Lancashire Medicines Management Group

POSITION STATEMENT: 'Zero Risk' Schemes in Advance of NICE

CCGs or Trusts should not sign up to 'zero risk' schemes, (unless associated with a EAMS). If patients are initiated on medicines using one of these schemes by provider trusts and do not subsequently fit commissioning criteria, treatment must continue to be funded by the initiating trust and will not be provided by CCGs.

NB. This position statement does not preclude access to treatment for individual patients where they meet the CCG Individual funding Request criteria or where treatment is provided in the context of a clinical trial or in accordance with the trusts unlicensed medicines policy.

'Zero Risk' Schemes

These are designed to supply medicines free-of-charge to a cohort of patients prior to publication of NICE guidance or whilst a local policy position is pending. They are led by the respective pharmaceutical manufacturer. The schemes state that the medicine will be supplied free of charge to patients who are anticipated will fit the future NICE/Local commissioning criteria. The schemes state that if NICE/commissioners do not approve the medication then the manufacturer will continue to supply it free of charge until the patient and clinician decided that the medicines should be stopped. If NICE/local commissioners approve the treatment, then the free supply ceases and the commissioner is expected to fund from either the date of publication or (in some cases) 3 months after publication.

Points to note about 'Zero Risk' Schemes are:

- Manufacturer led 'Zero Risk' schemes mean that the NHS can receive free of charge supplies for patients who are anticipated will meet the future NICE/Local funding criteria for the loading dose period (if applicable) and for up to 90 days after the product receives positive guidance
- The scheme covers the cost of the medicine only, and does not include the tariff activity charges that would be incurred. If a negative decision is published, the commissioners may still be expected to pick up the tariff activity costs, for activity that has not been commissioned
- If the published NICE TA/Commissioning position is not in line with the criteria anticipated by the scheme, then patients may be on treatment when they do not fit criteria, and the agreement on medicines supply in this scenario may not be covered by the scheme
- NICE TAs often state that patients who do not fit the criteria but have already started treatment can remain on the medicine. There is a risk that the scheme may be used to initiate patients on medication in a way ultimately not approved by NICE/commissioners.
- **The availability of such schemes may introduce INEQUITY into the health economy, with patients with equal clinical need being treated differently**
- The availability of such schemes may result in a devaluing of NICE and local commissioning processes
- It is recommended that trusts and CCGs do not to sign up to 'Zero Risk' schemes, unless associated with an MHRA led Early Access to Medicines Scheme (EAMS)- see definitions
- 'Zero Risk' schemes tend to relate to provision of free stock for a cohort of patients whilst a policy position is pending. This position statement does not preclude access to

treatment, which may include the provision of free stock, in the context of a clinical trial, via the IFR route or in accordance with the trusts unlicensed medicines policy.

Definitions

It is recognized that a range of terminology is used in relation to innovative pricing arrangements and provision of Free of Charge (FOC) stock. An overview of the terminology used is provided below to assist organizations in differentiating between them.

a. **'Zero Risk' Schemes:** These are **pharma-led** schemes which are designed to supply medicines, free of charge, to an identified **cohort of patients**, in **advance of NICE or a local commissioning** decisions. These differ from EAMs (see below) in that the medications have not been identified by the MHRA as providing a significant advantage over existing treatments for serious or life threatening conditions. It cannot be presumed that NICE/local commissioners will make a positive recommendation on use of the medication for the patient cohort identified by the manufacture. As such, these schemes have the potential to introduce inequity and to undermine the evidence based recommendations made by NICE/commissioners.

b. **Early Access to Medicines Schemes (EAMS)[1,2]:** The Early Access to Medicines Scheme was launched by the Medicines and Healthcare Regulatory Authority (MHRA) in April 2014. The UK scheme is intended to enable patient access to medicines for treatment of life threatening or seriously debilitating conditions, where there is an unmet need. It offers a way by which **unlicensed medicines** can be available to patients before approval of a license to **benefit public health**. It enables companies to gain additional knowledge and the NHS to gain experience of these medicines in clinical use.

As part of the process **the MHRA will give a scientific opinion on benefit/risk balance** of the medicine, based on the available data when the EAMs submission was made. For an EAMs to be granted The medicinal product must offer promise i.e. benefit or significant advantage over and above existing treatment options

The UK scheme operates within the current regulatory structure and is voluntary.
The **medicine is to be provided for free by the company during the scheme**. Through EAMS, NHS services should become familiar with the introduction of the new drug and to be equipped to monitor its introduction in mainstream clinical practice. **Pending a favorable NICE appraisal, drugs introduced through EAMS are expected to be introduced prior to the 90 day limit set out in the regulations.** CCGs and Trusts will be expected to implement the NICE TA within a 30 day period.

The MHRA EAMs is an example of **a compassionate access** to medicines program (which is the terminology used by the European Medicines Agency for access to promising new medicines in advance of licensing).[3]

c. **Patient Access Schemes (PAS)[4]:** A PAS is an **innovative pricing scheme** proposed by a pharmaceutical company and agreed between the company and the Department of Health (with input from NICE) in order to **improve the cost-effectiveness of a drug.** PAS proposals are made in the **context of a NICE technology appraisal**, with the aim of enabling a positive NICE recommendation.

Nb. The Term ‘Patient Access Scheme’ should only be used to refer to pricing agreements approved by the DoH and specifically referenced within the context of a NICE Technology Appraisal.

Acknowledgement: Pan Mersey Area Prescribing Committee.

References

1. http://ec.europa.eu/health/files/committee/stamp/2015-05_stamp2/5.pdf
2. https://www.england.nhs.uk/wp-content/uploads/2015/10/eams-letter-oct15.pdf
3. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000293.jsp
4. Webpage: NICE-The Patient Access Schemes Liaison Unit. Accessed via: https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit