NHS
Kent and Medway
Cancer Collaborative

Systemic Anti-Cancer Therapy Care Pathway

Prescribing and Dispensing of SACT

Pathway of Care

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1.0 OVERVIEW

1.1 Scope

This policy and care pathway has been developed by the Kent and Medway Chemotherapy Group to guide staff in the appropriate prescribing and preparation of systemic anticancer therapies (SACT).

1.2 Introduction

SACT is for the treatment of solid tumours and haematological cancers through the systemic delivery of agents that have antitumour effects. Ensuring that all cancer patients receive the appropriate treatment, prepared and delivered by suitably trained staff in a safe environment, will help to improve cancer outcomes.

1.3 Definitions

SACT includes intravenous, subcutaneous, intrathecal and oral cytotoxic chemotherapy, monoclonal antibodies, immunotherapies, bisphosphonates and other targeted therapies, as well as topical treatments for bladder cancer. With the exception of apalutamide, darolutamide, abiraterone and enzalutamide, hormonal treatment is excluded.

2.0 STANDARDS FOR PREPARATION AND PHARMACY

2.1 Overview of preparation and administration of SACT.

All SACT will be prepared and administered in designated areas. In cases where it is impossible to safely transfer a patient to a designated area, subject to agreement by the Lead Chemotherapy Nurse and relevant department manager, treatment may be administered by an appropriately trained practitioner. All areas where SACT is prepared and administered will have access to the electronic prescribing system, relevant guidelines and protocol documents (including spillage and waste disposal procedures, administration of systemic anti-cancer therapy guidelines, drug information and SACT protocols). KMCC protocols and guidelines are available on the KMCC website https://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/ .

In addition, wards, day units and outpatient areas will require protocols/guidelines for the prevention and management of complications arising from SACT, including emergencies such as anaphylaxis and extravasation.
A list of designated areas for preparation and administration of SACT should be held by the lead pharmacist for cancer/aseptic services (as relevant for each pharmacy department) and lead chemotherapy nurse, respectively and is available as an appendix to the KMCC Health and Safety, Handling and Administration Pathway.

SACT should be administered during normal working hours (8:00-18:00) when support services and expert advice are available. The following exceptions may apply:
Continuous infusions over an extended time period, e.g. ambulatory infusion pumps.
Time-specific doses or multiple daily doses, e.g. inpatient treatment for acute myeloid leukaemia.
Intravesical chemotherapy required to given within a specific time limit after surgery.

A process must be in place to ensure completion of treatment, outside of normal working hours, following an unexpected delay, e.g. due to equipment failure.

Intravenous and subcutaneous SACT should be stored in a separate designated area that has a suitable lockable storage fridge, if required, within the ward, outpatient area or pharmacy. If intrathecal systemic anti-cancer therapy is stored after production and before administration, it must be stored in a separate designated fridge within the pharmacy department. (Refer to local Intrathecal policy.)

The identified outpatient area may be used for other aseptic treatments and procedures on cancer patients, but should not be used for general outpatient/day case activity.

2.1 Facilities for Preparation

Preparation of parental SACT drugs must be carried out in an aseptic unit - normally located within a Pharmacy Department or outsourced from a licensed supplier, unless there is prior agreement for a specific drug to be reconstituted in a ward or day unit, following a risk assessment. The facility will contain appropriate equipment including; pharmaceutical Isolator(s) or a laminar air flow work station. The facility and equipment will need to meet the standards of Good Manufacturing practice (GMP) following the Quality Assurance of Aseptic Preparation service 5th Edition (QAAPs) and the Medicines and Healthcare Products Regulatory Agency Rules and Guidance for Pharmaceutical Manufacturers and Distributors, 2017 (referred to as the Orange Guide). To ensure the integrity of the Facility, Equipment, staff, Quality Assurance (QA) and QA Management Systems (QMS), the Pharmacy and Aseptic Unit are regularly audited / inspected by the Regional Quality Assurance Department or by the Medicines Inspector.

SACT Drugs must be prepared via a prescription, under the supervision of a Pharmacist, on a named patient basis if the Aseptic Unit is working under Section 10 of the Medicines Act 1968.

In exceptional circumstances there may be a need to prepare SACT drugs outside of normal pharmacy working hours. These circumstances and the procedures to follow are described in full by the Trusts local policy for out of hours administration and preparation of systemic anti-cancer therapy.

2.2 Authorisation Procedure

1. SACT must be initiated on a KOMS electronic action sheet (EAS) by:

- A consultant clinical haematologist/non-surgical oncologist or
- An associate specialist in clinical haematology/non-surgical oncology

2. Following submission of a KOMS EAS, SACT may be prescribed by;

- A consultant clinical haematologist/non-surgical oncologist or
- An associate specialist in clinical haematology/non-surgical oncology or
- A specialist registrar or equivalent who is undergoing supervised training from one of the above and has been authorised in writing by a consultant oncologist/haematologist or the Director/Deputy Director of the Kent Oncology Centre or the Lead Clinical Haematologist within a Trust, as being competent to prescribe systemic anti-cancer therapy at level 3 or above and who has completed electronic prescribing training and competency assessment.
- An accredited non-medical prescriber who is competent in the specific disease group and has prior agreement from a supervising designated prescribing practitioner (DPP) to prescribe SACT.
- All SACT prescribers should adhere to the guidelines and competencies within the UK SACT board guidance: https://www.uksactboard.org/publications

3. The Pharmacy must be supplied (ideally every 6 months) with a list of doctors who are approved to prescribe (intravenous/subcutaneous/oral and intrathecal) and administer (intrathecal) SACT. This list should be available within the Pharmacy department and all clinical SACT areas. Pharmacy should also keep a list of pharmacists who are trained and authorised to check SACT prescriptions, as well as a list of trained personnel authorised to prepare SACT. These lists should also be updated at least every 6 months. (For requirements relating to the intrathecal register refer to local intrathecal policy.)

2.3 Prescribing Process

For the purposes of this document the term prescription will also refer to "Patient Specific Directions" as defined by the Department of Health.

Prior to a patient starting a course of SACT, a KOMS EAS must be completed. This must specify the treatment plan for an individual patient.

The EAS must be completed and submitted by an authorised clinician (see section 2.2 above)

Any deviation in treatment from the standard SACT protocol must be documented on the action sheet. Where a SACT prescription is not in accordance with an agreed protocol, the KMCC Treatment Algorithm Deviation Policy should be followed.

Alterations to the standard electronic treatment regimen must be in accordance with the KMCC SOP for permitted alterations to SACT regimens.

Prescriptions for SACT drugs must be completed on a validated electronic prescribing system using a Kent and Medway Cancer Collaborative approved, standardised treatment regimen. The following exceptions apply:

- Off protocol treatment (prescribed electronically using **locally-approved** treatment regimen)
- Clinical trials
- Intrathecal chemotherapy (refer to local intrathecal policy)
- Intravesical chemotherapy
- IM methotrexate for GTD

Patient demographic details, including name, date of birth and hospital numbers are automatically transferred from KOMS to the electronic prescribing system, manual entry of patient details is prohibited.

The following information is either automatically generated or selectable on the electronic prescribing system: date prescribed, name of prescriber, treatment start date, regimen name, line of treatment, treatment intent, cycle number, drug name(s), dose and units, route of administration, additional administration instructions.

Electronic prescriptions must also contain the following information, added by the prescribing clinician:

- Treating consultant (Demographics – Providers)
- Primary diagnosis (Exam – Diagnoses)
- Cell histology (Exam – Diagnoses – Pathology)
- Performance status (Exam – Performance status)
- Height (Vital signs)
- Weight (Vital signs)
- Allergies/adverse drug reactions (History – Allergies)

Reason for any dose modifications. It is mandatory for this information to be contained within the electronic action sheet. It should be stated on the electronic prescription whether the dose modification is due to toxicity or another reason.

In the event of e-prescribing system failure, the KMCC business continuity plan describes the appropriate alternative process for prescribing, dispensing and administering SACT.

2.4 Dispensing

1. All parenteral SACT drugs will be dispensed within the pharmacy within normal working hours, except for specific drugs prepared on wards/day units or delivered by a homecare provider, following appropriate risk assessment. The dispensing process should follow local standard operating procedures and be in accordance with relevant national and regional legislation, policies and guidelines. In exceptional circumstances SACT may need to be dispensed out of hours. Refer to individual Trusts' local policies for out of hours administration and preparation of systemic anti-cancer therapy

All SACT prescriptions should be checked by a pharmacist who has undergone specialist training, demonstrated their competence and is locally authorised/accredited for the task. Prescriptions will not be accepted for dispensing unless they comply with the specified prescribing requirements in section 1.3. Each prescription must be signed electronically (unless for specific regimens that are only available as a paper proforma) , dated and approved by the screening pharmacist following completion of a clinical screen and dispensed by the releasing pharmacist or accredited technician after final release. Drug allergies and drug interaction checks should be conducted by nurses and pharmacy staff, this process is contained in each local acute Trust SOPs.

2. All Pharmacy departments must have Standard Operating Procedures describing the dispensing process from receipt of a prescription to final release. These Standard Operating Procedures should describe the training and competencies required for oncology and/or aseptic services pharmacists. These should be reviewed periodically (at least annually).

3. A record of the batch numbers and expiry for all aseptically prepared drugs used must be documented on the worksheet for each regimen/systemic anti-cancer therapy drug.

4. Special arrangements are required for the dispensing of intrathecal preparations of Cytarabine, Methotrexate and Hydrocortisone (refer to local intrathecal policy) as well as intravenous preparations of Vinca Alkaloids (see below).

5. When Vinca Alkaloids are prescribed, dispensed or administered in adult SACT units, the prescribed dose should be supplied from the hospital pharmacy in a ready to administer 50ml minibag of sodium chloride 0.9% (for some brands of Vinorelbine glucose 5% infusion may be used). The following warning should be prominently displayed on the label of ALL vinca alkaloid doses: **"For Intravenous Use Only – Fatal if Administered by Other Routes"** There should be judicious use of colour and design on the label, outer packaging and delivery bags to further differentiate minibags containing Vinca Alkaloids from other minibag infusions.(Ref: National Patient Safety Agency Rapid Response Report on using minibags to administer Vinca-Alkaloids-NPSA/2008/RRR004)

6. When Vinca Alkaloids are prescribed, dispensed or administered in paediatric SACT units, the dose will be dispensed in a syringe, diluted to a minimum volume of 10ml. The following warning should be prominently displayed on the label of ALL vinca alkaloid doses: **"For Intravenous Use Only – Fatal if Administered by Other Routes"**

7. Where facilities for preparation are compromised SACT may be purchased pre-prepared from an independent company licensed to do so. If this is the case then the ordering, receipt and subsequent release of such SACT will be conducted by the appropriate, trained pharmacy personnel at each local acute Trust.

2.5 Purchasing, Receipt and Storage

The purchasing, receipt and storage of SACT drugs in Pharmacy are carried out in accordance with agreed procedures by the Pharmacy Department at each site within Kent and Medway. The Pharmacy will ensure the effective control of the quality of these products.

1. Access to SACT drug storage areas must be limited to authorised staff.

2. Main stocks of SACT drugs will be held in the Pharmacy Department under appropriate conditions with continuous temperature monitoring.

3. Clinical trial supplies of SACT drugs should be kept separate from main stocks.

4. Ordering, receipt and management of all free-of-charge (FOC) SACT drugs, e.g. “compassionate supply”, must be managed by trained staff in the pharmacy department only. Medical and nursing staff are not permitted to order and receive SACT drugs.

5. SACT drugs should not be available as ward stock. They should always be dispensed for individual patients.

6. SACT drugs must be stored separately from other drugs in locked medicine cupboards or refrigerators as appropriate or within pharmacy.

7. Intrathecal SACT doses must be stored in a separate designated fridge within the pharmacy department (Refer to local intrathecal policy.)

8. Storage shelves must be designed in such a manner that the risk of breakage of containers of SACT drugs is reduced to a minimum.

9. Containers of prepared SACT agents, cytotoxic or otherwise, must be transported in designated transport bags or boxes deemed fit for purpose. The bags or boxes should be clearly labelled:

   “CYTOTOXIC DRUGS – HANDLE WITH CARE”

   Additional precautionary labels should be added to the containers and the transport bags or boxes as appropriate.

10. SACT drugs should be delivered to a registered chemotherapy nurse on the ward who takes responsibility for the appropriate storage, as defined on the attached additive label. Intrathecal chemotherapy must be issued directly to the doctor who will administer the drug or delivered to the ward by an accredited member of pharmacy staff and placed in a designated storage container. Refer to local intrathecal policy for specific information.

11. Pneumatic tubes (capsule pipelines powered by compressed air or vacuum) should not routinely be used for transporting cytotoxic agents, unless a full risk assessment has been undertaken and measures put into place to reduce the risk of spillage or contamination by cytotoxic drugs to negligible levels.

12. Staff involved in the transportation of cytotoxic drugs **must** be trained to follow the “Cytotoxic Spill” procedure. Records of training should be maintained in the relevant areas.

13. Damaged containers of SACT agents are to be discarded into a rigid sharps box fit for cytotoxic waste. These should be labelled as cytotoxic waste. If there is any contamination of the area or personal exposure to cytotoxic material, refer to the SACT Care pathway section on Health and Safety, section 1.8.

14. Any SACT drugs received, but not administered, must be safely returned to the Pharmacy Department in a designated transport bag or box for disposal or re-issue as soon as possible. A senior member of the Pharmacy aseptics team or the Oncology Pharmacist should be informed of the return.

3.0 GLOSSARY

Acronyms in common usage throughout KMCC documentation

BNF	British National Formulary
BOPA	British Oncology Pharmacy Association
CNB	Cancer Network Board
COSHH	Control of substances hazardous to health regulations.
CYP	Children & Young People (in relation to the IOG)
DCCAG	Diagnostic Cross Cutting Advisory Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
DGT	Dartford and Gravesham NHS Trust
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
EPS	Electronic Prescribing System
FP10(HNC)	Prescriptions issued by hospital doctors for dispensing in the community
GP	General Practitioner
HoP	High Level Operational Policy
IOSC	Improving Outcomes: A Strategy for Cancer
IV	Intravenous
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
KOMS	Kent Oncology Management System
LSESN	London & South East Sarcoma Network
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NHS	National Health Service
NMP	Non-medical prescriber
NPSA	National Patient Safety agency
NOG	Non Surgical Oncology Group *(Permanent oncologist sub group of the DOGs with a specific responsibility for chemo/rad pathways and advice to the DOG, Network and GEOGRAPHICAL LOCATIONs on new drugs)*
PoC	Pathway of Care *(Network agreed disease site specific clinical guidelines)*
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
QSIS	Quality service information system
QST	Quality Surveillance Team
RAT	Research and Trial Group *(Permanent sub-group of the DOGs with a specific responsibility for taking forward the clinical trials agenda)*
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
SACT	Systemic Anti-Cancer therapy
SACT regimen	Systemic Anti-cancer template on the electronic prescribing system
SACT protocol	Systemic Anti-cancer protocol on KMCC website

TTO	Treatment to take home
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

4.0 DOCUMENT ADMINISTRATION

The document is located in the Kent and Medway Cancer Network office, in hardcopy and in electronic format at www.kmcc.nhs.uk/kent-and-medway-cancer-collaborative-kmcc/	
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