Classification: Official

Publication approval reference: PAR996_ii

Medicines & Healthcare products Regulatory Agency

NHS

NICE National Institute for Health and Care Excellence

NIHR | National Institute for Health and Care Research

Medicines Repurposing Programme

Interim eligibility and prioritisation criteria

11 July 2022

Interim eligibility criteria

The purpose of the Medicine Repurposing Programme is to identify and progress opportunities to repurpose existing licensed medicines to improve clinical outcomes, patient experience and value for money through a tailored support programme.

The programme considers medicines with a potential repurposed use that is not within the terms of an existing marketing authorisation. For example, when the repurposed use:

- is for a new condition or patient group or requires a different dose or treatment schedule
- requires a reformulation, a different mode of administration or a different strength of the medicinal product.

Candidate medicines need to meet all the following eligibility criteria to be considered for entry into the programme. In exceptional cases, the programme's steering group may decide to waive one criterion.

Patient/service user benefit and evidence base

1. The available evidence shows that the repurposed medicine provides clinical outcomes and patient benefits that are as good as, or better than, the current NHS standard of care.

2. Some evidence of safety and efficacy in the repurposed use already exists, such as a completed phase 2 trial.[1]

3. Regarding the potential for future evidence, good quality evidence of safety and efficacy (such as a phase 3 trial) either already exists or could be generated.[2] Large-scale evidence generation may be challenging for rare conditions. The assessment will take this into account and will not disadvantage rare conditions.

Need for repurposing

4. There is current (or likely future) support or demand for the medicine from clinicians or patient groups, **or** there is a national policy requirement for its consideration (for example, if the repurposed medicine creates additional resilience in treatment options for a particular indication).

5. The opportunity to repurpose an existing medicine meets at least one of the following criteria:

   - the condition is life-threatening or seriously debilitating
   - there is a significant unmet patient or public health need
   - use of the medicine would result in cost savings to the NHS or wider social care system.

   When assessing potential cost savings, the programme will consider NHS and personal social services costs for the repurposed medicine compared with current standard of care. Thus, the cost analysis will include not only the cost of the medicine itself but also wider impacts such as the need for follow-up care. A detailed cost analysis may not be available at the initial consideration stage. Instead, when appropriate the programme will consider a summary analysis of the main elements in the care pathway.

[1] Phase 2 clinical trials are designed to study a medicine's efficacy and safety. The trial is conducted in people with the relevant condition or disease, and measures common short-term adverse effects and risks.
[2] Phase 3 clinical trials are designed to study a medicine's efficacy compared with the existing standard of care in large groups of people. These trials also monitor adverse effects and collect information that will allow the medicine to be used safely.

6. NHS patients do not currently have equitable access to the medicine in its repurposed use; that is:

   - the medicine is not currently used in the NHS for the repurposed indication, or at the repurposed posology, or in the repurposed formulation, or
   - there is some NHS use of the medicine in the repurposed indication/posology/formulation, but the variation in use is not explained by different clinical need, individual patient choice or the demographics of an area, and further action is expected to enable increased and equitable access.

Feasibility

7. The medicine is already licensed in Great Britain or the UK.

8. The work required is within the capability of the programme and its five partner agencies, feasible within the resources and capacity available, and likely to be successful in promoting increased and/or more equitable access within the NHS.

Interim prioritisation criteria

When a medicine meets the eligibility criteria, the programme's steering group will use the following criteria to inform decisions about which medicines to adopt into the Medicines Repurposing Programme, and their relative priority. The criteria act as a guide to deliberative discussion; there is no scoring system and medicines will be judged against each other for the available resource, which may vary from time to time. Each case will be assessed on its individual merits – not all criteria need to be met.

1. **The programme will prioritise those treatments with greater patient benefit compared with current NHS standard of care.** Patient benefit could include:

   - improved clinical outcomes – which could encompass length of life, quality of life or both
   - improved experience of care
   - reduced health inequalities.

   When discussing patient benefit, the steering group will consider the number of patients affected and the proportion likely to benefit from the repurposed medicine.

2. **The programme will prioritise treatments that have the potential to deliver good value for money for the NHS.** Medicines that increase costs may be eligible for the programme, provided they are expected to be cost-effective. The

steering group will also consider the value for money of the repurposing project itself, considering the expected expenditure, degree of risk and potential benefits to patients and the NHS.

Over time, the steering group would like to test and demonstrate the success and long-term viability of the programme by building a broad portfolio of medicines. The programme will therefore aim to encompass a range of conditions, care settings, commissioning arrangements and stages of development (pre- and post-phase 3 trials), and also to test different types of partnership agreement to secure a licence.

This document is named 'interim' because the programme is new and the criteria may change as it matures. The criteria will be reviewed after five medicines have entered the programme or in September 2022 – whichever is sooner. To inform that review, the programme will engage with stakeholders to understand the impact of the programme, including any unintended consequences.

Operational implementation

During the first year of the programme, topic selection will be based on submissions from clinicians, patient groups and industry using the candidate proposal form. During 2022 the programme plans to add in prospective horizon-scanning informed by searches of ongoing clinical trials.

Eligibility

Due to the range of potential applications, the programme team will conduct an initial eligibility assessment and short-list potential opportunities for the steering group to consider. When appropriate this assessment will be informed by discussions with:

- the nominating organisation
- the company that originally licensed the medicine
- clinical, commissioning and finance leads within NHS England
- patient organisations, medical research charities and clinicians
- clinical reference groups, the Rare Diseases Advisory Group, national clinical directors and specialty advisers to NHS England
- the five agencies that support the Medicines Repurposing Programme.

Medicines that do not meet the eligibility criteria will be 'stood down', meaning no further action would be taken until a patient group, clinician or company provides clear evidence to the programme that the situation or evidence base has materially changed, and that as a result the medicine may now meet the eligibility and prioritisation criteria.

The nominating organisation will be informed of the reasons the medicine was stood down.

Medicines will only be discussed by the steering group if they meet all the eligibility criteria, or if the decision regarding eligibility is marginal and requires discussion by the group.

Prioritisation

The programme team will complete an assessment form, including information to support the steering group's assessment of eligibility and prioritisation. The assessment form will be presented to the steering group for consideration. The steering group will decide from the following options:

- adopt the medicine into the programme
- monitor: take no immediate action and specify the time period(s) at which the programme team should check for potentially new and material information
- stand down, defined above.

The nominating organisation will be informed of the steering group's decision and its rationale. For projects on the monitor list, the programme team and the nominating organisation will agree a schedule for submitting updates to the programme.