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

All Wales implementation of COVID-19 NICE rapid guidelines

Purpose

The National Institute for Health and Care Excellence (NICE) has issued rapid guidelines to support the NHS and social care to respond quickly to the challenges of the coronavirus pandemic. They have been developed by NICE, supported by the specialist societies and royal colleges.

This guidance has been introduced to enable NHS Wales and social care to take account of the rapid guidelines from NICE when planning and providing services during COVID-19. .

Background

The aim of the NICE rapid guidelines is to allow greater flexibility in the management of patients during the COVID-19 pandemic and to ensure clinicians have additional treatment options through this time. These interim treatment regimens have been clinically assessed, and endorsed by NHS England and NHS Improvement who may also have agreed terms and conditions of supply with the marketing authorisation holder on behalf of the NHS across the UK.

The responsibility for using these interim treatment regimens lies entirely with the prescribing clinician, who must discuss the risks and benefits of interim treatment regimens with individual patients, their families and carers.

These guidelines do not constitute NICE guidance and any interim treatment change that is currently subject to an ongoing NICE technology appraisal will be superseded by the appraisal guidance should this be published during the COVID-19 pandemic. Some regimens may not have a UK marketing authorisation for the use listed (for further information see the General Medical Council's guidance on prescribing unlicensed medicines)

The interim treatment changes are for an initial 3-month period only and to address the challenges of the COVID-19 pandemic. Treatment regimens will revert to the standard treatment protocol after this period unless the guideline is updated.

In order to ensure that there is timely access to these medicines in Wales and in accordance with the NICE COVID-19 rapid guidelines, an interim process for submission and review has been developed. This enables a once-for-Wales decision to be made in an equitable, consistent and timely manner supporting clinicians in NHS Wales to access these medicines for their patients.

Criteria

1. AWTTC will coordinate the progression of medicines through the submission and review process to dissemination of approval to the service.

2. The marketing authorisation holder terms and conditions of supply is expected to be similar or equitable with that available to NHS England and shared with AWTTC via email (AWTTC@wales.nhs.uk) or via the AWTTC file share (the vault).

3. AWTTC and NHS Wales Shared Services Partnership will consider the appropriateness of each submission. If considered operationally acceptable, the All Wales Chief Pharmacist Group will sanction the sign-off of each contract by the All Wales Medicines Procurement Specialist Pharmacist on behalf of NHS Wales.

4. The All Wales Chief Pharmacist 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 administrative costs (e.g. testing, administration or significant monitoring requirements) will be considered on a case-by-case basis.

6. Following approval, the medicine will be available for use in Wales and access should not be progressed via the IPFR process.

7. AWTTC will inform the pharmaceutical company of the contract approval in NHS Wales and will disseminate the information to key individuals within health boards and Trust via AWTTC's WPAS Access to Medicines – commercial in confidence workspace on the Vault.

8. Agreed terms and conditions of supply for each medicine will be held centrally on the AWTTC Vault, which has restricted access to approved personnel, and actively monitored to ensure compliance.

9. Policy review date will be three months from the date of publication.

Appendix 1

Submission form

Please complete this form and attach all documentation shared with NHS England.

Name of licence holder	
Medicine name	
Indication	
Licence status (i.e. licensed, off-label or unlicensed)	
Type of Supply (e.g. Compassionate use, Named Patient Supply, Expanded Access Programme, Routine supply)	
Please provide detail of the benefits of this medicine during the COVID-19 pandemic	
Comparator treatment(s)	
Place in therapy	
Estimated number of patients living in Wales who would be eligible to receive this medicine	
Price of the medicine to NHS Wales	
Please confirm that the price of the medicine for NHS Wales is the same as for NHS England	
How is the price accessed by NHS Wales (e.g. rebate system, credit)?	
Please confirm that the conditions of your agreement are the same as those in NHS England	
Is the medicine associated with significant administration costs (e.g. testing, administration or significant monitoring requirements)?	
Is there a reimbursement to NHS Wales for the cost of associated administration/monitoring	
Is the medicine expected to help patients with life-threatening, long-lasting or seriously debilitating illnesses?	
Contact name and email address	

The completed form should be forwarded, together with all documentation shared with NHS England, by email to AWTTC@wales.nhs.uk or via file share (the Vault). Please contact AWTTC if you wish to access the Vault.