GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

New Treatment Fund:

Requirements for WHSSC

May 2021

Version 3.0

Contents

New Treatment Fund (NTF)

1 Situation

The Welsh Government launched the New Treatment Fund (NTF) in January 2017. This is a key commitment within the programme for Government – Taking Wales Forward. The fund will provide an additional £16 million annually for Health Boards and Trusts in Wales to support the faster introduction of new medicines recommended by the National Institute for Health and Care Excellence (NICE) and the All Wales Medicines Strategy Group (AWMSG).

The fund will be ring-fenced to ensure it is used for the intended purpose of helping NHS Wales prepare sustainable plans for the introduction of new medicines.

The NTF requires Health Boards and Velindre NHS Trust to make medicines recommended by AWMSG and NICE available as soon as is reasonably practicable and certainly within two months of the published recommendation (see section 2.4 below). This direction came in to force following notification from Simon Dean (Deputy Chief Executive, NHS Wales) on the 13 January 2017.

2 Background

2.1 New requirements for Health Boards and Trusts

Prior to the announcement of the NTF in Wales all medicines approved by NICE and AWMSG had to be made available within three months from the date that the final guidance was published (unless an extension had been authorised by the Secretary of State or the Cabinet Secretary).

Implementation of the recommendations in the NTF will now provide access to NICE approved drugs up to 8 weeks earlier than before and access to AWMSG approved drugs up to 30 days sooner.

2.2 NICE Technology Appraisals and Highly Specialised Technology Appraisals

For NICE recommendations, a medicine should be available no later than 60 calendar days after the first publication of the Final Appraisal Determination (FAD) for Technology Appraisals (TAs) or the Final Evaluation Determination (FED) for Highly Specialised Technologies (HSTs).

NICE technology appraisals include all those assessed using both the standard and 'fast track' process (see Figure 1).

2.3 Cancer Drugs – NHS England Cancer Drug Fund

Cancer medicines recommended for an interim period by NICE for funding through the NHS England Cancer Drug Fund (CDF) should be made available within two months of the first publication by NICE of the FAD (provided the manufacturer offers NHS Wales the same or similar package as NHS England, including price).

2.4 AWMSG Health Technology Appraisals (including the orphan and ultra-orphan status)

For AWMSG recommendations, a medicine should be available no later than 60 calendar days after publication of the decision (following ratification of the recommendation by Welsh Government).

2.5 Extension to the timescale

A three month timescale for the introduction of a medicine is being retained for use in exceptional circumstances, where the scale of service planning required will need longer than two months.

Where a Local Health Board or NHS Trust determines a longer implementation timeframe is required, a notification must be made in writing to the Welsh Government's Chief Medical Officer. The notification must be made within 3 weeks of the publication of the AWMSG recommendation or the NICE FAD/FED and must provide the reasons for that decision.

2.6 NICE Highly Specialised Technologies (HSTs)

Since 26 April 2017, when the Directions to Local Health Boards and NHS Trusts in Wales 2003 and the Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009 (Amendment) (Wales) Directions 2017 came into force, the process around HSTs has changed.

HSTs are now captured under the reference to 'recommended by the institute' meaning they have the same status as NICE technology appraisals – similarly a 'recommendation for use within the Cancer Drug Fund' would be captured by the updated definition.

This means HSTs must be implemented by HBs (and WHSSC as their agent) as soon as reasonably practicable and, in any event, within two months of the publication by the Institute of the FED (defined in the Directions as the final draft guidance produced by the Institute) in relation to that health care intervention.

In exceptional circumstances, where the scale of service planning necessary to make a health care intervention available will take longer than two months, this is amended to three months; and where a Local Health Board determines that these circumstances are satisfied in relation to a

health care intervention, it must, within 3 weeks of the publication by the Institute of the FED relating to that health care intervention, advise the Welsh Ministers, in writing, of its decision to provide the health care intervention within three months of the publication of the FED and its reasons for that decision.

Accordingly there is no longer a need for AWMSG to report the publication of HSTs or for WHSSC to raise objections to their implementation through AWTTC.

2.7 Compliance, monitoring and reporting

Across Wales, six of the seven health boards use the online "Inform" formulary software programme provided and maintained by the NHS Wales Informatics Service (NWIS). Abertawe Bro Morgannwg University Health Board and Velindre NHS Trust have separate formulary systems.

A health board formulary is an official list of medicines which may be prescribed within the health board to treat patients. Until a medicine is added to the formulary, prescribers may not be aware that it is available for use.

Two factors are used to measure the uptake of medicines approved by NICE or AWMSG by health boards or the trust.

These are:

- the time taken to add the medicine to the health board or trust formulary
- the extent of prescribing of the medicine to patients.

The extent of prescribing depends solely on therapeutic decisions of health professionals who prescribe. It is therefore important that the health boards and trust have effective mechanisms in place to ensure relevant clinical groups are made aware of newly recommended medicines in a timely manner. This is usually the responsibility of the medicines and therapeutic committees.

Formulary status for recommended medicines will be collect and reported monthly to Welsh Government for the seven health boards and Velindre.

3 Assessment

3.1 New requirements for WHSSC

This section describes a revised process for dealing with the introduction of the New Treatment Fund. The key stages and action points for teams within WHSSC are presented below and in Figure 1.

The following process is proposed for immediate introduction.

Horizon scanning

The WHSSC Medical Directorate and All Wales Therapeutics and Toxicology Centre (AWTTC) will continually monitor medicines that are scheduled for future appraisal. These include all medicines in the AWMSG work plan and those on the proposed list of NICE TAs and HSTs. The majority of these medicines will not be licensed for the indication under consideration. However once the manufacturer is granted marketing authorisation the appraisal process can start with an 'invitation to participate' or 'evidence submission' (see Figure 1).

WHSSC participation in the appraisal development process

In March 2017 WHSSC was approved as a 'General Commentator' for new topics going through the NICE TA and HST processes. This allows WHSSC the opportunity to input in to the scope of each appraisal and to formally respond at the consultation phase. We are not permitted to appeal any decision.

Throughout guidance development the Medical Directorate will:

- Seek input from Programme Teams on the draft scope and attend relevant NICE scoping workshops
- Share appraisal recommendations of NICE guidance (at consultation and at FAD/FED stage) with Programme Teams
- Work closely with the AWTTC and receive regular reports on AWMSG guidance in development
- Represent WHSSC on the New Medicines Group
- Attend all AWMSG meetings
- Provide regular progress reports to CDG.

Scoping

- An initial assessment of the extent and impact of the medicine within NHS Wales will be carried out once the final scope has been published (NICE TAs and HSTs) or AWTTC notifies WHSSC an appraisal is underway (AWMSG advice).
- This work will be undertaken by the Assistant Director (Evidence Evaluation) and the relevant programme team AMD and Planning Manager.
- A representative from WHSSC will attend the NICE scoping workshop.

Information gathering

- A full assessment of the extent and impact of the medicine within NHS Wales will be carried out by WHSSC once the NICE (HST or TA) or AWMSG appraisal process begins.
- This work will be carried out by the Assistant Director (Evidence Evaluation) and the relevant programme team AMD and Planning Manager.
- Data will be collected on the number of eligible patients, likely drug acquisition costs, potential for service change etc. This assessment will take place regardless of a positive, negative or partial recommendation. This will ensure that all relevant information is available should a negative recommendation be overturned after consultation or following a successful appeal.
- The Planning Manager will begin to draft either a Policy Position or a revised Commissioning Policy ready for presentation at a future WHSSC Policy Group meeting.

Consultation on NICE guidance (TAs and HSTs)

- Normally, formal consultation (when an ACD or ECD is produced) takes place only if the preliminary recommendations from the Appraisal Committee do not recommend use of the technology, limit the use of the technology further than the marketing authorisation for the indication being appraised, or if the company is asked to provide further clarification on their evidence submission.
- If an ACD or ECD is issued, consultees and commentators have four weeks to comment.

Publication of the FED/FAD or AWMSG approval

- A maximum of three weeks post publication of the NICE FED/FAD, WHSSC will report to Welsh Government any outstanding issues with regard to implementation of the NICE TA or HST advice within Wales (see section 2).
- In the event that no commissioning issues are identified, the NICE or AWMSG advice will be recommended for adoption and implementation within NHS Wales as soon as is reasonably practicable, and within no more than 60 calendar days post publication of the FED/FAD.
- The draft Policy Position or revised Commissioning Policy to be issued for consultation (minimum 4 weeks).
- The WHSSC Managing Director will write to the Lead Pharmacist at all HBs and Velindre to remind them to put the relevant medicine onto their formulary.
- WHSSC (Medical Directorate) will confirm the agreed drug acquisition cost for NHS Wales (including any PAS or WPAS) with the All Wales Medicines Procurement Specialist Pharmacist.

- WHSSC (Medical Directorate) will check to see if prescribing the drug is subject to a Managed Access Agreement (MAA). A MAA will usually give additional discount to that applied by the PAS. The MAA will usually contain the following information:
    - the clinical criteria for starting and stopping treatment
    - the data collection requirements
    - the length of the MAA (this can be up to 5 years)
    - agreement between the manufacturer and the NHS England to manage financial risk.
- Ideally all complex PAS and MAA must include NHS Wales at source.

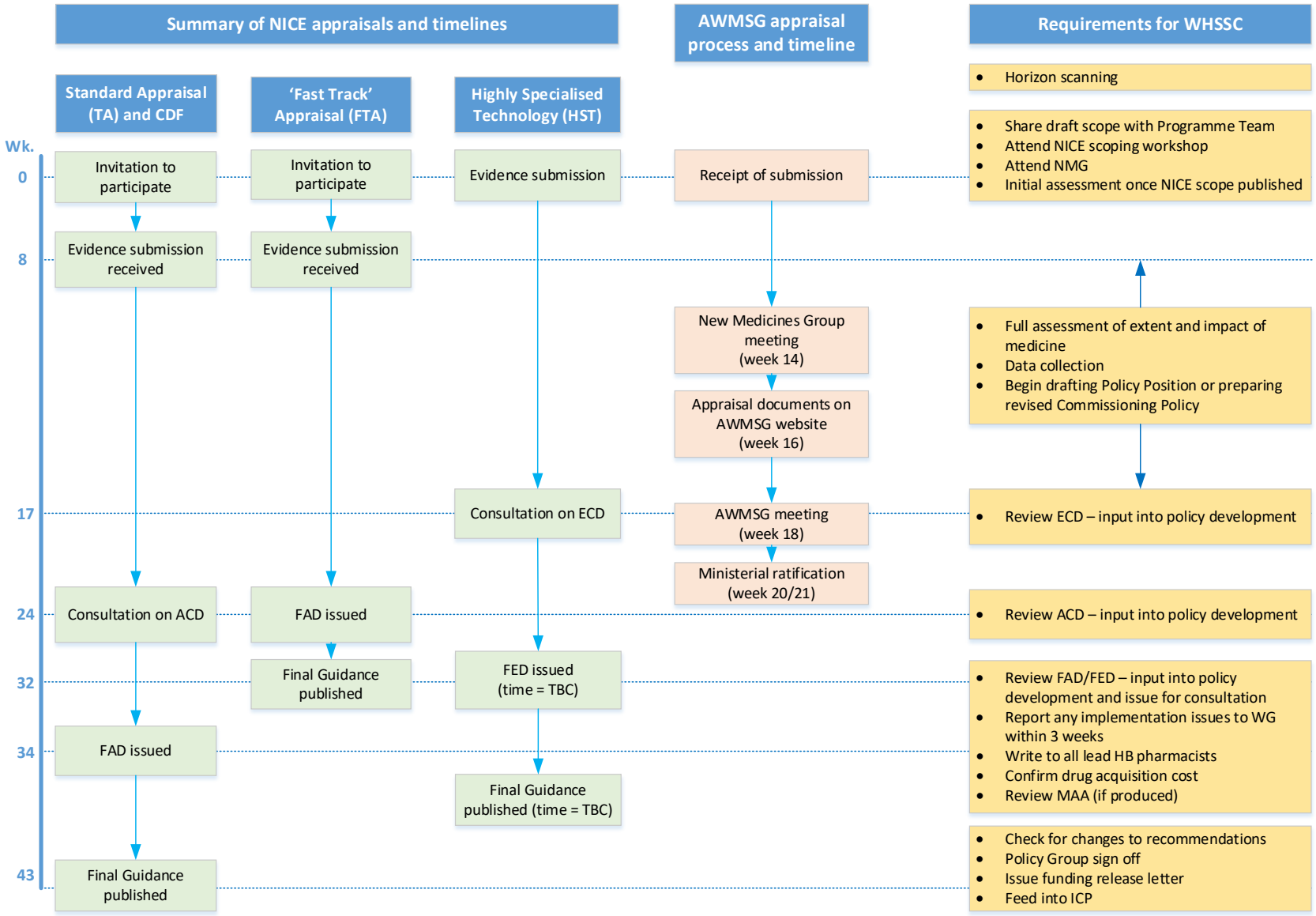
Appeals

- WHSSC will make regular checks to see if any appeal has been lodged against NICE (FAD/FED) or AWMSG draft advice.
- Should an appeal be lodged and accepted it is likely that a revised FAD/FED or AWMSG guidance will be issued. The draft WHSSC Policy Position or Commissioning Policy may need to be revised.

Publication of the final guidance

- The final recommendations will be checked for any change since publication of the FED/FAD.
- The final version of the WHSSC Policy Position or Commissioning Policy (new or updated) will be presented to the Policy Group for sign off.
- The WHSSC Director of Finance will send a Funding Release to all HB Directors of Finance Directors, copied to Medical Directors.
- The relevant Programme Team and Assistant Director (Evidence Evaluation) will ensure that the final appraisal decision is fed into the ICP development process.
- Individual HBs and Velindre will provide AWTTC and WG with the formulary status of the approved New Treatment Fund TA, HST or AWMSG medicines which are centrally commissioned by WHSSC in order to measure compliance with the 60 day target.

Figure 1


Summary of NICE appraisals and timelines
AWMSG appraisal process and timeline
Requirements for WHSSC
Standard Appraisal (TA) and CDF
'Fast Track' Appraisal (FTA)
Highly Specialised Technology (HST)
Wk.
0
8
17
24
32
34
43
Invitation to participate
Invitation to participate
Evidence submission
Receipt of submission
Horizon scanning
Share draft scope with Programme Team
Attend NICE scoping workshop
Attend NMG
Initial assessment once NICE scope published
Evidence submission received
Evidence submission received
New Medicines Group meeting (week 14)
Appraisal documents on AWMSG website (week 16)
Full assessment of extent and impact of medicine
Data collection
Begin drafting Policy Position or preparing revised Commissioning Policy
Consultation on ECD
AWMSG meeting (week 18)
Review ECD – input into policy development
Ministerial ratification (week 20/21)
Consultation on ACD
FAD issued
Review ACD – input into policy development
Final Guidance published
FED issued (time = TBC)
Review FAD/FED – input into policy development and issue for consultation
Report any implementation issues to WG within 3 weeks
Write to all lead HB pharmacists
Confirm drug acquisition cost
Review MAA (if produced)
FAD issued
Final Guidance published (time = TBC)
Check for changes to recommendations
Policy Group sign off
Issue funding release letter
Feed into ICP
Final Guidance published

4 Appendices / Annexes

4.1 Abbreviations

ACD	Appraisal consultation document
AMD	Associate Medical Director
AWMSG	All Wales Medicines Strategy Group
AWTTC	All Wales Therapeutics and Toxicology Centre
CDF	NHS England Cancer Drug Fund
ECD	Evaluation Consultation Document (NICE)
FAD	Final Appraisal Determination (NICE)
FTA	Fast Track Appraisal (NICE)
HB(s)	Health Board(S)
HSTs	Highly Specialised Technologies (NICE)
MAA	Managed Access Agreement
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
NTF	New Treatment Fund
NWIS	NHS Wales Informatics Service
PAS	Patient Access Scheme
STA	Single Technology Appraisal (NICE)
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

4.2 Glossary

All Wales Medicines Strategy Group (AWMSG)
The All Wales Medicines Strategy Group provides advice on medicines management and prescribing to the Welsh Government's Minister for Health and Social Services. The AWMSG acts in a strategic and advisory capacity and is an authoritative and expert channel through which consensus can be reached on the use of medicines within both primary and secondary care.

Appraisal Committee Document (ACD/NICE)
Sets out the Appraisal Committee's preliminary recommendations to NICE.

Appraisal process
The process of developing recommendations on the use of new and existing health technologies.

AWMSG approved drugs
AWMSG approved medicines and treatments which are available for use by NHS healthcare providers in Wales.

Cancer Drug Fund
A source of funding for cancer drugs in England.

Evaluation Consultation Document (ECD/NICE)
The document that allows stakeholders and individuals to comment on initial versions of the guidance so that their views can be taken into account when the final version is being produced.

Fast Track Appraisal
This is a technology appraisal that aim is to provide quicker access for patients to the most cost-effective new treatments.

Final Appraisal Determination (FAD)
The FAD sets out the Appraisal Committee's final recommendations to NICE on how the technology should be used in the NHS in England and Wales.

Health Boards
Health Boards (known officially as Local Health Boards) are the NHS bodies in Wales responsible for the health of the population within their geographical area. They are responsible for planning, designing, developing and securing the delivery of primary, community, in-hospital care services and specialised services. There are seven Health Boards in Wales.

Horizon scanning
The way of identifying treatments likely to become available to the NHS that may have significant implications for, clinical practice, service design and finance or potential disinvestments.

Managed Access Agreement (MAA)
A scheme in place between the NHS and manufacturer that describes the arrangements and responsibilities for the availability of a technology. It include outcome-based incentive for the manufacturer as well as a mechanism to monitor how well the medicine has worked in practice before future funding decisions are taken.

Multiple technology appraisal (MTA)
This is a technology appraisal that assesses several drugs or treatments used for 1 condition.

NHS Trust
Self governing, property owning bodies within the NHS, which manages hospital and community health services.

NHS Wales
The publicly funded healthcare systems of Wales.

NHS Wales Informatics Service (NWIS)
NWIS has a national role to support NHS Wales in making best use of IT skills and resources.

NICE approved drugs
NICE Technology Appraisal (TA) or Highly Specialised Technologies Evaluation (HST) approved medicines and treatments which are available for use by NHS healthcare providers.

NICE Highly Specialised Technology Appraisals
Makes recommendations on the clinical and cost effectiveness of new and existing highly specialised medicines and treatments. It only considers drugs for very rare conditions.

NICE Technology Appraisals
Guidance that makes recommendations on the use of new and existing drugs and treatments in the NHS.

New Medicines Group(NMG)
This is a subgroup of AWMSG. The subgroup considers the clinical and cost-effectiveness of a medicine, along with written evidence from the pharmaceutical company, clinical experts in the field and relevant patient organisations or support groups. The NMG makes preliminary

recommendations to AWMSG in relation to each medicine undergoing appraisal.

Orphan medicine
A medicine that has been granted EMA designated orphan status and is used to treat a condition with a prevalence of 1 in 50,000 or less in the UK.

Prescribers
A healthcare professional who can write a prescription.

Single Technology Appraisal (STA)
This is a technology appraisal that assesses a single drug or treatment.

Ultra-orphan
Ultra-orphan is the term given to drugs that are used to treat extremely rare diseases that are chronically debilitating or life-threatening. A Medicine with a European Medicines Agency (EMA) designated orphan status, which includes conditions affecting not more than five in 10 thousand persons", which is equivalent to 1,500 patients in Wales where the population is 3 million.

Welsh Health Specialised Services Committee (WHSSC)
The WHSSC is responsible for the joint planning of specialised and tertiary services on behalf of Health Boards in Wales.