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All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Comparators

Professor James Coulson

IPFR Workshop

Thursday 16 May 2024

GIG CYMRU NHS WALES

Shall I compare thee to a summer's day?
Thou art more lovely and more temperate:
Rough winds do shake the darling buds of May,
and summer's lease hath all too short a day;

Shakespeare W, 18th sonnet

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Comparators

Two contexts:

- Patient group – application of part 9a and 9b
- Intervention – next best alternative, standard of care, treatment choice

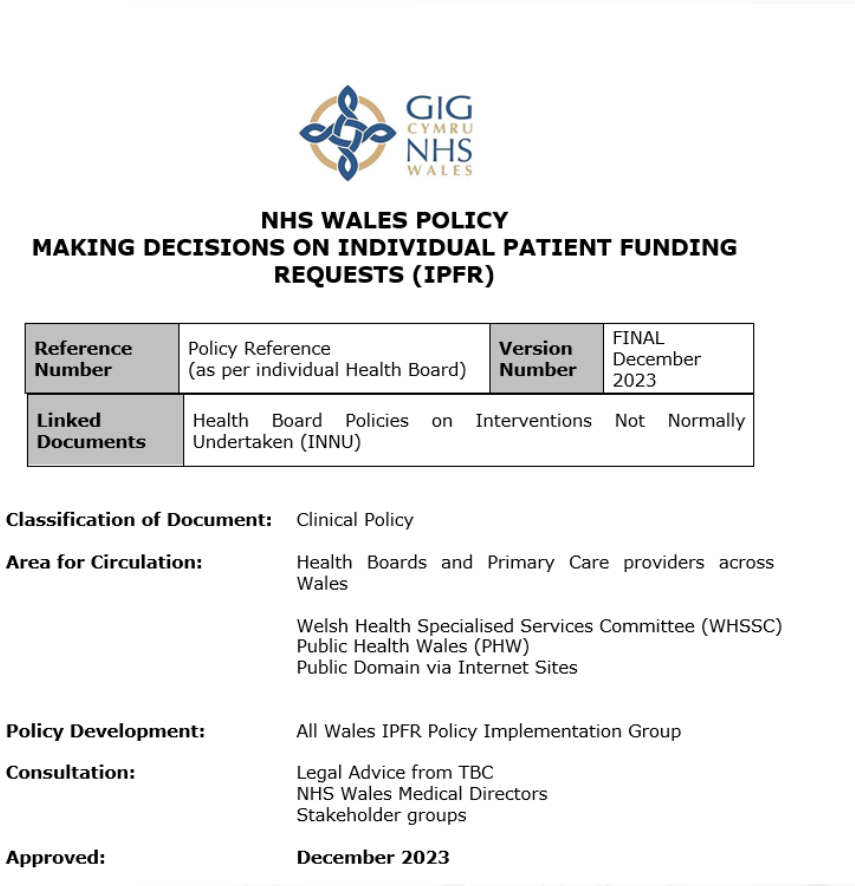
A patient will only be entitled to NHS funding for the requested intervention or drug if the panel conclude that the criteria under **either** **(a)** **or** **(b)** below are satisfied:
(a) If guidelines (e.g. from NICE or AWMSG) recommend NOT to use the intervention/drug, or the clinical access criteria of an applicable policy are not met: I. The clinician must demonstrate that the patient's clinical circumstances are significantly different to other patients for whom the recommendation is not to use the intervention. II. The clinician can demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to use the intervention, and III. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.
(b) If the intervention has NOT been appraised (e.g. in the case of medicines, by AWMSG or NICE), and there is no applicable policy in place: I. The clinician can demonstrate that the patient is likely to gain significant clinical benefit, and II. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.

Policy review and update 2017

- Findings of the independent review of the IPFR process and the report published by Welsh Government in 2017 states:
  - The patient's clinical circumstances should be considered in comparison with other patients with the same condition and at the same stage in the progression of that condition.
  - The words "significantly different to the general population of patients" mean that the patient's condition does not have substantially the same characteristics as other members of that population. For a patient to be significantly different, their particular clinical presentation was unlikely to have been considered as being part of the population for which the policy was made."

Policy update 2023

- Judicial Review of IPFR decision in Dec 2021
- IPFR Panel found to have not used the correct comparator group
- *de minimis* review of the policy advised by Welsh Government in 2021
- Publication and implementation 2024



NHS WALES POLICY
MAKING DECISIONS ON INDIVIDUAL PATIENT FUNDING REQUESTS (IPFR)

Reference Number	Policy Reference (as per individual Health Board)	**Version Number**	FINAL December 2023
Linked Documents	Health Board Policies on Interventions Not Normally Undertaken (INNU)		

Classification of Document:	Clinical Policy
Area for Circulation:	Health Boards and Primary Care providers across Wales Welsh Health Specialised Services Committee (WHSSC) Public Health Wales (PHW) Public Domain via Internet Sites
Policy Development:	All Wales IPFR Policy Implementation Group
Consultation:	Legal Advice from TBC NHS Wales Medical Directors Stakeholder groups
Approved:	**December 2023**

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2024 Policy updates

- Wording of the policy has been strengthened to ensure it reflects the correct intention.
- The role of the panel has been made clearer in terms of what they are being asked to consider and document.
- The ‘decision making guide’ has been moved to the appendices, retained as a guide.
- Other changes …….TOR updates, removal of JR process and change to ‘putting it right’

New policy wording

- Section 4 of the revised policy now states: *where a recommendation has been made not to use an intervention, the panel is required to consider whether the patients' clinical circumstances are significantly different to other patients for whom the recommendation is made not to use the intervention. That process will usually require a comparison between the patient for whom treatment is being requested, and other patients with the same medical condition who could have been offered the requested intervention if the relevant guidance and/or applicable policy allowed.*

Decision-making guide

Significant clinical benefit:

Is the clinical presentation of the patient's condition significantly different in characteristics to other members of that population?

And

Does this presentation mean that the patient will derive a greater clinical benefit from the treatment than other patients with the same condition at the same stage?

A patient will only be entitled to NHS funding for the requested intervention or drug if the panel conclude that the criteria under **either** **(a)** **or** **(b)** below are satisfied:

(a) If guidelines (e.g. from NICE or AWMSG) recommend NOT to use the intervention/drug, or the clinical access criteria of an applicable policy are not met:

I. The clinician must demonstrate that the patient's clinical circumstances are significantly different to other patients for whom the recommendation is not to use the intervention.

II. The clinician can demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to use the intervention, and

III. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.

(b) If the intervention has NOT been appraised (e.g. in the case of medicines, by AWMSG or NICE), and there is no applicable policy in place:

I. The clinician can demonstrate that the patient is likely to gain significant clinical benefit, and

II. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.

Sources for interventions and comparators

- Application form should provide clarity on:
  - Treatments used so far
  - Available guidance/pathways
  - MDT advice/specialist advice where pathway is uncertain
  - Alternative treatment options (including rationale for why not chosen)
- Alternative resources:
  - NICE/AWMSG: licensed and HTA-approved alternative treatments
  - AWMSG Guidelines/HTW Guidance
  - NICE Clinical Guidelines/interventional guidelines/evidence summaries
  - Clinical Knowledge Summaries
  - National/local guidelines
  - NHSE, SMC

Example - part 9a - case 2 – sperm banking

- Bilateral testicular atrophy secondary to what is presumed to be a perinatal vascular event. Not expected to have any residual fertility.
- The patient's father wishes to bank his sperm to allow the patient the potential use for the future, as opposed to an unrelated sperm donor. This would offer them the opportunity to retain a genetic link to any future children.
- Request: Fertility preservation via the collection of the father's sperm and the freezing and storage of that sperm for the patient's use in the future.

Example Part 9 a – case 2 - continued

- Policy states recommended for: *Men and adolescent boys preparing for medical or surgical treatment that is likely to make them infertile should be offered semen cryo-storage.*
- The father is not undergoing treatment
- *Cryopreserved material should be stored for an initial period of 10 years. After which the IVF provider should review patients and consider continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility.*
- The child will still be a teenager in 10 years-time.
- Clinical access criteria are not met.

Comparator group?

What intervention are we comparing to?

What patient group are we comparing to?

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Example Part 9a – comparator group

- **Comparator/intervention:** donated sperm of unrelated person

- **People not included in the policy:** Men and adolescent boys that are infertile/likely to become infertile due to a reason other than medical or surgical treatment that is likely to make them infertile.

- Consider whether the patient's clinical presentation means that the patient would derive a greater clinical benefit from having access to his father's donated sperm than the next best alternative treatment (donated sperm of an unrelated person).

Example – part 9b – case 1

- Request for ‘triplet therapy’ with azacitidine, venetoclax and gilteritinib - relapsed acute myeloid leukaemia.
- Bridge to transplant
- No applicable policy
- No HTA advice (off-label combination)

Comparator group?

What intervention are we comparing to?

What patient group are we comparing to?

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Example Part 9b – case 1 – comparator group

- **Comparators**:

  Application form:

  - Palliative care stated as alternative option (with life expectancy of 2-3 months)
  - Intensive chemotherapy potentially much more toxic and AML expected to be relatively resistant.
  - Clinical trials not currently available
  - Gilteritinib monotherapy has not worked sufficiently well

  MDT approval for triplet therapy

Comparator group – case 1 - continued

- NICE: Gilteritinib for treating relapsed or refractory acute myeloid leukaemia - TA642 published, 12 August 2020 – evidence section discusses comparators (2019)
- Cancer clinical network pathways – ‘in development’
- British Society haematology – included in NICE evidence section
- ESMO – consider also applicability to Welsh patients?
- Other?

Comparator group – case 1 - continued

- **Patient group:** Patients with relapsed/refractory AML

- Consider whether the patient's clinical presentation (relapsed/refractory AML) means that the patient would derive a greater clinical benefit from having access to off-label triplet therapy than the next best alternative treatment (palliative care?).

Remember

- There is never a right or wrong answer provided you have followed the process….
- Consistency in policy and approach, together with clarity about clinical criteria for treatment and a consistent approach to dealing with IPFR requests should reduce the need for patients to have to go through a review or appeal process at any level.
- Clearly document your decision criteria and rationale

Diolch am wrando
Thank you for listening

https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/ipfr/

https://cttcg.gig.cymru/mynediad-at-feddyginiaethau/mynediad-at-feddyginiaethau-yng-nghymru/ceisiadau-cyllido-cleifion-unigol-ipfr/

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