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WHSCC Prioritisation Process for the 2020/23 Integrated Commissioning Plan (ICP)

An Overview

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1. Introduction

NHS Wales and WHSSC must ensure that investment decisions are:

- affordable and offer value for money
- supported by convincing evidence of safety and effectiveness, and
- made using a process that is consistent and transparent.

To achieve this WHSSC has developed a process that enables it to compare competing proposals for new investment so that these can be prioritised and subsequently implemented.

Health care decision making requires balancing the demand of new technologies and services against finite resources. This inevitably leads to commissioners of health care making choices between many attractive alternatives and saying no to some things that are worthy and desirable.

Innovation within healthcare provides a stream of new treatments and interventions. Within the field of specialised services these often represent treatments of high cost for low patient numbers.

This process adopts the principles of Prudent Healthcare[1] and supports implementation of the Future Generations Act in Wales[2]. The process sets out to reduce inappropriate variation using evidence based practices consistently and transparently with the public, patients and professionals as equal partners through co-production.

Identifying topics for prioritisation

The dual processes of horizon scanning and prioritisation can help ensure the NHS in Wales effectively commissions' clinical and cost effective services, and makes new treatments available in a timely manner. Horizon scanning identifies new interventions which may be suitable for funding, and prioritisation allows them to be ranked according to a set of pre-determined criteria, including their clinical and cost effectiveness. This information when combined with information around demands from existing services and interventions will underpin and feed into the development of the WHSSC Integrated Commissioning Plan (ICP).

A comprehensive overview of the entire WHSSC prioritisation process algorithm for 2019/20 is presented in Figure 1 (see page 12).

[1] Prudent Healthcare: https://gov.wales/topics/health/nhswales/about/prudent-healthcare/?lang=en
[2] Well-being of Future Generations (Wales) Act (2015): https://futuregenerations.wales/

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Purpose

This document describes the methodology that WHSSC uses in order to determine the relative prioritisation of new interventions within specialised services for 2020/21. This methodology has been adapted from the model used by WHSSC over the last two years and incorporates several elements from other published prioritisation processes, particularly those used by NHS England[3], the National Specialised Services Committee in Scotland[4] and the system favoured in Canada[5].

[3] NHS England, Commissioning Operations, Specialised Commissioning (April 2016) Developing a method to assist investment decisions in specialised commissioning: next steps. https://www.england.nhs.uk/commissioning/spec-services/key-docs/
[4] National Specialist Services Committee, NHS Scotland (2015) Annual Prioritisation Round 2015-2018. http://www.nsd.scot.nhs.uk/services/specserv/
[5] CADTH. https://www.cadth.ca/

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2. Horizon scanning and prioritisation of interventions by WHSSC for funding in 2020/21

2.1 Horizon Scanning

The use of horizon scanning is now firmly embedded in WHSSC's commissioning practice and has been applied successfully for the past three years.

Horizon scanning identifies and monitors new and emerging health technologies that are likely to have a significant impact on the delivery of healthcare. Horizon scanning aims to support planning and priority setting and to assist in the prioritisation and allocation of resources. It has enabled WHSSC to provide reliable estimates of future expenditure in order to inform development of the ICP.

Information sources

Horizon scanning can vary in its extent and complexity dependent upon the time and resource available and requires a systematic examination of all relevant information sources.

Since 2016, WHSSC has developed a much more robust and systematic horizon scanning function and arrangements are now in place with the All Wales Medicines Strategy Group (AWMSG) and Health Technology Wales (HTW) to identify future medical and non-medical technologies. Both organisations draw on the following existing published resources and this is supplemented by a close examination of other published sources of information (Table 1):

- NICE Health Tech Connect
- UK Pharma Scan
- Specialist Pharmacy Service (SPS)
- NIHRIO Technology Briefings
- Euro Scan

A horizon scanning exercise was carried out by the Medical Directorate at WHSSC between January and June 2019 to inform this process. A finalised record is available on request.

The horizon scanning process generated three lists.

i. Interventions where there is currently an obligation to fund (NICE TA/HST guidance and AWMSG guidance). Interventions for obligatory funding will require an impact assessment, policy development and Equality Impact Assessment (EIA) before progressing directly into ICP development. All of these have been excluded from the prioritisation process.

ii. All NICE TA/HST guidance and AWMSG appraisals which have been turned down. All of these have been excluded from the prioritisation process.

iii. New interventions that need to be considered through a process of prioritisation. These will be the interventions considered by the Panel.

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Table 1: List of information sources for horizon scanning

Organisation	Information source
• NICE Highly Specialised Technologies (HST) Guidance Work Programme. Positive assessments are currently obligatory to fund in Wales	https://www.nice.org.uk/guidance/indevelopment?type=hst
• NICE Technology Appraisal (TA) Guidance Work Programme. Positive assessments are obligatory to fund in Wales	https://www.nice.org.uk/guidance/published?type=ta
• Other NICE guidance. There are a range of different types of guidance produced by NICE which are not mandatory. Of these the Interventional Procedures Guidance (IPG) and Medical Technologies Guidance are the area's most likely to impact on specialised services	https://www.nice.org.uk/guidance/published?type=ip and https://www.nice.org.uk/guidance/published?type=mtg
• All Wales Medicine Strategy Group (AWMSG) Evidence Appraisal Work Programme: Positive assessments are obligatory to fund in Wales (subject to Cabinet Secretary approval)	http://www.awmsg.org/
• Health Technology Wales (HTW)	http://www.healthtechnology.wales/
• Interim Pathways Commissioning Group (IPCG). This group considers an unlicensed medicine or one outside of the normal treatment pathway identified via the 'One Wales' process.	https://www.awttc.org/pams/one-wales-interim-commissioning-process
• NHS England Commissioning through Evaluation (CtE) scheme	https://www.england.nhs.uk/commissioning/spec-services/npc-crg/comm-eval/
• WHSSC Commissioning Teams	Lead Planners and Associate Medical Directors, WHSSC
• Individual Patient Funding Requests (IPFR): The IPFR process often provides early indications of clinical demand for new treatments	Patient Care Team, WHSSC
• Provider Health Boards and Trusts: WHSSC formally approaches providers on an annual basis to identify new interventions for development	Health Boards and Trusts
• NHS England (NHSE) propositions. Many specialised services are delivered in England for the population of Wales and new service developments within England can stimulate demand from within Wales	NHSE Clinical Reference Groups (CRGs), Clinical Priorities Advisory Group (CPAG), Rare Diseases Advisory Group (RDAG)
• Scottish Medicines Consortium	https://www.scottishmedicines.org.uk/Home
• Northern Ireland and Social Care Board	http://www.hscboard.hscni.net/
• Clinicians with a special interest in a clinical condition may lobby for commissioning of emergent therapies	Individual clinicians
• Welsh Government strategic priorities.	Welsh Government

2.2 Prioritisation

The scoring and ranking of interventions by the WHSSC Prioritisation Panel is carried out using methodology described in the All Wales Prioritisation Framework (2011) (see Attachment 3 and All Wales Prioritisation Framework). The framework presents a fair and transparent process to ensure that evidence-based healthcare gain and value for money is maximised.

The following key principles have been applied:

- That the process is specific for Wales and therefore reflects the needs and priorities of our population.
- The process reflects current Welsh Government (WG) policy and in particular the principles of Prudent Health Care[6].
- That in line with the principles of Prudent Health Care[6] we do not (wherever possible) duplicate work already completed within the other UK nations around evidence evaluation and prioritisation.
- That where the process identifies interventions where the evidence for clinical or cost effectiveness is very weak or there are safety concerns, no routine commissioning should be recommended.
- The need to ensure appropriate and timely engagement and consultation with colleagues in NHS Wales during the entire prioritisation process.

All voting members of the Panel will be asked to score each intervention against a set of pre-determined criteria in order to develop recommendations on their relative priority. These criteria are described further in Section 6. Each intervention presented to the Panel will be supported by a comprehensive evidence review.

Group decision support systems (GDSS) (provided by the Swansea Centre for Health Economics[7]) are integrated into the process to facilitate decision-making, gain consensus and improve the use of time in the meeting. This method employs a voting system and a set of wireless handsets to enable parallel, simultaneous and anonymous individual input. Voting in this way allows final recommendations to be made in a collegial atmosphere, without conflict or disagreement.

Based on the combined mean scores you will be asked to split the list of topics to be discussed into 'high', 'medium' and 'low' for prioritisation within the ICP. Only those with a high priority will be included for consideration within the ICP.

[6] https://gov.wales/topics/health/nhswales/about/prudent-healthcare/?lang=en
[7] Swansea Centre for Health Economics

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Topics assessed to date

The WHSSC Prioritisation Panel is now well established and provides a robust and evidence based process for assessing new interventions. Since the WHSSC prioritisation process was revised in 2016 a total of 43 new propositions have been assessed by the Panel.

The results/recommendations are as follows:

- High priority for inclusion in the ICP (n=12)
- Medium priority for inclusion in the ICP (n=9)
- Low priority for inclusion in the ICP (n=11)
- Removed from the prioritisation process (n=11), for example subsequent NICE/AWMSG appraisal, already commissioned or recommended via IPFR.

Although the low and medium priority topics were not considered they were highlighted to the Commissioning Teams with many schemes featuring on the WHSSC Risk Management Framework (RMF). This framework sets out the risks of low and medium priority/unfunded schemes across the three domains of patient, provider and commissioner. The RMF aids in informing the schemes to be considered for inclusion in the ICP and also manages the risks for those schemes not funded.

Static list

Historically the high priority propositions have been forwarded for consideration within the WHSSC ICP whilst propositions ranked medium and low have remained unfunded and have not been reassessed for inclusion in a future ICP.

In 2019/20 WHSSC introduced an additional step in the prioritisation process with the creation of a 'static list' for low and medium priority topics. Topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on their priority. However all topics on the static list will be routinely reviewed every three years. Topics assigned to the static list will be classified as 'not for routine commissioning' but can continue to be requested via IPFR.

The following was agreed:

- High priority topics – these will continue to be prioritised for consideration within the ICP by the WHSSC Management Group (MG) and Clinical Impact Assessment Group (CIAG).
- Low priority topics – these will go straight to the 'static list'.
- Medium priority topics – these will be considered by the Prioritisation Panel for a second time the following year. If the topic

is scored medium or low priority it will be immediately transferred to the 'static list'.

Therefore in addition to new topics identified this year via horizon scanning, you will also be asked to consider and score the medium priority topics from last years' prioritisation panel meeting.

Wherever possible an evidence update has been carried out for those topics scored as 'medium' and these will be presented to you during the Panel meetings.

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3. List of interventions to be prioritised (2020/21)

3.1 New interventions

The horizon scanning process has identified **11** new interventions for consideration (Attachment 4). These were presented and discussed at the first Panel meeting on the 17th September 2019.

3.2 Medium priority topics from the static list

A total of **4** medium priority topics currently sit on the WHSSC static list for review this year (Attachment 4). These were presented and discussed at the second Panel meeting on the 19th September 2019.

3.3 Evidence evaluations

Each intervention/proposition presented to the Panel was supported by an evidence review. A presentation on how the evidence was retrieved and appraised was provided at the first Panel meeting.

The evidence review for each draft policy proposition was either carried out by colleagues at NHS England or by the team at Cedar (Cardiff University) or AWMSG.

For all the English policy propositions the Panel were presented with a copy of the Commissioning Policy document which contains a summary of the evidence. This should be sufficient information for you to score the clinical effectiveness of the intervention. However the full evidence reviews (including the evidence tables) are available on request from WHSSC.

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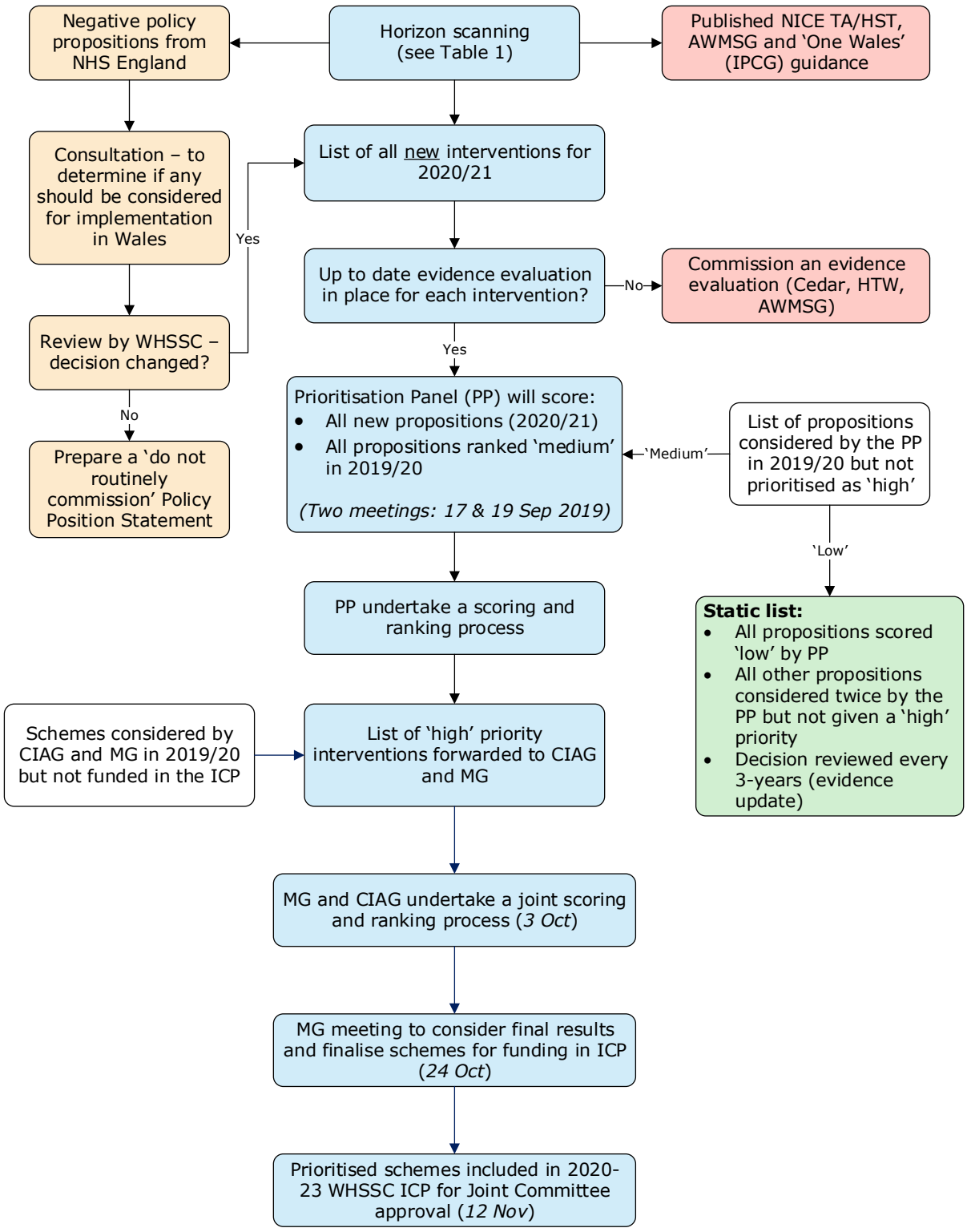
Figure 1. The WHSSC Prioritisation Process algorithm for 2020/21



4. Scoring

Each intervention was scored from 1 - 10 against all of the criteria described below. A high score indicates consistency with each of the criteria.

4.1 Criteria for prioritisation

The proposed criteria that will be used in prioritisation are:

- Quality and strength of the evidence of clinical effectiveness
- Patient benefit (clinical impact)
- Economic assessment
- Burden of disease – nature (severity) of the condition
- Burden of disease – population impact
- Potential for improving/reducing inequalities of access.

As a result of feedback received following last years' prioritisation process the criterion 'Burden of disease' has been split into two elements - nature (severity) of the condition and population impact – and these will be scored separately. In addition a summary table is now included with suggested 'weights' applied to each criterion (Table 2)

The review of priorities takes into account how the different criteria work together, including the balance of:

- clinical benefits and clinical risks
- the timing of the application with the urgency of the clinical need, what clinical alternatives are available, and the need to strengthen the evidence for clinical benefits
- cost per patient or treatment, clinical benefits per patient, and the robustness of the evidence for clinical benefits (clinical and cost-effectiveness of the treatment)
- overall cost impact and overall benefits from national commissioning (overall value for money of a national commissioning approach)

4.2 Equality and human rights

Although the criteria of 'equality and human rights' will not be explicitly scored in the prioritisation process, members are asked instead to carefully consider and be mindful of the impact of the *protected characteristics* within each of the proposals being presented.

WHSSC and NHS Wales must demonstrate that it understands the potential effect of adoption of clinical commissioning policies on people with characteristics that have been given protection under the Equality Act (2010)[8], especially in relation to their health outcomes. We must also

[8] Equality Act 2010 | Equality and Human Rights Commission

consider both the Social Services and Well-being (Wales) Act (2014)[9] when considering the well-being for people who need care and support (and carers who need support) and the Human Rights Act (1998)[10].

Therefore WHSSC should have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the act.
- Advance equality of opportunity between people who share a protected characteristic and for those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

These are often referred to as the three aims of the general equality duty and apply to the following protected characteristics:

- Age
- Disability
- Sex (gender)
- Gender reassignment
- Pregnancy and maternity
- Race
- Belief (or non-belief)
- Sexual orientation
- Marriage and civil partnership

[9] http://www.legislation.gov.uk/anaw/2014/4/pdfs/anaw_20140004_en.pdf
[10] The Human Rights Act | Equality and Human Rights Commission

5. Output from the Prioritisation Panel

Once the Prioritisation Panel has considered all the interventions (both new and those included from the static list) and assigned each a mean score, these will be tabulated and presented back to the Panel at their second meeting. Although members will be permitted to discuss the final results, a re-vote on any intervention or a change to the order of the results will be at the discretion of the Chair.

Members will then be asked to split the final prioritised list into 'high', 'medium', 'low' and 'no routine commissioning' based on their overall % score. These data when combined with information around demands from existing services and interventions will underpin and feed into the development of the WHSSC Integrated Commissioning Plan (ICP) for 2020-23 (see figure 1).

5.1 Recommended for 'no routine commissioning'

For any intervention where the Panel considers the evidence base to be too weak (or uncertain) (and therefore there should be no routine commissioning), a negative policy proposition will be taken out to public consultation and an EIA carried out. The policy will be reviewed in the light of this consultation and if the negative position is still supported then the process will be quality assured by the Prioritisation Panel before being accepted.

The Panel may also be faced with a proposition where the evidence base is weak (or uncertain) and the expected volume of eligible patients is expected to be very small (<1 per year). In these circumstances the Panel will also have the option to recommend that the intervention is considered via the IPFR route.

In those circumstances where a decision for no routine commissioning is endorsed, WHSSC will be required to carry out an assessment of current use of the intervention, quality assure the process and where necessary develop an implementation plan. The development of an implementation plan may be required if some patients are already receiving the treatment or are on the patient pathway through the IPFR route or because the Health Board has funded the treatment.

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6. Definitions for each of the assessment criteria

A summary of each criterion and suggested weighting is provided in Table 2.

A) Quality and strength of the evidence of clinical effectiveness

You will be asked to form recommendations on the relative prioritisation of the policy proposals using the principle of clinical effectiveness. You should only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness. This criterion considers (i) the *quality* of the evidence to support the use of the intervention and (ii) the *strength* of evidence available.

Briefly the levels of quality of the evidence can be summarised as follows:

1. Randomised trials (high)
2. Observational studies (medium)
3. Case series/case reports (low).

However the quality may be compromised by several factors including:

- Limitations in the design and implementation of available studies suggesting high likelihood of bias
- Indirectness of evidence
- Unexplained heterogeneity or inconsistency of results
- Imprecision of results (wide confidence intervals)
- Publication bias.

It should be noted that for much of highly specialist care the quantity and quality of the available evidence can be sparse.

Each policy proposition includes an evidence evaluation which provides a comprehensive critique of the clinical studies identified in the evidence review. This will include an assessment of bias and the generalisability of the evidence to help Panel members.

The quality of the evidence on the effectiveness of the intervention is described using established methods for grading research evidence. Commissioning policies developed by NHS England and Cedar have usually been developed using GRADE (The Grading of Recommendations Assessment, Development and Evaluation) methodology[11].

[11] The Grading of Recommendations Assessment, Development and Evaluation. http://www.gradeworkinggroup.org/

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B) Patient benefit (clinical impact)

This is defined as the potential for the technology to have an impact on patient-related health outcomes (from no expected change in outcomes to major potential improvements in outcomes). This criterion considers the balance of harms and effects based on the evidence presented in the evaluation.

Direct patient benefit may be demonstrated in one or more of the following ways. A drug, medical device or intervention could be life-saving, life-extending, life-improving (where the improvement in symptoms or functional capacity is detectable by the patient) or it provides reduced risk of developing a condition or disease.

Will this intervention have a positive effect on mortality, longevity and health related quality of life compared to the currently available treatment(s)?.

The Panel should also consider the potential for the intervention to have an impact on patient related health outcomes.

The potential benefit of each proposed investment can be described using the following metrics:

- Survival
- Progression free survival
- Mobility
- Quality of life
- Pain
- Anxiety/depression
- Replacement of more toxic treatment
- Dependency on care giver/supporting independence
- Safety

Some health metrics record clinical benefits rather than direct patient benefits, but these can be used as surrogate measures of patient benefit if it can be demonstrated that they provide an accurate, early indication of the direct patient benefit.

Where direct evidence of patient benefit is not available it may be inferred from the available clinical evidence. However, this should take into account the quality of the evidence for any clinical or patient benefit.

Members should not include in their consideration of patient benefit the following factors, societal benefit, the absolute cost of the intervention or considerations of affordability, any financial savings arising from it, the number of patients needed to be treated to give rise to the patient benefit, the prevalence of the underlying condition/illness.

The clinical benefit offered by the intervention is described in the independent review of the clinical evidence of each policy proposition.

C) Economic assessment

The treatment or intervention should demonstrate *value for money* and the role of the Panel is to try and assess the impact of the technology on healthcare spending in Wales.

The panel should consider the following key factors:

- Has evidence of a cost utility analysis been presented? If yes, has this demonstrated that the new intervention is cost effective compared to the existing treatment or intervention?
- Affordability
    - What are the costs of the intervention, including initial acquisition costs and running costs compared to the current 'gold standard' treatment?
    - Are there opportunities for cost savings by introducing this new technology?

Again it should be recognised for that for highly specialised treatments and interventions, evidence of cost effectiveness may be sparse or completely lacking. The Panel should take this into account when trying to assess the whether the new intervention has the potential for improved efficiency and cost effectiveness in the treatment of the condition/disease.

D) Burden of disease

Assessing this criteria involves the consideration of two main issues: the (serious) nature of the condition and the size of the population effected (individual, small cohort or large population). Panel members this year will be invited to vote on both of these criteria separately.

The following serves as guidance to Panel members in assessing the overall 'burden of disease' and highlights some of the considerations each Panel member will need to take.

D1) Serious condition

Regulatory bodies such as NICE and the FDA interpret the term *serious* follows:

'…. *a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one*'.

To satisfy this criterion, an intervention must be intended to have an effect on a serious condition or a serious aspect of a condition, such as a direct effect on a serious manifestation or symptom of a condition or other intended effects, including the following:

- A diagnostic product intended to improve diagnosis or detection of a serious condition in a way that would lead to improved outcomes.
- A product intended to mitigate or prevent a serious treatment-related side effect (e.g., serious infections in patients receiving immunosuppressive therapy).
- A product intended to avoid or diminish a serious adverse event associated with available therapy for a serious condition (e.g., product that is less cardiotoxic than available cancer therapy).
- A product intended to prevent a serious condition or reduce the likelihood that the condition will progress to a more serious condition or a more advanced stage of disease.

D2) Population impact

This is defined as the number of people (the size of the population) who are likely to benefit or be affected by the intervention or recommendation. Technologies that affect a large percentage of the population should score higher on this criterion. The Panel should also consider the issue of population impact separately when scoring each intervention in terms of access and reducing inequity (see section E).

E) Potential for improving/reducing inequalities of access

Members of the Prioritisation Panel must have regard to the need to reduce inequalities between patients when accessing health services and considering the outcomes achieved. The Panel may wish to identify potential health inequalities that may be present with the adoption of a specific policy proposition, and provide WHSSC with advice on how to commission services with a view to reducing health inequalities. This may influence the Panel's recommendation on the relative prioritisation of a specific policy proposition.

Introduction of new highly specialised treatments have the potential to affect equity, for example many specialised technologies are only available in a small number of major treatment centres.

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In addition there is inequity for some patients in Wales who are currently unable to access treatments and services already routinely commissioned across the other devolved administrations within the UK.

The Panel is asked to consider the following:

- whether introduction of the new treatment/intervention would help NHS Wales reduce inequalities between people in the general population in their ability to access these services and increase their potential for improved outcomes
- what will implementation of this policy mean for the individual patient/group of patients and the wider community?
- will this service or intervention contribute to reducing or widening health equalities within Wales?

This criterion should also consider the current availability of (effective) treatments contained within the concept of 'unmet need'. An unmet clinical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet clinical need includes an immediate need for a defined population (i.e. to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs).

- Is there currently no available therapy to treat this condition?
- If a therapy already exists for this condition has an improved effect on an outcome(s) of the condition compared with available therapy been demonstrated?

In some disease settings, an intervention that is not shown to provide a direct efficacy or safety advantage over available therapy, may nonetheless provide an advantage that would be of sufficient public health benefit to qualify as meeting an unmet clinical need.

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Table 2: WHSSC prioritisation criteria

Criterion	Definition (weight)	Suggested scores	Score definition
Quality and strength of the evidence of clinical effectiveness	This criterion considers the quality and strength of the available evidence to support the use of the intervention [15%]	8-10	High quality evidence presented to support intervention
		5-7	Moderate quality evidence presented to support intervention
		2-4	Low quality evidence presented to support intervention
		1	No/negligible evidence to support intervention
Patient benefit (clinical impact)	Potential for the intervention to have an impact on patient-related health outcomes (benefits and harms) [15%]	8-10	Major potential to improve clinical outcomes
		5-7	Moderate potential to improve clinical outcomes
		2-4	Little potential to improve clinical outcomes
		1	No expected improvement in clinical outcomes
Economic assessment	Impact of the intervention on healthcare spending [25%]	8-10	Demonstrates significant value for money / cost effectiveness
		5-7	Demonstrates moderate value for money / cost effectiveness
		2-4	Demonstrates limited value for money / cost effectiveness
		1	Demonstrates little/no value for money / cost effectiveness
Burden of disease – nature of the condition	The (serious) nature of the condition involved [15%]	Refer to section D1 p18	

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Burden of disease – population impact	The size of the population that would be affected (or would benefit) by the intervention [15%]	9-10	>50 eligible patients per year
		7-8	10-50
		4-6	1-10 per year
		1-3	< 1
Potential for improving/reducing inequalities of access	The intervention has the potential to introduce, increase or decrease equity in health status [15%]	9-10	Major potential to decrease (improve) inequalities of access
		6-8	Minor potential to decrease inequalities of access
		5	Will not affect inequality of access
		3-4	Minor potential to increase inequalities of access
		1-2	Major potential to increase inequalities of access