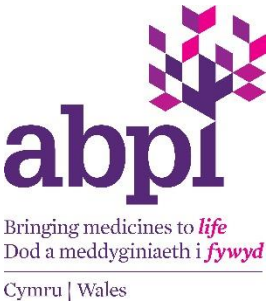


Welsh Medicines Procurement and Logistics Advisory Group

Delivering safe affordable medicines to our patients

Market Access in NHS Wales

(An overview of terminology and process)

Contents **Page**

Contents **Page**

Foreword

This document has been developed in partnership between the All Wales Medicines Procurement Pharmacist representing the Welsh Medicines Procurement and Logistics Advisory Group (WMPLAG) and ABPI Wales.

The Welsh Medicines Procurement and Logistics Advisory Group report to the All Wales Chief Pharmacist Group and have a broad membership of finance, procurement, quality assurance (QA), clinical and chief pharmacist representation from across NHS Wales.

This document is intended to specifically inform ABPI members, describing some of the terminology, processes and procedures they may choose to consider when planning market access for their medicines in NHS Wales, especially when those plans include alternative commercial or supply chain arrangements.

The patient remains a key focus for WMPLAG from a procurement and logistics perspective with the aim of always, where appropriate, supporting access to medicines as close to the patient's home as possible.

We hope this document will help enable constructive commercial and supply chain dialogue between WMPLAG and ABPI members, within the policy context as captured within 'A Healthier Wales'[i].

Mark Francis

All Wales Medicines Procurement Specialist Pharmacist

Rick Greville

ABPI Director - Wales and Distribution & Supply

Healthcare Technology Assessment

Health technology assessment (HTA) is a multidisciplinary activity that systematically examines the safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology – usually a medicine, medical device or clinical/surgical procedure.[ii]

In the UK, HTA broadly focuses on two questions:

- Clinical effectiveness – how do the health outcomes of the technology compare with available treatment alternatives?
- Cost-effectiveness – are these improvements in health outcomes commensurate with the additional costs of the technology?

The outcome of HTA by both National Institute for Health and Care Excellence **(**NICE) and All Wales Medicines Strategy Group (AWMSG) strongly impacts on the availability of medicines for patients in Wales.

Where no positive HTA outcome is available for a medicine, a clinician may be able to obtain funding for their patient where they can demonstrate that a significant clinical benefit is expected and that the cost of the treatment is in balance with the expected clinical benefit. This will be outlined in more detail later in this document (see Funding Mechanisms for medicines without HTA approval).

National Institute for Health and Care Excellence (NICE)[iii]

NICE positive guidance carries mandatory funding in Wales.[iv]

Technology Appraisals (TA)

TA's are recommendations on the use of new and existing medicines and treatments within the NHS. Recommendations are based on a review of clinical and economic evidence.

- Clinical evidence shows how well the medicine or treatment works.
- Economic evidence shows how well the medicine or treatment works in relation to how much it costs the NHS - does it represent value for money?

NICE TA's can take several forms:

- A Single Technology Appraisal (STA) which covers a single technology for a single indication. This will include consideration of the Budget Impact Test (BIT) or include a Cancer Drugs Fund (CDF) process, dependent on the technology. See below for further information on BIT and CDF.
- A Multiple Technology Appraisal (MTA) which normally covers more than one technology, or one technology for more than one indication.
- A Highly Specialised Technologies (HST) which covers a single technology for a very rare single indication
- On 1 April 2017, a Fast Track Appraisal (FTA) process was introduced, intending to speed up access to the most cost-effective new treatments.

Budget Impact Test (BIT)[v]

On the 1st April 2017, NICE introduced a BIT for technologies within its TA programmes (including HST), with the intention of assessing the resource or financial impact of a technology over the first 3-years of its use within the NHS in England (NHS(E)).

If the budget impact exceeds £20million in any of the first 3-years, NHS(E) may engage in commercial discussions with the Marketing Authorisation (MA) Holder, in an attempt to agree a Commercial Access Arrangement (CAA). These discussions are designed to mitigate the impact that funding the technology would have on the wider NHS budget.

Cancer Drugs Fund (CDF)[vi]

The "new" CDF process is part of the NICE TA work programme. All cancer drugs / indications expecting to receive a marketing authorisation (license) will be appraised by NICE.

NICE can now make one of three recommendations when they appraise cancer drugs:

YES – Recommended
NICE have recommended the medicine for routine commissioning, as per their usual process, and it will become available within two-months of the publication of the Final Appraisal Determination (FAD) in Wales.

NO - Not Recommended
NICE do not recommend the medicine and it will not be made routinely available to patients in Wales.

Recommended for use within the CDF **(new)**
NICE consider that there is plausible potential for the medicine to satisfy the criteria for routine commissioning, but there is significant remaining clinical uncertainty which needs more investigation, through data collection in the NHS or clinical studies.

A Managed Access Agreement (MAA) will need to be agreed between NHS(E) and the company for use in England (see later in this document).

Highly Specialised Technologies (HST)[vii]

HST evaluations are recommendations on the use of new and existing highly specialised medicines and treatments. NICE only consider medicines for very rare conditions.

The majority of topics selected for the HST programme are identified by the National Institute for Health Research Innovation Observatory. They aim to notify the Department of Health and Social Care of key, new and emerging healthcare technologies that might need to be referred to NICE against the following timeframes:

- new drugs, in development, at 20 months to marketing authorisation
- new indications, at 15 months to marketing authorisation.

A single HST evaluation can only cover a single technology for a single indication.

Fast Track Appraisal (FTA)[viii]

On 1 April 2017, NICE introduced an FTA for technologies that offer exceptional value for money. The aim is to provide quicker access for patients to the most cost-effective new treatments.

A technology will be appraised through the FTA process if:

- The company's base-case incremental cost-effectiveness ratio (ICER) is less than £10,000 per quality-adjusted life year (QALY) gained.
- It is likely that the most plausible ICER is less than £20,000 per QALY gained, and it is highly unlikely that it is greater than £30,000 per QALY gained. or
- A cost comparison case can be made that shows it is likely to provide similar or greater health benefits at similar or lower cost than technologies already recommended in technology appraisal guidance for the same indication.

If a positive recommendation is made through the FTA process, NHS England / commissioners have committed to providing funding for the technologies within 30 days of guidance publication.

Other Access Schemes Covering England and Wales

Early Access to Medicines Scheme (EAMS)[ix]

The EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation, when there is a clear unmet medical need.

Under the scheme, the Medicines and Healthcare Products Regulatory Agency (MHRA) will give a scientific opinion on the benefit / risk balance of the medicine, based on the data available when the EAMS submission is made. The opinion lasts for a year and can be renewed.

The scheme is voluntary and the opinion from MHRA does not replace the normal licensing procedures for medicines. The scientific opinion will be provided after a 2-step evaluation process:

1. the promising innovative medicine (PIM) designation
2. the early access to medicines scientific opinion

All Wales Medicines Strategy Group (AWMSG)

AWMSG positive recommendations, once ratified by Minister, carries mandatory funding in Wales.[x]

To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intends to publish final TA advice for the same medicine and indication(s) within 12-months of the date of marketing authorisation. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

In addition to new medicines receiving their first licence, new indications and formulations of previously licensed medicines can also be considered for appraisal by AWMSG.
An initial company submission (Form A) must be completed regardless of whether the product fits one or more of the AWMSG exclusion criteria or a submission has been forwarded to the NICE or the Scottish Medicines Consortium (SMC).

Full Submission[xi]

If AWMSG Steering Committee decides a full appraisal is required, the manufacturer is expected to submit comprehensive information, which is used by the All Wales Toxicology and Therapeutics Centre (AWTTC) – the AWMSG Secretariat - together with additional relevant information, in the preparation of their assessment report.

Full details of the process, timelines and templates for the process are available on the AWMSG website at www.wales.nhs.uk/awmsg/

Limited Submission[xii]

A limited submission may be deemed appropriate by the AWMSG Steering Committee in any of the following circumstances:

- A significant new formulation which has a pro-rata or lower cost per treatment e.g. slow release, new chemical salt of established medicine
- A license extension which is deemed minor by the AWMSG Steering Committee e.g. use in paediatrics
- If the anticipated usage in NHS Wales is considered by the AWMSG Steering Committee to be of minimal budgetary impact
- If the estimated difference in cost compared with the appropriate comparator(s) is deemed by the AWMSG Steering Committee to be small
- Follow on biologic medicines, i.e. a biologic product which is identical to an existing product (produced on the same production line in the same factory) but with a different product license

When a limited submission is deemed appropriate by the AWMSG Steering Committee, applicant companies may provide less information than routinely required in a Full Submission with the aim of proving clinical effectiveness / equivalence. However, evidence of budgetary impact in comparison to the comparator medicine(s) should be demonstrated.

AWMSG reserves the right to request a full submission in relation to any medicine at any time during its appraisal process. The decision of the AWMSG Steering Committee in this respect is final and binding.

Orphan / Ultra-Orphan Medicines[xiii]

In recognition of the clinical needs of patients with rare diseases, and acknowledging the potentially high costs of treatment, the appraisal committee will take broader considerations into account when appraising ultra-orphan medicines than those for orphan medicines, or for other medicines.

The incremental cost per QALY of orphan, ultra-orphan and medicines developed specifically for rare diseases will be included as an indicator of relative cost-effectiveness, whenever possible, within the appraisal. It should be noted that the cost per QALY is only part of a wider judgment of the value of a new medicine and societal aspects will also be an important component in the discussions and deliberations.

Where the cost per QALY is above the normal thresholds applied, additional criteria for appraising these medicines will be considered. These will include, but will not be limited to:

- The degree of severity of the disease as presently managed, in terms of survival and quality of life impacts on patients and their care

- Whether the medicine addresses an unmet need (e.g. no other licensed medicines)
- Whether the medicine can reverse or cure, rather than stabilise the condition
- Whether the medicine may bridge a gap to a "definitive" therapy (e.g. gene therapy) and that this "definitive" therapy is currently in development
- The innovative nature of the medicine
- Added value to the patient which may not adequately be captured in the QALY (e.g. impact on quality of life such as ability to work or continue in education/function, symptoms such as fatigue, pain, psychological distress, convenience of treatment, ability to maintain independence and dignity)
- Added value to the patient's family (e.g. impact on a carer or family life)

Life-extending, End-of-Life Medicines[xiv]

Additional criteria are taken into account by AWMSG when appraising medicines, which may be life-extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses.

The criteria for appraising life-extending, end-of-life medicines apply when the most plausible, incremental cost-effectiveness ratio (ICER) estimate exceeds £30,000 per quality-adjusted life-year (QALY) gained, and the following conditions are satisfied:

- The medicine is indicated for patients with a short life expectancy, normally less than 24 months (e.g. estimated from the median survival of patients in the control group of the pivotal study) and;
- There is sufficient evidence to indicate that the medicine offers an extension to life, normally of at least an additional three months, compared to current NHS treatment.

The estimates of the extension to life should be robust and shown (or reasonably inferred) from either progression free survival or overall survival. When these conditions are met, AWMSG will consider:

- The impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age, and;
- The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost-effectiveness of the medicine to fall within the current threshold range.

In addition, AWMSG will need to be satisfied that:

- The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression free survival or overall survival (taking account of trials in which cross-over has occurred and been accounted for in the effectiveness review) and;
- The assumptions used in the economic modelling are plausible, objective and robust.

Welsh Government Policy relating to Access to New Medicines

New Treatment Fund[xv]

The NHS in Wales is expected to fund, and resource medicines and treatments recommended by NICE's and the AWMSG's appraisal process. Since January 2017, as an integral part of the Welsh Government's New Treatment Fund, medicines with positive TA guidance must be available:

- no later than two months from the date AWMSG final guidance is ratified by Welsh Government
- no later than two months from the date of first publication of NICE's final guidance FAD or Final Evaluation Determination (FED)).

HTA and Procurement Jargon – Glossary of Terms

Whilst HTA processes may be well understood, it is just one part of an increasingly complex set of arrangements that can impact on the availability of new medicines to patients across Wales. The following is an attempt to list and define related terminology commonly used in relation to HTA and the procurement of medicines.

Managed Access Agreements[xvi]

Managed Access Agreements (MAA) are a relatively new arrangement following agreement between NHSE and NICE, through which, patients may receive new treatments while long-term data on them is still being gathered, at substantially discounted cost and before final funding decisions are taken.

Cancer Drugs Fund (CDF) MAA[xvii]

The CDF MAA consists of two key components:

- Data Collection Arrangement – this sets out the outcomes that need to be collected to resolve the key areas of clinical uncertainty.
- CDF Commercial Agreement[xviii] – this determines the cost of the drug during the managed access period.

NOTE: NICE documentation defines CAA as Commercial Access Agreements[xix]. Confusingly, other NICE and NHS England documentation also refers to similar terminology:

- CDF Commercial Agreement[xx]
- Commercial Access Arrangements[xxi]
- CDF Commercial Access Arrangements[xxii]

It remains unclear why different terms are used, seemingly interchangeably. One definition of commercial access arrangements in the CDF addendum alludes to it being a proposal from the company and the commercial access agreement being the finalised understanding.[xxiii]

In the context of the CDF, companies are asked to agree a CAA with NHS(E). These CAAs will be considered in the NICE TA. A glossary of terms published in relation to one STA for a cancer medicine is shown on page 16.

In Wales, details of an agreed MAA is encouraged to be shared by the manufacturer NHS(W) via the Chair of the AWDCC. On occasions, an alternative MAA may need to be agreed with NHS(W), which offers equivalent value for the period of the recommendation.

HST MAA[xxiv]

For drugs recommended for use within the HST Programme, a MAA will need to be agreed between the company, NICE and NHS(E). An MAA in the HST Programme may include:

- A proposal that addresses a significant uncertainty in the evidence base identified by the evaluation Committee (for example, a plan for generating further evidence for a patient population that is covered by the marketing authorisation but not represented in the clinical trials);
- A duration of the arrangement, with a rationale, that is agreed by the key stakeholders: the company, NHS(E) and patient groups;
- Clearly defined starting and stopping criteria with identified entry and exit points throughout the treatment pathway;
- Treatment continuation criteria;
- A list of outcomes for which data will be collected;
- How data will be collected and analysed;
- An agreement on how regular the outcomes in the MAA will be reviewed;
- The funding arrangements;
- A statement that describes what will happen to patients receiving treatment who are no longer eligible for treatment if a more restricted or negative recommendation is issued after the guidance has been reviewed following data collection;
- Financial risk management plans agreed between NHS(E) and the company that undertake risk-sharing for the duration of the agreement;
- An acknowledgement by patient groups of the role and responsibilities they hold within the arrangement.

In the context of the MAA, when the evidence of clinical effectiveness or impact of an HST on other health outcomes is either absent, weak or uncertain, the NICE Evaluation Committee may recommend that the technology is used only in the context of research or the technology is recommended as an option, but that formal data collection is conducted alongside routine use.

Before issuing such recommendations, the Committee will consider the following factors:

- The need for and potential value to the NHS of additional evidence that can inform the future development of NICE guidance and clinical practice on the use of the technology;
- The uncertainty in the analysis and what is needed to reconsider the decision in the light of research findings;
- Whether the data collection is feasible;
- The extent of irrecoverable costs incurred from introducing the technology and plans to mitigate this risk;
- The likelihood that the research needed will report;
- The time it is likely to take for research findings to be available to inform subsequent NICE guidance and clinical practice;
- Other factors that may impact on the data generation, such as other research that is underway or likely to be commissioned and completed.

In order to form the guidance, the Evaluation Committee will take account of commercial agreements (agreed with NHS(E)) and/or Patient Access Schemes (PAS) (agreed with NICE).

In Wales, this means the medicine will be funded, but there is an expectation that details of the MAA or equivalent is shared by the manufacturer with via the Chair of the All Wales Drugs Contracting Committee (AWDCC) and agreed by NHS Wales before the recommendation is implemented.

Commercial Access Agreements (CAA)

A CAA is a proposal from a company to NHS(E) to manage the cost of a drug to the NHS.

On occasions, simple Patient Access Schemes (PASs) may be considered as a type or component of CAA's.

A full list of medicines with various commercial arrangements is available from NICE: https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit/list-of-technologies-with-approved-patient-access-schemes

NOTE:

The NICE document *"Technology Appraisal and Highly Specialised Technologies programmes procedure for varying the funding requirement to take account of net budget impact"* [ii] refers interchangeably to "commercial discussions", "commercial agreement", "commercial engagement", "commercial arrangements" and – on one occasion in the document – "commercial access arrangements".

Unfortunately, it is unclear why this terminology has been used interchangeably.

CDF Commercial Agreement[xxv]

When NICE decides to recommend a technology for use within the CDF, the company will be invited to propose a CAA, or amend an arrangement that has already been proposed.

In order for a cancer drug to be recommended for use through the CDF, it must display plausible potential for satisfying the criteria for routine use, taking into account the application of the End of Life criteria where appropriate. Companies should work with NICE and ask for advice about the assumptions used in the consideration of clinical and cost effectiveness by the Appraisal Committee, which must form the basis of their proposal for a commercial access arrangement.

HST Commercial Agreement[xxvi]

A reconsideration step is available at specific points in the HST evaluation process. A reconsideration step provides the opportunity, if required, to develop new, or enhance existing Managed Access proposals and for NICE to discuss with the company, and NHS(E) one or more of a number of elements, for example;

- identification of sub-group(s)
- clinical tests
- starting and stopping criteria
- Patient Access Schemes
- conditions for collection of data
- commercial agreements between the company and NHS England

BIT Commercial Agreement[xxvii]

NHS(E) will offer to engage in commercial discussions with companies whose technologies have been appraised by NICE and where the BIT has been engaged before requesting a variation to the funding requirement.

The commercial engagement between the company and NHS(E) will be conducted in parallel with the appraisal or evaluation timescales. NHS(E) must provide a progress update to NICE at least 5-working days before the first appraisal or evaluation committee meeting. Any commercial agreements confirmed at this point will be to specifically manage the net budget impact of the technology and will not be taken into account by the Appraisal or HST committee in determining the cost effectiveness of the technology.

In Wales, the outcome of commercial discussions relating to BIT is expected to be shared by the manufacturer with NHS Wales (NHS(W)) via the Chair of the All Wales Drugs Contracting Committee (AWDCC). On occasions, an alternative CAA may be agreed with NHS(W), which offers equivalent value for the duration of the NICE recommendation.

Patient Access Scheme (PAS)[xxviii, xxix]

PAS are proposals that can facilitate patient access to a new medicine where NICE's assessment of value, on the current evidence base, is unlikely to support the company's proposed list price.

A PAS can only be proposed by the company and there are both *simple* and *complex* schemes. Complex schemes may include, for example, free stock, dose capping or schemes based on patient outcomes.

Full details of the principles agreed for such schemes are set out in Chapter 5 of the 2014 The Pharmaceutical Price Regulation Scheme (PPRS).

Simple PAS[xxx]

"Simple discount schemes must meet the simple discount criteria, which ensure that a PAS imposes no significant ongoing additional burden on the NHS, as set out in the PASLU process guide and the relevant PAS proposal template. The other option for a scheme member would be to change the list price of the product."[xxxi]

Complex PAS[xxxii]

Complex schemes include all other types of PAS. This could potentially incorporate a wide range of models. To date, components of PAS have included:

- Rebates;
- Stock supplied at zero cost;
- Dose capping;
- Outcome-based schemes.

In Wales, a PAS that has been previously approved by the Department of Health and is associated with a positive NICE appraisal recommendation will be accepted by NHS(W). Verification of the details of the scheme is expected to be shared by the manufacturer with NHSW via the Chair of the AWDCC

Welsh Patient Access Scheme (WPAS)[xxxiii, xxxiv]

WPAS are proposed by a pharmaceutical company within the AWMSG HTA process and agreed with the Welsh Government, following input from the Patient Access Scheme Wales Group (PASWG).

Simple

To qualify as a simple WPAS the applicant must offer a discount or price reduction:

- From the list price, applied for all supplies of the product applicable to all current and future indications (within the duration of the WPAS);
- Which applies to the original invoice, or the indicated price for the product;
- Which requires no additional administration to receive the price offered; 'additional' means over and above the administration required for procuring the medicine without a PAS (a single contract is allowed);
- Which will remain in place until or after AWMSG review (3 years).

The details of a simple scheme would routinely remain commercial in confidence.

Complex

If any of the above criteria are not met, then the scheme would be considered complex. Any proposed scheme that would operate in the primary care setting would be considered complex and should be submitted using the complex WPAS submission form. Schemes involving homecare may be considered complex or simple, depending upon the proposed operation of the scheme.

The details of a complex scheme would not routinely remain commercial in confidence.

Rebate Schemes[xxxv]

Definition taken from work undertaken by Bath and North East Somerset CCG.

Pharmaceutical rebate schemes are contractual arrangements offered by pharmaceutical companies, or third-party companies, directly to Health Boards or Primary Care organisations on prescribing expenditure for branded medicine(s).

- It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS.
- Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision-making processes or formulary development.
- Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources.

The CCG will need to be assured that the schemes offered do not breach any other UK legislation, in particular reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing made under the 2006 Act, the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness.

Medicines Procurement in Wales

Across NHS Wales, the integrated health service structure provides chief pharmacists with overall accountability for patient safety and expenditure related to medicines and pharmacy services in both the managed sector and primary care. The medicines procurement contract process managed by NHS Wales Shared Services Partnership (NWSSP) – Procurement Services with the support of an All Wales Medicines Procurement Specialist Pharmacist (AWMPSP) who provides clinical procurement leadership.

The NWSSP invite and manage all the medicine contract categories and services for the 7 health boards and Velindre Trust. The AWDCC act as the awarding body for these contracts and ensure compliance with all the legal and governance requirements under the public procurement regulations. The AWDCC includes health board medicine procurement lead pharmacists, the All Wales Quality Assurance (QA) pharmacist, chief pharmacist representation, a finance director and the medicines procurement category manager.[xxxvi]

Other medicines procurement services that are part of this national approach include;

Commercial agreements related to new medicines or indications that have been subject to HTA process by AWMSG or NICE

Any commercial agreements that form part of a health technology appraisal whether or not it is part of a managed access agreement will be agreed via the chair of the All Wales Drug Contracting Committee. This will ensure all the necessary governance requirements are followed and all the

organisations within NHS Wales will be equally and simultaneously able to access the medicine for their local population at the same cost.

Medicines Homecare Services

The Health Boards and Velindre Cancer Centre are working collaboratively in their approach to the delivery of medicines aligned to NHS Wales care closer to home strategy – A Healthier Wales our plan for Health and Social Care.

The collaboration is working in a virtual team to standardise practice, share experience and have a once for Wales philosophy to these services.

For example:

1. Adherence to the NHS Wales terms and conditions for provision of services or goods;
2. A standard serviced level agreement (SLA) for NHS Wales that can be shared with the homecare providers to ensure all parties are aligned;
3. Patient care and experience as the primary driver for the requirement for a medicine homecare service option;
4. An NHS Wales supplier engagement process to drive performance through regular supplier review meetings including the NHS standard KPI set for homecare services.

Primary Care Rebate Schemes - A Once for Wales Approach

All primary care rebate schemes must meet ethical, financial and governance requirements and that they can be administered to the requirements of the supplier. It is likely that individual schemes will be being implemented by multiple Health Boards and so there are considerable opportunities to benefit from economies of scale by adopting an All Wales approach, with a single point of access and administration.

The AWDCC on behalf of all Health Boards, will advise the Chief Pharmacists whether, or not, an individual proposal is suitable for adoption on a One Wales basis. The development of this strategy and standardised process for assessing and implementing any primary care rebate scheme has:

- Eliminated the assessment and approval burden for any rebate agreements offered to the individual Health Boards
- Ensured parity and equity of access to medicines for the patients of Wales and across Health Board boundaries
- Improved and standardized the governance of rebate schemes and reduce potential variability on the way they are managed across NHS Wales
- Enabled a digital solution to be commissioned by the Chief Pharmacists to automate the calculation and monitoring of all the rebate agreements with minimal additional administrative burden

Free of Charge Medicines[xxxvii]

HTA by AWMSG or NICE is the preferred approach for advising on the clinical effectiveness and cost effectiveness of newly licensed medicines. However, in the absence of, or whilst awaiting publication of HTA advice, some pharmaceutical companies may wish to offer NHS Wales a free of charge medicine supply agreement, to enable patients and clinicians' early access to a medicine at no cost.

Health board chief pharmacists and AWTTC Patient Access to Medicines Service (PAMS) will co-ordinate the free of charge medicine supply agreements on behalf of NHS Wales.[xxxviii] This policy will only apply to newly licensed medicines, where the MA holder has engaged in HTA via either AWMSG or NICE, and where the recommendation remains outstanding.

Each offer from a MA holder is expected to satisfy the following criteria:

- The medicine has been submitted for HTA by AWMSG or NICE, but a significant delay (e.g. over 6 months) is anticipated before guidance is expected.
- The medicine is not associated with significant additional administration costs (e.g. testing, administration or significant monitoring requirements).
- The medicine is fully free of charge and the offer is not a partial price discount.
- The MA holder makes a written commitment to supply the medicine for the specified indication free of charge until:

    - 60 days following publication of positive HTA guidance by AWMSG

    - 60 days following publication of a positive FAD or FED and, where appropriate, with an agreed commercial access agreement or patient access scheme in place

    - if the patient(s) continue to require it on clinical grounds if the HTA guidance is negative.

Medicines expected to help patients with life-threatening, long lasting or seriously debilitating illnesses, where no suitable licensed medicine is available, will be prioritised.

Funding Mechanisms for medicines without HTA approval

Individual Patient Funding Request - Wales[xxxix]

Individual Patient Funding Requests (IPFRs) are defined as requests to a Health Board, Trust or Welsh Health Specialised Services Committee (WHSSC) to fund NHS healthcare for individual patients who fall outside the range of services and treatments that the organisation routinely provides or commissions - this includes the funding of medicines which do not have HTA approval for the specific indication under consideration. Funding decisions will be determined on the information provided by the clinician to demonstrate the significant clinical benefit expected from the treatment for the patient and whether the cost of the treatment is in balance with the expected clinical benefit.

Since March 2015, AWTTC has worked with IPFR panels and WHSSC to implement recommendations from an independent review[xl] to strengthen and improve the IPFR process in Wales. This has given AWTTC a Wales-wide view on the treatments being requested by clinicians and has enabled the establishment of a One Wales Interim Commissioning Process, which may provide consistent and equitable funding of non-routinely funded medicines e.g. not HTA approved, unlicensed or off-label medicines, in defined ‘patient cohorts’ .

One Wales Interim Commissioning Process[xli]

Potentially beneficial, non-routinely funded medicines for specified patient cohorts may be identified by Health Board IPFR panels, WHSSC, Chief Pharmacists or clinical experts and submitted to AWTTC. The decision as to whether a One Wales Interim Commissioning Process is be initiated is sanctioned by the AWMSG Steering Committee, before review by the Interim Pathways Commissioning Group (IPCG), which advises the Executive Committee of Health Board Chief Executives as the final decision-makers with regard to One Wales Interim Commissioning.

Evidence collation by AWTTC differs depending on whether a medicine is licensed or unlicensed/off-label.

Licensed Medicine

An appraisal via early HTA would always be the preferred approach for routine funding of licensed medicines in Wales, however, in the absence of a robust evidence base, a licensed medicine may be considered for funding via the One Wales route. Once sanctioned for inclusion on the work programme, AWTTC will contact the holder of the MA and explore their willingness to make a binding commitment to;

- engage in a future NICE or AWMSG HTA (within a specified time, normally 12 months), and;
- provide the evidence to progress a One Wales Interim Commissioning Process.

In collaboration with the MA holder and clinicians, AWTTC will produce an Evidence Status Report (ESR) for consideration and recommendation by the IPCG.

Unlicensed Medicine

Once the need for a One Wales decision has been identified for an unlicensed medicine or outside of normal treatment pathway, AWTTC will contact the manufacturer to inform them that an ESR is being produced and invite them to submit appropriate non-promotional evidence of safety and efficacy in the specified patient cohort.

All NHS Wales organisations are expected to comply with the final decision of the Executive Committee of Health Board Chief Executives and the MA holder will be informed of the decision by AWTTC.

The duration of a One Wales Interim Commissioning decision will be agreed on a case-by-case basis. For licensed medicines, it is unlikely to exceed 18 months and would normally be 12 months or until publication/ratification of NICE TA guidance/AWMSG recommendation. Commissioning decisions regarding unlicensed medicines or unapproved pathways will be reviewed annually or earlier if new evidence becomes available.

Cancer – England

All new cancer drugs / indications expected to receive a marketing authorisation referred to NICE by DH Ministers

Legend – Source of Funding
Interim Funding – If agreed between NHS(E) and marketing authorisation holder
CDF Managed Access Scheme - Expectations on MA holder to include:
- Data Collection Tool – as agreed with NICE
- Commercial Access Agreement – as agreed with NHSE
- A commitment to the CDF Financial Control Mechanism

Notes
•It is possible for drugs to change recommendation between publication of the Appraisal Consultation Document and the Final Appraisal Determination and between the Final Appraisal Determination and Final Guidance. Those changes are not shown on the diagram.
•In some cases, NICE may go straight to publishing a positive Final Appraisal Determination i.e. skip publication of the Appraisal Consultation Document. Where this is possible, NICE will aim to publish the Final Appraisal Determination prior to Marketing Authorisation

NICE First Appraisal Committee Meeting (In Private)

Committee for Medicinal Products for Human Use Opinion Published

Usually ~ three months (but may be less)

Appraisal Consultation Document - YES

Appraisal Consultation Document - NO

Appraisal Consultation Document - CDF

Interim Funding

90 Day Target

Final Appraisal Determination - YES

Final Appraisal Determination - NO

Final Appraisal Determination - CDF

Interim Funding

MA Holder to refund any difference to subsequent Managed Access Scheme price

Interim Funding

CDF Managed Access Agreement signed and commenced as close to Final Appraisal Determination as possible

CDF Managed Access Scheme

Interim Funding

90-day legal funding directive (30 days for EAMS)

Final Guidance - YES

Final Guidance - NO

Final Guidance - CDF

IFR Only

Usually (but not exclusively) no more than 2 years

CDF Managed Access Scheme

MA holder liable to pay rebate on over-subscription of CDF

BASELINE FUNDING / ROUTINE USE

NICE Full Review *

Interim Funding / CDF Managed Access Scheme

Appraisal Consultation Document - YES

Appraisal Consultation Document - NO

Final Appraisal Determination - YES

Final Appraisal Determination - NO

Final Guidance - YES

Final Guidance - NO

90-day legal funding directive (30 days for EAMS)

BASELINE FUNDING / ROUTINE USE

IFR Only

References
NHS England - Appraisal and Funding of Cancer Drugs from July 2016... -
https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf
Letter from Welsh Government to Assembly Members (Jan 2017) –
http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Welsh%20Government%20New%20Treatment%20Fund%20Announcement%20January%202017.pdf
Letter from Welsh Government to Health Board Chief Executives (Jan 2017) -
http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Launch%20of%20New%20Treatment%20Fund%20January%202017.pdf
Letter from Welsh Government on Commercial & Managed Access Arrangements –
https://myabpi.abpi.org.uk/sites/WIG/_layouts/15/WopiFrame.aspx?sourcedoc=/sites/WIG/Documents%20of%20Interest/Letter%20to%20RG%20ABPI%20re%20Access%20Agreements%20041116.pdf&action=default

Cancer – Wales

Notes
•It is possible for drugs to change recommendation between publication of the Appraisal Consultation Document and the Final Appraisal Determination and between the Final Appraisal Determination and Final Guidance. Those changes are not shown on the diagram.
•In some cases, NICE may go straight to publishing a positive Final Appraisal Determination i.e. skip publication of the Appraisal Consultation Document. Where this is possible, NICE will aim to publish the Final Appraisal Determination prior to Marketing Authorisation

All new cancer drugs / indications expected to receive a marketing authorisation referred to NICE by DH Ministers

NICE First Appraisal Committee Meeting (In Private)

Committee for Medicinal Products for Human Use Opinion Published

∞ **Legend – Source of Funding**
CDF Managed Access Scheme - Expectations on MA holder to include:
Equivalent Commercial Access Agreement as agreed in England and shared/agreed with Mark Francis (Chair, All Wales Drug Contracting Committee (AWDCC))

Appraisal Consultation Document - YES

Appraisal Consultation Document - NO

Appraisal Consultation Document - CDF

Usually ~ three months (but may be less)

CDF MAA discussions commence in England

No Funding

No Funding

MA holder to engage with NHSW to discuss equivalent MAA for Wales ∞

Final Appraisal Determination - YES

Final Appraisal Determination - NO

Final Appraisal Determination - CDF

No Funding

60-day legal funding directive (? EAMS)

CDF Managed Access Agreement signed in England and commenced as close to Final Appraisal Determination as possible. Funding available within 60 days of FAD if equivalent offer agreed with NHS Wales

NEW TREATMENT FUND AND BASELINE FUNDING / ROUTINE USE

Final Guidance - YES

Final Guidance - NO

Final Guidance - CDF

IPFR Only

NEW TREATMENT FUND AND BASELINE FUNDING / ROUTINE USE

Usually (but not exclusively) no more than 2 years

Year 1 – Baseline Funding (inc. NTF)?

Year 2 – Baseline Funding

NICE Full Review *

Appraisal Consultation Document - YES

Appraisal Consultation Document - NO

BASELINE FUNDING / ROUTINE USE?

Final Appraisal Determination - YES

Final Appraisal Determination - NO

WG are minded not to expect refund of funding, if medicine receives final guidance "no".

60-day legal funding directive (? days for EAMS)

BASELINE FUNDING / ROUTINE USE

Final Guidance - YES

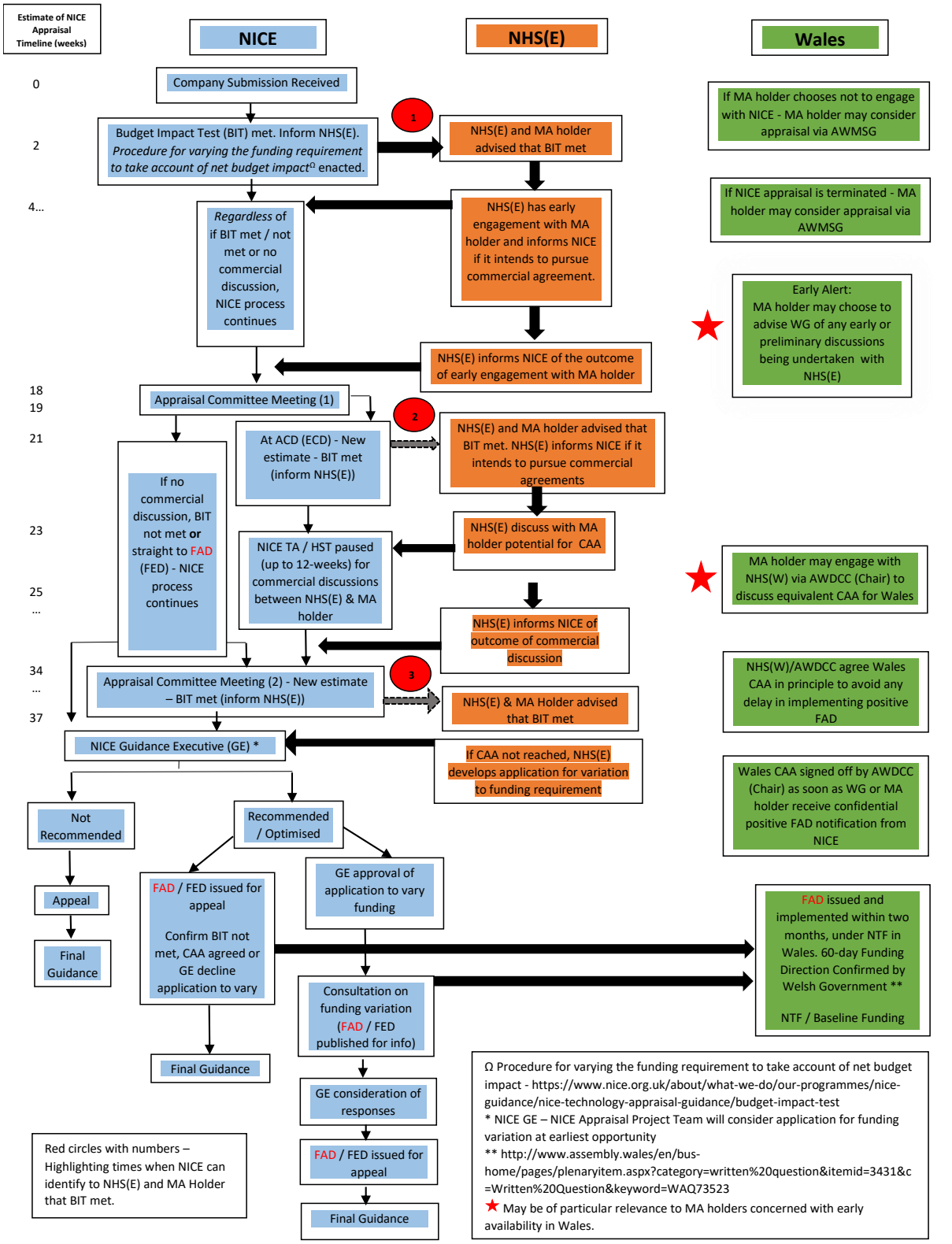
Final Guidance - NO

IPFR Only

* - Patients treated pre-NICE Full Review will continue to be treated until their clinician decides on an alternative option.

References
NHS England - Appraisal and Funding of Cancer Drugs from July 2016... - https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf
Letter from Welsh Government to Assembly Members (Jan 2017) –
http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Welsh%20Government%20New%20Treatment%20Fund%20Announcement%20January%202017.pdf
Letter from Welsh Government to Health Board Chief Executives (Jan 2017) - http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Launch%20of%20New%20Treatment%20Fund%20January%202017.pdf
Letter from Welsh Government on Commercial & Managed Access Arrangements –
https://myabpi.abpi.org.uk/sites/WIG/_layouts/15/WopiFrame.aspx?sourcedoc=/sites/WIG/Documents%20of%20Interest/Letter%20to%20RG%20ABPI%20re%20Access%20Agreements%20041116.pdf&action=default

Flowchart which aims to capture interaction between NICE & NHS(E) regarding the new NICE BIT – Some considerations for impact on medicines availability in Wales



Acronym Decoder – Quick Lookup:

ACD - Appraisal Consultation Document

AWDCC – All Wales Drug Contracting Committee

AWMSG – All Wales Medicines Strategy Group

BIT – Budget Impact Test

CAA – Commercial Access Arrangement

ECD - Evaluation Consultation Document

FAD – Final Appraisal Determination

FED – Final Evaluation Determination

GE – NICE Guidance Executive

HST – Highly Specialised Technologies

IPCG - Interim Pathways Commissioning Group

IPFR – Individual Patient Funding Request

MA Holder – Marketing Authorisation Holder

NHS(E) – NHS England

NICE – National Institute for Health and Care Excellence

NTF – New Treatment Fund

TA – Technology Appraisal

WG – Welsh Government

WHSSC – Welsh Health Specialised Services Committee

WMPLAG - Welsh Medicines Procurement and Logistics Advisory Group

Contact Details:

For further information on this document, please contact:

ABPI Cymru Wales
2, Caspian Point
Pierhead Street
Cardiff, CF10 4DQ

Telephone: 029 20 454297
Email: wales@abpi.org.uk

[i] https://gov.wales/topics/health/publications/healthier-wales/?lang=en
[ii] http://www.bandolier.org.uk/painres/download/whatis/What_is_health_tech.pdf
[iii] https://www.nice.org.uk/about
[iv] http://www.wales.nhs.uk/sitesplus/documents/1064/WHC%20%282003%29%20New%20directions%20to%20Local%20Health%20Boards%20and%20NHS%20Trusts%20in%20Wales%20to%20fund.pdf
[v] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test
[vi] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund
[vii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf
[viii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/process-guide-addendum-fast-track.pdf
[ix] https://www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-how-the-scheme-works
[x] http://awttc.creation.agency/organisation/pams
[xi] http://www.awmsg.org/industry_form_b.html
[xii] http://www.awmsg.org/industry_form_c.html
[xiii] http://www.awmsg.org/industry_orphan.html
[xiv] http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/AWMSG%20policy%20on%20appraising%20life-extending,%20end%20of%20life%20medicines.pdf
[xv] http://gov.wales/topics/health/nhswales/fund/?lang=en
[xvi] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund
[xvii] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund
[xviii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/process-and-methods-guide-addendum.pdf
[xix] https://www.nice.org.uk/guidance/ta402/documents/committee-papers
[xx] https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf
[xxi] https://www.england.nhs.uk/cancer/cdf/
[xxii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/process-and-methods-guide-addendum.pdf
[xxiii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/process-and-methods-guide-addendum.pdf
[xxiv] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf
[xxv] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/process-and-methods-guide-addendum.pdf
[xxvi] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf
[xxvii] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/TA-HST-procedure-varying-the-funding-direction.pdf
[xxviii] http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf
[xxix] http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Wales%20Patient%20Access%20Scheme%20frequently%20asked%20questions.pdf
[xxx] https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit
[xxxi] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/621983/2014_PPRS_Scheme.pdf

[xxxii] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/621983/2014_PPRS_Scheme.pdf

[xxxiii] http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/Wales%20Patient%20Access%20Scheme%20process%20guidance.pdf

[xxxiv] http://www.awmsg.org/healthcare_wpas.html

[xxxv] http://www.bathandnortheastsomersetccg.nhs.uk/assets/uploads/2015/11/PrinciplesPharmRebScheme05Nov15.pdf

[xxxvi] https://www.sps.nhs.uk/wp-content/uploads/2017/12/Guide-to-medicine-procurement-in-the-UK-Dec17-v-4.pdf

[xxxvii] https://www.awttc.org/pams/all-wales-free-charge-medicine-supply-policy

[xxxviii] https://www.awttc.org/pams/all-wales-free-charge-medicine-supply-policy

[xxxix] https://www.awttc.org/ipfr

[xl] https://gov.wales/written-statement-individual-patient-funding-request-ipfr-review

[xli] https://openrepository.awttc.org/app/serve/resource/stuj4180