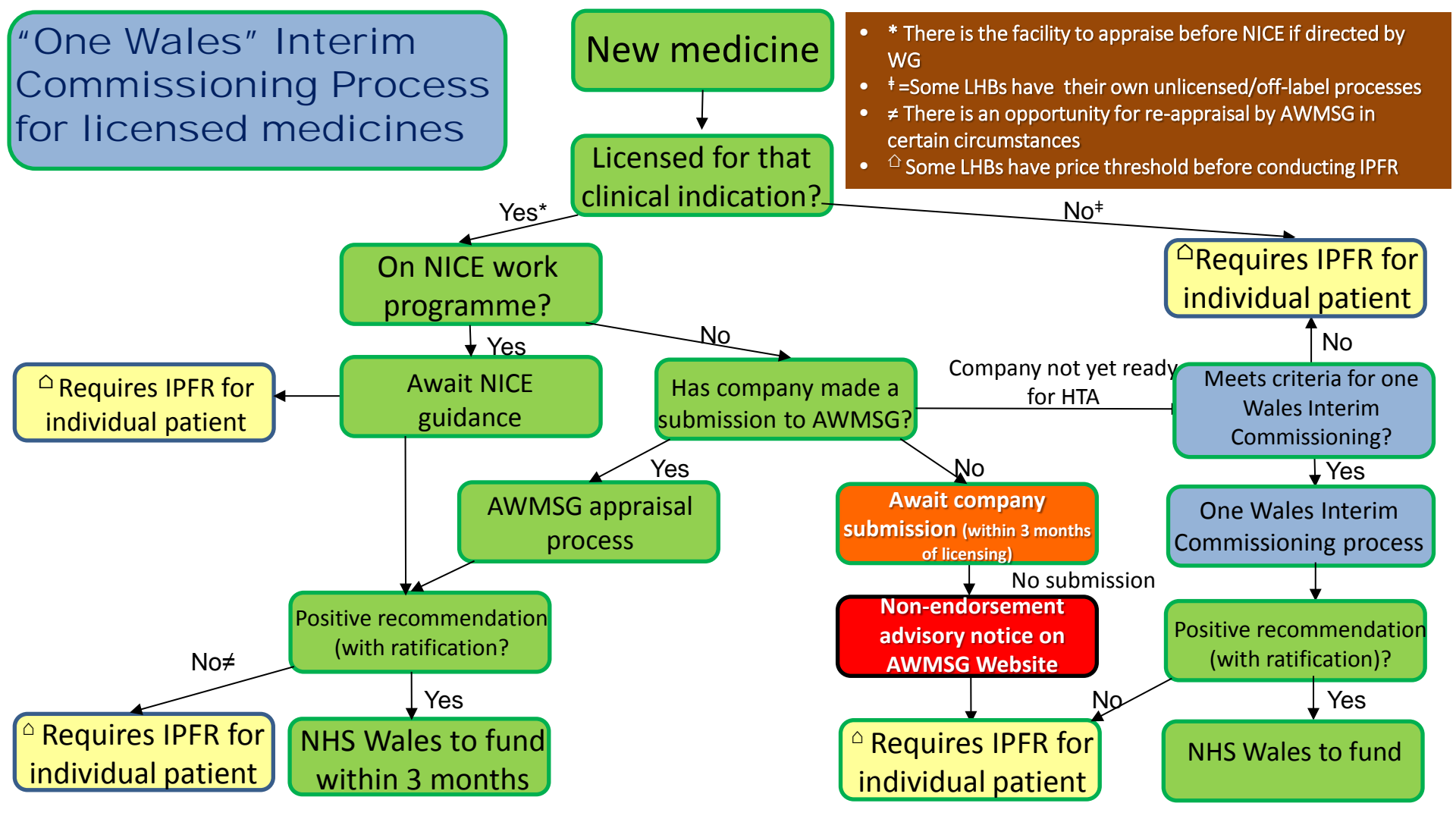
Yes

△ Requires IPFR for individual patient

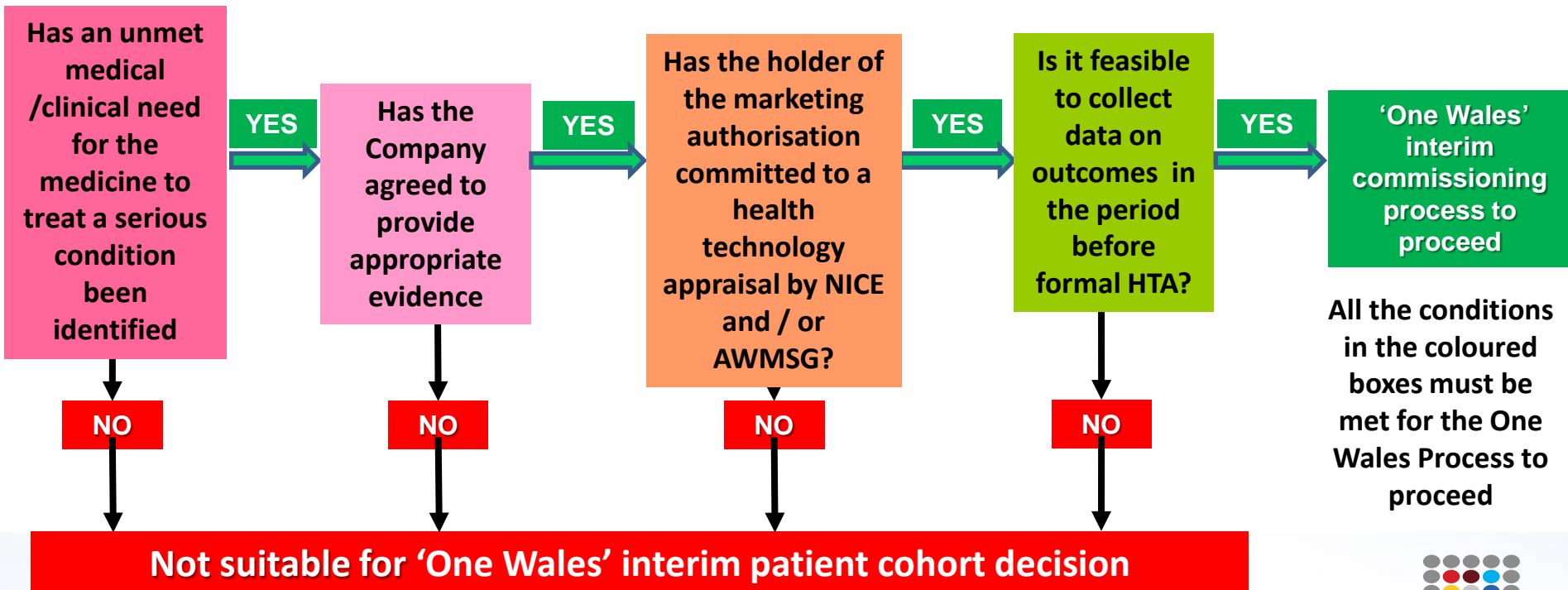
NHS Wales to fund within 3 months

△ Requires IPFR for individual patient

NHS Wales to fund



“One Wales” Decision Tool for licensed medicines



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 Commissioning Process for off-label use

New medicine

Licensed for that clinical indication?

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- ≠ There is an opportunity for re-appraisal by AWMSG in certain circumstances
- ⊠ Some LHBs have price threshold before conducting IPFR

Yes*

On NICE work programme?

No‡

⊠ Requires IPFR for individual patient

Yes

Await NICE guidance

No

Has company made a submission to AWMSG?

No‡

Meets criteria for one Wales Interim Commissioning?

⊠ Requires IPFR for individual patient

Company not yet ready for HTA

Yes

AWMSG appraisal process

Yes

Await company submission (within 3 months of licensing)

One Wales Interim Commissioning process

Positive recommendation (with ratification?)

Non-endorsement advisory notice on AWMSG Website

Positive recommendation (with ratification?)

No≠

Yes

No submission

No

⊠ Requires IPFR for individual patient

NHS Wales to fund within 3 months

⊠ Requires IPFR for individual patient

NHS Wales to fund

“One” Wales Interim Pathway Commissioning Group (IPCG) decisions, May 2016 to date

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

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



Conclusions

- Health technology Appraisal (HTA) remains the most important mechanism to ensure patients can access clinically effective and cost-effective medicines in a timely fashion
- In certain circumstances, the one-Wales Interim Commissioning process may allow time to collect outcome data to allow subsequent definitive HTA of licensed medicines/ indications or to establish an all Wales approach for certain off-label indications
- The individual Patient Funding Request (IPFR) Process may enable individual patients to access treatments and devices not normally available via the NHS. It working is presently being reviewed in Wales



Acknowledgements

Gail Woodland

Ann-Marie Matthews

Karen Samuels

Kath Haines

Tony Williams

Ruth Lang

Rosie Spears

Jess Davies

Rest of the AWTTTC team at University Hospital Llandough



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