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

All Wales guidance - free of charge medicine supply

Temporary update to guidance during COVID-19 pandemic only (see Appendix 2)

Updated 12 May 2020

Temporary update to include compassionate supply of **unlicensed medicines.**
The COVID-19 pandemic has resulted in the requirement to change clinical practice to allow for continued administration of treatment whilst minimising attendance at clinics and wards, and optimising patient safety. The All Wales guidance - free of charge medicine supply will now include compassionate supply of certain unlicensed medicines for which there is a service and/or patient benefit during the COVID-19 pandemic. The pharmaceutical company should make their submissions to the All Wales Therapeutics and Toxicology Centre (AWTTC) at AWTTC@nhs.wales.uk. The process for the consideration of compassionate supply of unlicensed medicines during the COVID-19 pandemic and the submission form are described in Appendix 2.

N.B. The updates relating to unlicensed use of medicines are only applicable during the COVID-19 pandemic; they will be reviewed 3 months from the published date of this document, or before that in the light of a significant change in the situation.

Purpose

This guidance introduces controls to ensure equity and consistency in patient and clinician access to medicines offered to NHS Wales as free of charge in the following circumstances:

a. **Newly licensed medicines,** where the marketing authorisation holder has engaged in health technology assessment (HTA) by the National Institute for Health and Care Excellence (NICE) or AWMSG, and where the recommendation remains outstanding.

b. **Unlicensed medicines (during the COVID-19 pandemic).**
An unlicensed medicine is defined by the General Medical Council (GMC) as medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. There are clinical situations when the use of unlicensed medicines or medicines outside the terms of the licence (i.e. 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. Refer to the GMC website for Prescribing Guidance: Prescribing unlicensed medicines.

Background

a. Newly Licensed medicines

HTA by NICE or AWMSG remains the preferred approach for advising on the clinical-effectiveness and cost-effectiveness of newly licensed medicines. Pharmaceutical companies must continue to be strongly encouraged to engage promptly in the HTA process. It is not our intention to undermine, but to complement the well-established and accepted HTA, One Wales Cohort Funding and Individual Patient Funding Request (IPFR) processes by producing this guidance.

In the absence of, or whilst awaiting publication of HTA guidance, some pharmaceutical companies have offered NHS Wales a free of charge medicine supply agreement to enable patients and clinicians access to a particular medicine at no cost. Inequity and inconsistency in patients' access to medicines may arise when not all health boards/trusts and the Welsh Health Specialised Services Committee (WHSSC):

- are offered the same access arrangement,
- are aware that an opportunity for such access exists,
- *accept the offer.*

b. Unlicensed medicines

Please refer to local and national guidance to prescribers (e.g. from the General Medical Council) concerning prescribing of unlicensed medicines:
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines

In accordance with EU [Directive 2001/83/EC, Art. 87 (European Commission)] and UK [Human Medicines Regulations 2012 (SI 2012/1916, part 14 (HM Government, 2012)] Law and the ABPI Code of Practice [Code of Practice for the Pharmaceutical Industry (PMCPA, 2019)] pharmaceutical companies may only promote licensed medicines and indications that are covered by the medicine's marketing authorisation.

Criteria

a. Newly licensed medicines

1. The All Wales Chief Pharmacists' Group will consider the appropriateness of every free of charge medicine supply agreement offered by marketing authorisation holders/ manufacturers.

2. Each offer from a marketing authorisation holder/manufacturer would be expected to satisfy the following criteria:

    - The medicine has been submitted for HTA by NICE or AWMSG, but a significant delay (e.g. over 6 months) is anticipated before HTA guidance is expected.

    - The medicine is fully free of charge and the offer is not a partial price discount.

- A written commitment has been made by the marketing authorisation holder 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 final appraisal determination (FAD) or final evaluation determination (FED) and, where appropriate, with an agreed commercial access agreement or patient access scheme in place
    - as long as the patient(s) continue to require it on clinical grounds if the HTA guidance is negative.

3. Marketing authorisation holders should submit their form (see Appendix 1) to the All Wales Medicines Procurement Specialist Pharmacist, via AWTTC (AWTTC@wales.nhs.uk).

4. The All Wales Chief Pharmacists' Group will take into account nationally agreed criteria, including consideration of clinical efficacy versus clinical risk. Medicines expected to help patients with life-threatening, long lasting or seriously debilitating illnesses, where no suitable licensed and HTA-approved alternative is available for that same indication, will be the priority.

5. Medicines with associated significant administration costs (e.g. testing, administration or significant monitoring requirements) will be considered on a case-by-case basis.

6. The All Wales Chief Pharmacists' Group will inform the health board Chief Executives' Committee of their decision when appropriate.

7. Following approval, and up to the publication of HTA advice, the medicine will be available for use in Wales and access should not be progressed via the IPFR process.

8. Free of charge medicine supply agreements will be held centrally, and actively monitored to ensure compliance.

9. A free of charge medicine supply agreement will terminate 60 days after publication of a FAD or FED by NICE or HTA guidance by AWMSG with an agreed commercial access agreement or patient access scheme in place, where appropriate. If HTA guidance is negative and the patient has already enrolled, the agreement will continue for as long as required on clinical grounds.

b. **Unlicensed medicines**

1. The part of the guidance relating to unlicensed use of medicines is only applicable during the COVID-19 pandemic. This section will be reviewed in 3 months from the published date of this document, or before that in the light of a significant change in the situation.

2. The process for the consideration of compassionate supply of unlicensed medicines during the COVID-19 pandemic and the submission form are detailed in Appendix 2.

Appendix 1

All Wales guidance - free of charge medicine supply

Submission for licensed medicines

Name of licence holder	
Medicine name	
Indication	
Licence date	
HTA (NICE/AWMSG) submission date	
Anticipated HTA (NICE/AWMSG) publication date	
Is a significant delay (i.e. over 6 months) anticipated before HTA guidance/advice is expected?	
Launch date	
Comparator treatment(s)	
Place in therapy	
Estimated number of patients living in Wales who would be eligible for free of charge supply	
List price (if known)	
Is the medicine fully free of charge (i.e. zero cost)?	
Do you agree to supply the medicine free of charge until 60 days following publication of positive HTA guidance, i.e. publication of a final appraisal recommendation (FAR) by AWMSG, or final NICE appraisal determination (FAD) or final evaluation determination (FED) and, where appropriate, with an agreed commercial access agreement or patient access scheme in place, or for as long as clinically appropriate?	
Is the medicine associated with significant administration costs (e.g. testing, administration or significant monitoring requirements)?	
Is the medicine expected to help patients with life-threatening, long-lasting or seriously debilitating illnesses?	
Is there a suitably licensed and HTA-approved alternative medicine available for the same indication?	

The completed form should be forwarded by email to AWTTC@wales.nhs.uk

Appendix 2:

Compassionate supply of unlicensed medicines during COVID-19 pandemic

Purpose

This addition to the guidance introduces controls to ensure equity and consistency in patient and clinician access to compassionate supply of unlicensed medicines across NHS Wales during the COVID-19 pandemic.

The European Medicines Agency (EMA) defines compassionate use as; "…. A treatment option that allows the use of an unauthorised medicines. Compassionate-use programmes are for patients in the European Union (EU) who have a disease with no satisfactory authorised therapies or cannot enter a clinical trial. They are intended to facilitate the availability to patients of new treatment options under development".

In some cases clinicians may approach a manufacturer directly to request the supply of a new medicine that does not have a UK product licence to be used for a patient under their direct responsibility. This is often on a "named patient basis"

Some manufacturers may run "expanded access programmes". A company may choose to run an expanded access programme to allow early access to their medicine, for example, for patients who have been treated with the medicines during a clinical trial and wish to continue treatment. In an expanded access programme, patients are usually followed up in the same way as patients in a clinical trial.

Some pharmaceutical companies may introduce compassionate supply arrangements to enable patients and clinicians access to a particular medicine at no cost during the COVID-19 pandemic. However, in accordance with EU [Directive 2001/83/EC, Art. 87 (European Commission)] and UK [Human Medicines Regulations 2012 (SI 2012/1916, part 14 (HM Government, 2012)] Law and the ABPI Code of Practice [Code of Practice for the Pharmaceutical Industry (PMCPA, 2019)] pharmaceutical companies may only promote licensed medicines and indications that are covered by the medicine's marketing authorisation.

The All Wales Chief Pharmacists' Group will consider the appropriateness of compassionate supply of unlicensed medicines on a case-by-case basis during the COVID-19 pandemic.

Criteria

1. The All Wales Chief Pharmacists' Group will consider the appropriateness of every compassionate supply arrangement for unlicensed medicines.

2. To comply with this guidance the arrangement must be fully free of charge and not a partial price discount.

3. The pharmaceutical company should submit details of the arrangement (see Form below) to the All Wales Medicines Procurement Specialist Pharmacist, via AWTTC (AWTTC@wales.nhs.uk).

4. The All Wales Chief Pharmacists' Group will take into account any nationally agreed criteria, including consideration of clinical efficacy versus clinical risk. Medicines expected to help patients with life-threatening, long lasting or seriously debilitating illnesses, where no suitable licensed and HTA-approved alternative is available for that same indication during the COVID-19 pandemic will be the priority.

5. Medicines with associated significant administration costs (e.g. testing, administration or significant monitoring requirements) will be considered on a case-by-case basis.

6. The All Wales Chief Pharmacists' Group will inform the health board Chief Executives' Committee of their decision when appropriate.

7. Following approval, the medicine will be available for use in Wales during the COVID-19 pandemic and access should not be progressed via the IPFR process.

8. Compassionate supply arrangements will be held centrally, and actively monitored to ensure compliance.

9. Each compassionate supply arrangement will be reviewed after three months, or sooner in light of significant new information.

Submission for unlicensed medicines during COVID-19 pandemic

Name of pharmaceutical company	
Medicine name	
Indication	
Licence status (i.e. off-label/unlicensed)	
Do you have plans to submit for a licence for the indication under consideration? If so, when is the licence expected?	
If a licence is expected, do you have plans to submit for HTA for the indication under consideration with NICE/AWMSG at a future date? Please provide further details	
Please provide detail of the benefits of this medicine during the COVID-19 pandemic	
Please list any comparator treatment(s)	
Place in therapy	
Estimated number of patients living in Wales who would be eligible for free of charge supply	
List price (if available)	
Is the medicine fully free of charge (i.e. zero cost)?	
Please detail amount of free supply likely to be available for patients in NHS Wales (quantity/duration of supply)	
Is the medicine associated with significant administration costs (e.g. testing, administration or significant monitoring requirements)?	
Is the medicine expected to help patients with life-threatening, long-lasting or seriously debilitating illnesses?	
Is there a suitably licensed and HTA-approved alternative medicine available for the same indication?	

Please forward the completed form by email to AWTTC@wales.nhs.uk