Kent and Medway Cancer Collaborative

KMCC Position Statement:

Access to Free of Charge Drugs Outside of Clinical Trials (via Access Schemes or Early Access to Medicines Schemes)

1.0 Exclusions from Scope

- Compassionate use schemes as defined by the EMA: https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use
- Free of charge medicines available within clinical trials.

2.0 Position Statement

2.1 MHRA Early Access to Medicines Schemes (EAMs)

NHS England (NHSE) support MHRA early access to medicines schemes (EAMs) which aim to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. Non-surgical Oncology Sub-groups (NOGs) should review all EAMs and assess whether it is appropriate for these to be incorporated into the list of KMCC approved Systemic Anti-Cancer Therapy Protocols, and identify which Trusts in KMCC should be asked to deliver this treatment; implementation issues such as the availability of an on-site aseptic unit will be taken into account as part of the assessment. Each Trust should consider the request to open the EAMs, and give clear reasons if they are unable to make this treatment available. Where an EAMs scheme is opened within a Trust in Kent and Medway, a KMCC approved protocol and electronic prescribing regimen will be made available. A KMCC Algorithm Deviation application **is not required**.

2.2 Access Schemes or Free Of Charge (FOC) Schemes

Other access schemes or Free of Charge (FOC) schemes are outside of the normal NHSE commissioning frameworks and any risk, financial or otherwise remains with the Trust.

In addition, NHSE does not generally commission the use of routinely funded medicines when they are used in combination with Free of Charge medicines. It is anticipated that additional information and agreement may be required for any combination therapy.

Whilst Kent and Medway Cancer Collaborative does not encourage access to investigational drugs outside of a clinical trial or EAMs, in principle we believe that cancer patients for whom licensed drugs offer no further treatment options should have access to an investigational drug through an access scheme, provided the following conditions are met:

- All treatment possibilities with licensed drugs have been considered and it is agreed that they offer no further clinically appropriate options.
- The patient is not eligible for entry into any relevant clinical trial currently open in that Trust.
- The prescriber believes the risk/benefit profile of the new therapy is favourable to the patient.
- The prescriber takes full responsibility for the use of this medicine for an individual patient.
- The manufacturer should guarantee in writing that the medicine will be provided free of charge for the full duration of the patient's treatment, regardless of whether a license is granted for the medicine. Where this is not the case, Trusts should have an exit plan in the event of closure of the scheme. Treatment should not commence until this has been considered, and the Chief Pharmacist and / or the Chair of the Drugs and Therapeutics Committee is satisfied and has approved the exit strategy. If no funding source is identified, then the exit strategy must be discussed with the patient as part of the consent process and must contain the scenario where the drug may be discontinued on the basis of cost.

Drugs supplied within the context of a Free of Charge or Access Scheme will not be included within the Oncological Treatment Guidelines as they are either not licensed or not commissioned, or both. Use of free of charge medicines made available through access schemes would constitute an algorithm deviation, and clinicians should follow the KMCC Algorithm Deviation Policy ensuring the application has been signed by a supporting consultant who specialises in that particular tumour type and also the Clinical Director for Oncology or their nominated deputy. Implementation issues must be identified within the application.

Where a treating clinician wishes to prescribe a drug which is available through an access scheme, they must in the first instance submit the KMCC Algorithm Deviation application to the pharmacy department at the treating Trust, and follow the Trust's Policy or process for the use of free of charge drugs /access schemes (or make an application for a new drug through the Drugs and Therapeutics process). This must happen in advance of the patient being offered the treatment. In addition, where appropriate, the policy for the use of unlicensed medicines must be followed.

Drug supplies must ***always*** be made exclusively via the established pharmacy department supply chain with drugs delivered directly to the pharmacy department. Pharmaceutical companies must not enter into any agreement to supply drugs to individual clinicians.

3.0 Resources

Reference should be made to the following documents:

- The Specialist Pharmacy Service advice on Free of Charge (FOC) medicines schemes available at: https://www.sps.nhs.uk/wp-content/uploads/2018/07/FOC-medicine-scheme-policy-v-3.0-Final.pdf

- The KMCC Organisational Structure and Governance Processes for a Central Collaborative Team Sup-porting the Maintenance of Oncological Treatment Guidelines (treatment algorithms) and Systemic Anti-Cancer Therapy (SACT) Protocols in Oncology and Haematology across the Kent and Medway Cancer Collaborative (including the maintenance of the SACT prescription on an Electronic Prescribing System) available at: http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/

- KMCC algorithm deviation policy: http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/