Standards for the Pharmacy Verification of Prescriptions for Cancer Medicines

The minimum standards required for the pharmacy verification of prescriptions for cancer medicines for use in cancer patients

British Oncology Pharmacy Association

Version 4.2

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Endorsed by ROYAL PHARMACEUTICAL SOCIETY

Contents

Section 1: Introduction and Background

1.1 BOPA originally introduced standards for Pharmacy Verification of Prescriptions for Cancer Medicines in 2009. This fourth version of the standards has been produced by a sub-group of BOPA members, with representation from the four UK nations, specialist cancer pharmacy representation from the fields of paediatric oncology, adult oncology and haemato-oncology and pharmacy technicians.

1.2 BOPA has released a position statement supporting the development of the pharmacy technician role to undertake structured and supported clinical verification of SACT.

1.3 This review extends the scope of the standards to verification being undertaken by suitably trained Registered Pharmacy Professionals, including pharmacists and pharmacy technicians. For the purposes of this document these staff groups will be referred to throughout as **Registered Pharmacy Professionals (RPP)**.

1.4 This document describes what key steps a RPP must take when checking prescriptions for systemic anticancer therapy (SACT). For the purposes of this document this will be referred to as '**Verification'**. It is recognised that there are other terms in common use to describe this process, e.g. 'clinical checking' or 'validation', 'screening' or 'approval'.

1.5 SACT verification is an essential step to ensure the safe use of SACT, providing assurance that the prescribed treatment is appropriate for the patient's disease and their clinical condition, that doses are accurate and tailored for the individual patient and to reduce risk of medication errors.

1.6 SACT must not be administered by a HCP, or taken by a patient until an appropriately trained RPP has verified the prescription.

1.7 These SACT verification standards are linked to the BOPA SACT verification e-learning, and competency assessment modules, alongside the broader BOPA SACT verification passport.

Section 2: Scope

2.1 In Scope

2.1.1. For the purposes of these standards, SACT encompasses; cytotoxic chemotherapy, monoclonal antibodies, targeted therapies, immunotherapy and other biological therapies used in the treatment of cancer. This list is not exhaustive, and it is recognised that new systemic anticancer treatments are constantly being developed which will require verification that meets the same standards as other named SACT agents.

2.1.2. All routes of administration are within scope, with the exception of intrathecal SACT for which separate guidance exists across the UK (see section 5).

2.1.3. It is noted that SACT medicines dispensed as part of a clinical trial may be classed as investigational medicinal products (IMPs) and additional checks may be required according to the clinical trial protocol and GMP guidelines.

2.1.4. The principles within this document are relevant for both adult and children & young people (CHYP) practice. Additional checks for paediatrics or differences between adult and CHYP processes are highlighted throughout the document.

2.2 Out of Scope

2.2.1. Hormonal treatments - although it is recognised that there is a need for relevant checks to be made when these agents are being used concurrently with other SACT agents.

2.2.2. Radiopharmaceuticals: IRMER legislation applies to radiopharmaceuticals. Although out of the scope of these guidelines, some agents will require monitoring and dosing will be dependent upon critical tests. Therefore, local pharmacy and medicines governance processes should consider the principles within these guidelines when agreeing processes that ensure safe use of these agents.

Disclaimer: Defined scope is for guidance. Individual organisations may choose to undertake verification for specific medicines currently excluded from the BOPA scope for SACT verification.

Section 3: Governance & Professional Responsibilities

3.1 Governance and oversight

3.1.1. Pharmaceutical verification is one part of the overall medicines optimisation processes used for SACT from treatment decision and consent, through prescribing, to administration and monitoring of patients on treatment. These standards are intended to provide National Guidance to SACT Services on this part of the process, and should be used to inform local pharmacy policies, procedures and practices as part of the full SACT pathway.

3.1.2. This document must be used in conjunction with local organisation / Cancer Network / Health Board Policies on Medicines Governance and safe use of SACT, alongside relevant national guidance documents and policies (see section 5).

3.1.3. Overall responsibility for the safe use of SACT and ensuring all appropriate standards are in place will be determined by an individual organisation's governance structure but may, for example, rest with an appropriate governance committee, such as a multidisciplinary SACT group.

3.1.4. Local policy should define what the responsibilities of each healthcare professional involved in the full SACT pathway are - including RPPs involved in SACT verification.

3.1.5. The standards set out in this guidance document should be considered the gold standard for SACT verification. It is recognised that SACT services vary due to local service and operational arrangements. Where services are required to deviate from these standards for operational or logistical reasons, local risk assessment should be undertaken and alternative pathways / policies devised which ensure all appropriate checks are undertaken which ensure the safe use of SACT, clearly defining the responsibilities of each member of the multidisciplinary team involved in the process. The alternative process should clearly state whether it is transitional (with time limits) or permanent and be approved by the appropriate governance committee

3.1.6. If a Non-Medical Prescriber (NMP) Pharmacist prescribes SACT, it is still necessary for a pharmaceutical verification step to be undertaken by a different RPP. The Royal Pharmaceutical Society of Great Britain Prescribing Competency Framework states that NMPs must '*ensure separation of prescribing and dispensing whenever possible. Where a pharmacist is both prescribing and dispensing a patient's medication, a second suitably competent person should normally be involved in the checking process*.'

3.1.7. Clinical capacity for RPPs to verify SACT prescriptions and deliver pharmaceutical care to cancer patients must be monitored as part of SACT service monitoring and planning and be used to inform organisational workforce and capacity planning activities.

3.1.8. All SACT must be prescribed in the context of an approved protocol and prescribed via an electronic prescribing system. Standards and guidance for electronic SACT prescribing systems can be found in National guidance documents (see section 5).

3.1.9. Where paper copies of electronic prescriptions are printed off in advance for verification, preparation or administration purposes it is essential to have systems in place to ensure that the paper copy still reflects the electronic version and no changes have been made after printing.

3.2 Levels of practice for Pharmacists and Pharmacy Technicians

3.2.1. Levels of practice for SACT verification are defined within the BOPA Cancer Pharmacy Education and training standards as level 2a, 2b & 2c:

- Level 2a: pharmacy staff who can validate simple SACT prescriptions as defined and agreed by local SACT governance processes and policy - excluding cycle 1. E.g. oral SACT such as hydroxycarbamide, imatinib, enzalutamide, or flat dosed SACT which is usually well tolerated. Most pharmacy technician SACT verification is expected to be undertaken within this level of practice.
- Level 2b: validate all SACT excluding cycle 1.
- Level 2c: validate all SACT including cycle 1 (see section 4).

3.2.2. It is recognised that additional specific training will be required when moving into new more complex areas of practice, e.g. Haematopoietic Stem Cell Transplant (HSCT), clinical trials or moving from day-case areas to in-patient practice.

3.2.3. Staff working in adult practice and moving into paediatric practice and vice versa will need to undertake additional specific training to ensure competency.

3.2.4. Specific competency-based training for specialist areas such as HSCT and paediatrics is available as part of the BOPA SACT verification passport.

3.3 Education, training and competency assessment

3.3.1. Education & training for any level of SACT verification should precede practice, and competency assessment should form part of the process prior to any RPP working independently.

3.3.2. BOPA has defined specific educational competencies outlining the knowledge and understanding that an appropriately trained RPP verifying a SACT prescription must have within the BOPA SACT verification passport.

3.3.3. Pharmacists and technicians verifying prescriptions for SACT must be able to recognise situations where they need to seek advice / support from appropriate sources such as senior colleagues and respond appropriately; in particular, where the complexity required exceeds their own personal level of competence or where there is reason for concern about the patient's suitability for the prescribed treatment.

3.3.4. CPD activities should reflect the practitioner's area of practice, ensuring that competencies are maintained, and clinical knowledge kept up to date.

3.3.5. If an RPP has a significant period of time out of practice - specified by local policy – they should undertake specific refresher training and review of competencies on return to work. Where local policy does not specify a time-period BOPA suggests 6 months.

3.4 SACT protocols and electronic prescribing systems

3.4.1. All SACT is prescribed in the context of a written evidence based SACT protocol. This may be replaced by an approved clinical trial protocol or national guideline, e.g. for paediatric practice, when appropriate.

3.4.2. The SACT protocol (or alternative as described), is an essential source of information for the verifying RPP and must be readily accessible when verification is taking place. Refer to BOPA guidance on the contents of a SACT protocol or relevant National Guidance, e.g. CEL30 in NHS Scotland.

3.4.3. The SACT protocol is used to build treatment courses and cycles within the electronic prescribing system. Robust clinical governance systems must be in place for the construction of protocols and associated prescriptions on electronic prescribing and administration systems. This includes:

- assigned responsibilities.
- procedures for validation, double checking of entries, and the use of test prescriptions prior to approval and release for use.

3.5 Prescription format

3.5.1. All prescriptions for SACT must be prescribed on an approved SACT electronic prescribing and administration system and comply with current legal requirements and local, regional, or national prescribing policy. Local policies for transcription of oral SACT and supportive medication should also be in place.

3.5.2. Where possible, there is a single SACT prescription for all medicines included in the treatment regimen, including all appropriate supportive care and hydration. Where additional supportive therapies are prescribed separately, this will be clearly indicated within the protocol, additional prescribing note on the prescription or local/regional guidelines.

3.5.3. Where non-electronic prescribing is used, this should only be undertaken in exceptional circumstances as defined by local policy – e.g. as part of contingency plans for e-prescribing system down-time. Prescriptions must be on computer-generated, tamper proof document-controlled forms using agreed regimens, be readily accessible in the patient's record, and the process have undergone robust risk assessment.

3.6 Staff who are authorised to consent and prescribe SACT

3.6.1. SACT consent must be obtained by a trained and appropriately experienced healthcare professional as determined by local, regional or national policy.

3.6.2. Only appropriately qualified, competent practitioners, as defined by local policy, are given permissions to prescribe SACT.

3.6.3. Prescribers are only granted prescribers access to their organisation's electronic prescribing system access after meeting training and competency assessment standards as determined by local policy. Once deemed competent to prescribe SACT they should be added to a local register of SACT prescribers.

3.6.4. Staff verifying SACT must be able to confirm that the SACT prescriber is authorised to enable checks to be made during the verification process.

Section 4: The Standards

4.1 Pharmacy verification standards for cycle 1 of a new SACT regimen (See appendix 1: Verification checklist examples)

4.1.1. Check the prescriber is authorised to prescribe Cycle 1 SACT in your organisation.

4.1.2. Check that the patient has been consented for treatment.

4.1.3. Check that the regimen prescribed matches the intended documented treatment plan and/or clinic letter.

4.1.4. Check the prescribed drugs are part of an approved regimen or protocol, which is appropriate for the diagnosis and line of therapy. Use local/network protocols and /or formulary for guidance.

4.1.5. Follow local non-formulary processes where non-formulary drugs or protocols are prescribed.

4.1.6. Ensure patient is eligible for treatment based on diagnosis (staging, pathology, genetic/genomic results, tumour markers).

4.1.7. Check regulatory, monitoring and funding approvals are in place (e.g. blueteq or pregnancy prevention programmes). See appendix 2 for information on funding routes for cancer medicines across the UK

4.1.8. Check that the regimen is appropriate based on patient's medical history, performance status (PS), staging and SACT history.

4.1.9. Check patient allergy status.

4.1.10. Check for potential interactions, contra-indications and duplication between all planned SACT & supportive medication and patient's concurrent medication.

4.1.11. Consider potential for adrenal suppression. Ensure the patient is appropriately informed, and a steroid emergency card has been supplied if appropriate. (NHS Scotland see section 5.4 (d))

4.1.12. Confirm that cycle frequency is appropriate.

4.1.13. Ensure an up-to-date height, weight and BSA (where relevant) is calculated and documented on the prescription.

4.1.14. Ensure that relevant pre-treatment critical tests have been completed and reported prior to treatment (e.g. Cardiac function, cumulative dosing, genomic testing) as these may impact eligibility for, or dosing of SACT.

4.1.15. Ensure pre- treatment Virology screening (e.g. Hepatitis B testing), has been completed, reported and actions taken where appropriate. See local policy or protocol for specific tests required.

4.1.16. If radiotherapy is being administered concurrently, check dates of radiotherapy and dosing schedule as per SACT Protocol

Table 1: Example sources of information for verification

- ✓ Patient's clinical record
- ✓ SACT Protocol
- ✓ Consent form
- ✓ Treatment plans
- ✓ Local/network formulary
- ✓ Medicines interactions checking websites e.g. Stockley's, Cancer Drug Interactions
- ✓ Local policies and guidelines – e.g. antiemetic guidelines, GCSF guidelines
- ✓ Renal & hepatic dose adjustment guidelines – e.g. Lancet guidelines
- ✓ Macmillan treatment information
- ✓ Electronic medicines compendium

Note this is not an exhaustive list

Table 2: Additional checks in specialist areas for first cycles

Paediatrics	Clinical trials	HSCT	CAR-T (Lymphodepletion)
▪ Check two separate weights and ensure height/weight reflects normal limits for patient age. ▪ Ensure surface area calculated using Boyd formula. ▪ Ensure regimen is suitable for the age/weight of the child. Check protocol for dose adjustments. ▪ Consider if dose adjustments are needed in patients at extremes of BMI centiles	▪ Randomisation confirmation (if applicable) ▪ Trial eligibility / inclusion criteria ▪ Trial protocol for regimen details ▪ Trial ID number on prescription ▪ Treatment batch allocations available ▪ Prescriber on delegation log ▪ Ensure you have been added to delegation log ▪ Stock- commercial or trial specific ▪ Follow local processes	▪ Recipient pre-transplant assessments ▪ Donor investigations & assessments ▪ Transplant documentation e.g. recipient +/-donor clearance ▪ Consider dose adjustments in obesity as per local policy ▪ Special blood requirements ▪ Graf versus Host Disease prophylaxis prescribed as per protocol if applicable ▪ Supportive care prescribed as per protocol	▪ Washout period prior to lymphodepletion ▪ Avoid steroids if possible ▪ Confirm patient's CAR-T cells have been manufactured or available on site (as per local governance arrangements) ▪ Tocilizumab doses available

4.2 **Pharmacy verification standards for ALL cycles of treatment (including cycle 1).**

4.2.1. Check prescription details and patient demographics

4.2.1.1. Check the prescriber is authorised to prescribe SACT in your organisation and the SACT prescription includes all details required for dispensing, labelling and administration. Check that the prescription meets legal requirements and all required signatures are in place.

4.2.1.2. Check patient details are present: Name, Treatment location, NHS/local patient number, date of birth

4.2.1.3. Check patient allergy status, interactions or contraindications against any new medicines prescribed since last cycle (when information accessible).

4.2.1.4. Ensure an up-to-date weight, and body Surface area (BSA) is on the prescription when relevant for dosing. Ensure weight is regularly updated throughout treatment at a minimum frequency determined by local policy.

4.2.1.5. Confirm intended start date and exact duration of treatment of that cycle and confirm cycle frequency is appropriate in relation to timing of last cycle.

4.2.1.6. Ensure cycle-by-cycle declarations have been completed (e.g. pregnancy prevention programmes).

4.2.1.7. Ensure formulation is clear and when relevant specific brand and /or supply / stock is specified on the prescription to enable dispensing staff to identify correct supply – e.g. compassionate use or free of charge stock

Table 3: Additional checks for paediatrics in all cycles

Paediatrics
▪ Ensure regimen still suitable for age/weight of the child. ▪ Ensure weight checked prior to every cycle.

4.2.2. Dosing & administration

4.2.2.1. Check drug dose calculations (Flat, BSA, weight, AUC) and units are appropriate. Ensure final doses are correctly calculated and are prescribed by the appropriate route of administration.

Note: SACT for adult patients should be dose banded where bands are available.

- NHS England, Wales and NI according to National Dose Banding Tables
- NHS Scotland – refer to SOPPG dose banding tables

BSA Capping ▲

As part of individual practice, some clinicians may cap BSA when dosing SACT as part of local / individual practice. Ensure this decision is clearly documented in treatment plan

4.2.2.2. There must be a local policy in place which determines when treatment doses should be recalculated if the patients' weight changes during the course of treatment. Recalculated dose should be rechecked as above.

Weight change % thresholds ▲

As per local policy, some organisations may allow weight change within a specific +/- % allowance before the SACT dose needs to be recalculated / amended. Ensure awareness of local practice

4.2.2.3. Ensure maximum doses for individual drug e.g. vincristine will not be exceeded. Refer to SACT protocols for details.

4.2.2.4. Ensure maximum lifetime cumulative doses for e.g. anthracyclines will not be exceeded. Refer to SACT protocols for details

4.2.2.5. **For AUC dosed drugs**: Local policy should determine what method of calculation is used based on availability of nuclear medicine and specific patient criteria.

4.2.2.5.1. **Using estimated GFR**: If a patient's serum creatinine and/or weight changes significantly during the course of treatment, the most recent serum creatinine should be used to re-calculate a creatinine clearance and dose as determined by local policy. In adult patients this calculated dose should be used to inform the new dose band as per NHS dose banding tables.

4.2.2.5.2. **Using nuclear medicine measured GFR:** Unless there is a significant change in serum creatinine, repeat testing of GFR is not usually required. Check local policy regarding thresholds for repeating nuclear medicine GFR tests.

Warning: it is NOT appropriate to use the previous banded dose to work out a percentage dose change threshold as this risks under or overestimating the actual carboplatin dose when banding.

Table 4: Additional considerations for paediatrics in AUC dosing

Paediatrics
▪ AUC dose usually calculated from the DPTA half life

4.2.2.6. **Check dose modifications**

4.2.2.6.1. Ensure the reason for dose modification is clearly documented

4.2.2.6.2. Ensure dosing appropriate as per renal and hepatic function, as well as PS and recent toxicity assessments

4.2.2.6.3. Ensure any dose modifications applied for previous cycles have been carried forward as appropriate.

Caution ▲

Ensure you have a clear understanding of how your local CEPMA systems calculates dose modifications. Some systems may require a dose change to be expressed as a % dose modification as a % of original dose. For 2nd or subsequent dose modifications, the dose reduction in relation to the original dose needs to be selected, i.e. for an 80% dose to be reduced by a further 20%, this must be requested as a 60% dose reduction of the original (100%) dose.

4.2.2.7. **Check fluid and administration**

4.2.2.7.1. Check appropriate fluid and volumes have been prescribed for the drug and dose prescribed

4.2.2.7.2. Check rate of infusion is appropriate for dose and volume

4.2.2.7.3. Where specific access route of administration is necessary e.g. central administration, ensure the patient has an appropriate access in place

Table 5: Additional considerations for paediatrics in dosing

Paediatrics – Other dosing considerations
▪ Dose banding not usually used in children. ▪ The dose should be suitable for the age and or weight of the child. ▪ Drug fluid volume should be a suitable for the age of the patient and the drug concentration should fit locally agreed concentrations ranges with the pharmacy aseptic unit. ▪ Check infusion rates and scheduling are correct. ▪ The correct supportive care is prescribed with the treatment. E.g. mesna with Ifosfamide infusions. ▪ Hydration is prescribed with nephrotoxic drugs and the type of fluid, volume and electrolyte content is suitable for the age and weight of the child. ▪ For oral preparations the dose scheduling and formulation needs to be appropriate for each CHYP. Metronomic dosing often required. ▪ Pharmacokinetic directed dosing is used in certain protocols/patients.

4.2.3 Laboratory values / regimen specific testing

Ensure all critical tests are taken within time ranges appropriate for the SACT prescribed as defined within local organisational policy

4.2.3.1 **Check laboratory values** (e.g.: FBC, U&Es LFTs) as defined within SACT protocol

4.2.3.2 **Check renal function** and ensure drug doses are modified accordingly where appropriate as per drug/regimen literature. This can be done via Measured (51Cr-EDTA, DTPA) or Calculated methods (e.g: Cockroft and Gault or modified Schwartz in children) ensure you are aware of your organisations chosen method of calculation.

4.2.3.3 **Check hepatic function** and ensure drug doses are modified accordingly where appropriate as per drug/regimen literature.

4.2.3.4 Ensure that regimen / disease specific checks that are required periodically throughout treatment are carried out (e.g.: cardiac function, endocrine testing, genomic testing). Refer to SACT protocol for details on specific testing.

4.2.3.5 Ensure toxicity assessment has been carried out and documented as per SACT protocol. Ensure appropriate dose adjustments have been made as required, according to the SACT protocol

Table 6: Additional considerations for paediatrics in laboratory values

Paediatrics
▪ In paediatrics, additional regimen checks may also include audiology and tubular reabsorption of phosphate. ▪ Cardiac function is usually monitored using FS% in children.

4.2.4 Supportive medications

4.2.4.1 Check pre-medications has been prescribed if appropriate, and adjusted if necessary in response to recorded toxicities

4.2.4.2 Check hydration has been prescribed as per protocol

4.2.4.3 Check appropriate supportive medications have been prescribed and any required modifications or adjustments to supportive medicines to manage toxicities experienced with previous cycles have been actioned

4.2.4.4 Re-consider potential for adrenal suppression and action accordingly.

4.2.5 Final verification signature

4.2.5.1 When satisfied that the prescription is correct sign and date prescription as a record of verification. This may be an electronic signature when using an e-prescribing system.

Notes:

1. Advanced dispensing or preparation can occur prior to verification but patients must not have SACT administered or issued to them until verification is completed.

2. Verification activities listed may be undertaken at different points in time. Whilst it is important to follow all checks listed there may be a separation of different checks prior to final signature

Section 5: Bibliography, Key Guidance Documents and References

5.1 Department of Health HSC 2008/01 Updated National Guidance on the Safe Administration of Intrathecal Chemo

5.2 Standards for the safer use of EPMA systems for use in SACT services. UK Chemotherapy Board version 3.0 Feb 2022

5.3 Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy. Updated November 2022

5.4 NHS Scotland Specific Guidance:

a. Scottish Government Health Department CEL (2009) 21: Safe Administration of Intrathecal Cytotoxic Chemotherapy

b. Scottish Government Health Department CEL 30 (2012) Revised 2023 – (Revised) Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy

c. Guidance on Consent for SACT in Adults. Healthcare Improvement Scotland. Oct 2020

d. Steroid emergency card to support early recognition and treatment of adrenal crisis in adults. Healthcare Improvement Scotland July 2021

Section 6: Document Control

Title	BOPA: Standards for the Clinical Pharmacy Verification of Prescriptions for Cancer Medicines: Version 4.0 TBC
Authors Editors version 4.0	**Chair -** Heather Dalrymple, National Clinical Lead, Cancer Medicines – Healthcare Improvement Scotland; **Secretary** - Suriya Marshall, The Royal Wolverhampton NHS Trust; **Steering group** - Netty Cracknell, Ramsay Health Care UK, Michal Sladowski – Weston Park Cancer Centre Sheffield, Clayton Wong - Nuffield Health Cancer Centre London (IHC). **SLWG members -** Mollie Bishop The Royal Marsden NHS Foundation Trust (Technician rep), Lorna Cairns - Western Health and Social Care Trust (N.Ireland), Miguel Capomir - East Kent Hospitals University NHS Foundation Trust, Vicky Holden - Leeds Teaching Hospitals NHS Trust, Maria Jinks - Northumbria Healthcare NHS Foundation Trust, Claire Kennedy - The Churchill and The Horton Hospitals (Technician rep), Sana Mahmood - East and North Hertfordshire NHS Trust, Tracy Parry - Betsi Cadwaladr University Health Board (Wales), Ian Purcell - Nottingham University Hospitals NHS Trust, Craig Russell - NHS Ayrshire & Arran (Scotland), Lamia Samrin - Great Ormond Street Hospital for Children, Raakhee Shah – UCLH

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Owner	BOPA.

Change History

Draft	Date	Author/Editor	Summary of Change
1.1	21.09.09	Steve Williamson	Initial draft
1.2	07.10.09	David Thomson	Split document into 2 separate documents. General updates.
1.3 &1.4	07.10.& 20.10.09	Ewan Morrison & Mary Maclean	Editorial comments, updates and changes to reflect UK perspective
1.5	7.11.09	BOPA committee	Incorporation of SFH and editing
1.6	14.11.09	Netty Wood	References & comments
1.7	18.12.09	Steve Williamson	Membership Consultation
2	3.12.12	Steve Williamson	Draft Version 2
2.2	11.03.13	Steve Williamson	Changed following consultation to members
2.3	02.04.13	Steve Williamson/ Helen Flint	Final version reviewed by committee
3.0	06.03.18	Steve Williamson	Draft update of policy for sub committee review. Updated references to electronic systems, added details guidance from previous supporting document as an appendix (revised and updated from previous version)
3.1	13.03.18	BOPA Committee	Reviewed by BOPA Exec. Version for consultation.
3.2	17.07.18	Steve Williamson	Updated following comments from GAP
3.3	09.10.18	GAP Sub group Seonaid McLachlan	Updated following comments from SOPPG
4.0	21.04.23	BOPA SLWG Heather Dalrymple	Full review & update of document. Inclusion of pharmacy technician SACT verification
4.1	18.09.23	Netty Cracknell	Addition of Royal Pharmaceutical Society endorsement logo.
4.1	20.11.23	Netty Cracknell	Addition of excluding cycle 1 from 2a

Proposed Target Audience	All BOPA Members.
Proposed Circulation List	All BOPA Members. All chief pharmacists.
Contact details	contact@bopa.org.uk

Appendix 1: Verification Checklist Examples

Example SACT verification checklist(s)

Cycle 1 Only	
Treatment plan	
SACT regimen prescribed matches the intended documented treatment plan and/or clinic letter	
Prescribed drugs are part of an approved regimen or protocol, which is appropriate for the diagnosis and line of therapy (refer to formulary / network protocols / NICE / CDF/ SMC / NCMAG, AWMSG)	
Prescriber is authorised to prescribe Cycle 1 SACT	
Patient has been consented for treatment	
Cycle frequency is appropriate (check radiotherapy planning when relevant)	
Patient eligibility	
Patient is eligible for treatment based on diagnosis (staging, pathology, genetic/genomic results, tumour markers), & SACT treatment history	
Regimen is appropriate based on patient's medical history, performance status (PS), staging and SACT history	
Regulatory, monitoring and funding* approvals are in place. *Follow local non-formulary processes where non-formulary drugs or protocols are prescribed	
Pre-screening	
Medical history completed – including patient allergy status	
Drug history - including previous SACT. Check for potential interactions, contra-indications and duplication between all planned SACT / supportive medication and patient's concurrent medication. Check for cumulative dosing if appropriate & prior toxicities which may impact on dosing. Consider potential for adrenal suppression.	
Up-to-date height, weight and BSA (where relevant) is calculated and documented on the prescription	
Relevant pre-treatment critical tests have been completed and reported prior to treatment (e.g. Cardiac function, genomic testing, CT scans) – refer to protocol / SPC	
Pre- treatment Virology screening (e.g. Hepatitis B testing), has been completed, reported and actions taken where appropriate	

All Cycles (including cycle 1)	
Prescription details and patient demographics	
Prescriber is authorised to prescribe SACT in your organisation	
SACT prescription includes all details required for dispensing, labelling and administration.	
Prescription meets legal requirements and all required signatures are in place	
Patient details correct: Name, Treatment location, NHS/local patient number, date of birth	
Check patient allergy status, interactions or contraindications against any new medicines prescribed since last cycle (when information available)	
Recent weight*, and body Surface area (BSA) recorded. *Weight is regularly updated throughout treatment at a min frequency determined by local policy	
Confirm intended start date and exact duration of treatment of that cycle and confirm cycle frequency is appropriate in relation to timing of last cycle	
Ensure cycle-by-cycle declarations have been completed (e.g. pregnancy prevention programmes	
Ensure formulation is clear and when relevant specific brand and /or supply / stock is specified on the prescription to enable dispensing staff to identify correct supply	
Dosing & Administration	
Drug doses calculated and prescribed correctly (including banding where appropriate) - inc. appropriate dose units and route of administration.	
If the patients' weight has changed - ensure treatment doses have been recalculated if required in line with local policy.	
Ensure maximum doses for individual drug e.g. vincristine will not be exceeded. Refer to SACT protocols for details	
Ensure maximum lifetime cumulative doses for e.g. anthracyclines will not be exceeded.	

Refer to SACT protocols for details	
Check Dose modifications. ▪ Ensure the reason for dose modification has been clearly documented. ▪ Ensure dosing appropriate as per renal and hepatic function, PS and recent toxicity assessments	
Ensure any dose modifications applied for previous cycles have been carried forward as appropriate	
Check appropriate fluid and volumes have been prescribed for the drug and dose prescribed and rate of infusion is appropriate for dose and volume	
Ensure patient has appropriate access in place e.g. central VAD, PICC when relevant	
Laboratory values/Regimen specific Testing: *Ensure all critical tests are taken within time ranges appropriate for the SACT prescribed as defined within local organisational policy*	
Laboratory values (e.g. FBC, U&Es, LFTs, TFTs) meet limits as defined within SACT protocol / SPC / clinical trial protocol	
Renal function - ensure drug doses are modified when appropriate as per SACT protocol / SPC / clinical trial protocol	
Hepatic Function - ensure drug doses are modified when appropriate as per SACT protocol / SPC / clinical trial protocol	
Ensure regimen / disease specific checks are carried out in accordance with SACT protocol / SPC/ clinical trial protocol (e.g.: cardiac function, endocrine testing, genomic testing, BP, urinalysis).	
Toxicity assessment has been carried out and documented with appropriate dose adjustments made as necessary according to SACT protocol / SPC / clinical trial protocol	
Supportive Medications	
Pre-medications has been prescribed as appropriate, and adjusted if required in response to recorded toxicities	
Appropriate supportive medications have been prescribed and any required modifications or adjustments to supportive medicines to manage toxicities experienced with previous cycles have been actioned	
Hydration has been prescribed as per protocol or in addition if required	
Re-consider potential for adrenal suppression and action accordingly	
Final verification signature	
When satisfied that the prescription is correct, sign & date the prescription	

Appendix 2: Funding Routes

1. NHS England

1.1 Routine access to SACT:

1.1.1. Licensed cancer medicines for routine use in England are appraised via the National Institute for Health and Care Excellence (NICE). Those medicines which receive a positive NICE Technology Appraisal associated with them are available through routine commissioning.

1.1.2. The cancer drugs fund (CDF) functions as a managed access program alongside the NICE Technology appraisal process. It acts as:

- Managed access program for drugs which have not received positive NICE approval but have potential to meet criteria as existing trial data matures and/or data is collected via use within the CDF.
- Interim funding for all newly recommended licensed cancer drugs approved by NICE, giving patients access to these treatments many months earlier than before.

1.1.3. Drugs entering the CDF will do so for an agreed period as part of the managed access agreement. Once this period is complete NICE will re-appraise the drug for a final decision on commissioning. In NHS England, all new patients receiving newly NICE approved SACT, or SACT included in the Cancer Drug Fund (CDF) must be registered on the High-Cost Drug management system (Blueteq) by their clinician and must have the relevant Blueteq form completed and approved prior to commencing treatment. Please note, some locally commissioned treatments will also require registration and approval via this system.

1.1.4. Some more established SACT medicines with NICE approval do not require individual patient approval via the Blueteq system.

1.2 Routes for access to non-routine or non-approved SACT

1.2.1 A variety of routes for access to non-approved cancer medicines exist in NHS England. This includes, but is not limited to:

- Early Access to Medicines Schemes (EAMS): These are MHRA approved schemes which give patients access to new medicines that do not yet have an EU product licence (Marketing Authorisation) or be available (marketed) yet in the UK but where there is a clear unmet medical need). EAMS are usually only open for a limited time.
- Project Orbis. A framework for concurrent submission and review of oncology products amongst international regulatory authorities.
- Individual funding requests: Completed as part of an online portal and assessed by an NHSE panel.
- Commercial / compassionate use programmes
- Top-up payments or private healthcare in addition to NHS treatment (see below)

- Check that local organisation governance approval is in place to use any drugs that are being accessed through any non-approved route.

1.2.2 Prior to commencement of any treatment, a check to ensure funding is in place is made as part of the SACT verification process.

1.3 Arrangements for children & young people with cancer (CHYP)

1.3.1 Some SACT is licensed and commissioned for use in CHYP. Others may be suitable and commissioned for post pubertal children in line with the details specified in the NHS England commissioning of medicines for children in specialised services. In such situations, a separate Blueteq form is available for CHYP. For younger children options include local funding, free of charge (FOC) scheme or submission of a policy proposition nationally to NHSE.

2. NHS Scotland

2.1 Routine access to SACT:

2.1.1. Licensed cancer medicines for routine use in NHS Scotland are approved via the Scottish Medicines Consortium (SMC). In addition, the National Cancer Medicines Advisory Group (NCMAG) makes decisions for off-label and off-patent use of cancer medicines, which sits outside of the SMC remit. Once medicines are approved local or regional formulary processes are followed to add these onto formulary.

2.2. Routes for access to non-approved SACT

2.2.1. A variety of routes for access to non-approved cancer medicines exist in NHS Scotland. This includes, but is not limited to:

- Early Access to Medicines Schemes (EAMS) which have been accepted for use in Scotland
- Peer Approved Clinical System Tier 2 (PACS T2) - for medicines requests for licensed medicines which are not recommended, or submitted to but awaiting assessment, by the SMC
- pre-HTA access schemes managed by National procurement, or local non-formulary medicines application processes which are managed at health board level.
- Commercial / individual compassionate use programmes
- Top-up payments or private healthcare in addition to NHS treatment (see below)

2.2.2. The patient's Consultant must make an application for use of a non-approved SACT regimen or supportive treatment on an individual patient basis. Health boards will have medicines governance processes that describe the application and approval processes to be followed before prescribing takes place. In terms of SACT verification, the RPP must be

able to identify non-approved treatments and check to confirm approval before verifying cycle 1 of any new treatment.

3. NHS Wales

3.1 Routine access to SACT:

3.1.1. Licensed cancer medicines for routine use in NHS Wales are approved via the National Institute for Health and Care Excellence (NICE) or All-Wales Medicines Strategy Group (AWMSG). In addition, medicines approved by NICE for use under the NHS England Cancer Drugs Fund (CDF) would be available for routine use in Wales. The New Treatment Fund supports the implementation of new medicines in Wales.

3.1.2. The One Wales Medicines process is available where a group of patients might benefit from a medicine that isn't routinely available. The process results in a decision that applies to all of Wales.

3.1.3. One Wales can be used for medicines when:

- the medicine's licence holder commits to a future HTA of a licensed medicine;
- the EMA or MHRA have not licensed a medicine;
- the EMA or MHRA have licensed a medicine only to treat a different
- condition(s); or
- a medicine isn't included in current treatment guidelines and no other suitable
- medicine is licensed to treat the condition

3.1.4. In Wales from 1st April 2023, all new patients receiving SACT which is included in the AWMSG-published list must be registered on the Blueteq system by their consultant prior to commencing treatment.

3.2 Routes for access to non-approved SACT

3.2.1. EAMS/Free of Charge Medicines Supply - Check that the NHS Wales 'All Wales Guidance – free of charge medicine supply' has been followed. Check also that local organisation governance approval has been given to use any drugs that have been through an Early Access to Medicines Scheme (either formalised NHS EAMs or manufacturers own scheme). EAMS may only be approved for a limited time. These will generally not have an EU product licence (Marketing Authorisation) or not yet be available (i.e. marketed) in the UK. In addition check to see if a regimen has been approved by local commissioners via an individual funding request system.

3.2.2. Individual Patient Funding Requests (IPFR) - Where routine funding is not available and a clinician feels that the patient is likely to gain a significant clinical benefit from the proposed intervention; and can demonstrate that the value for money of the intervention for that particular

patient is likely to be reasonable, the All Wales IPFR Policy should be used.

3.2.3. Commercial / individual compassionate use programmes

3.2.4. Private / Self-funded Patients or Top-up payments - (See below)

4. NHS Northern Ireland (NI)

4.1 Routine access to SACT:

4.1.1. Licensed cancer medicines for routine use in Northern Ireland are approved through the managed entry process, with commissioning decisions based on NICE recommendations. In the absence of NICE guidance, guidance from NHS Scotland via the SMC or NHS Wales is followed. NICE guidance takes precedence over SMC or Welsh guidance.

4.1.2. In NI all new patients receiving newly NICE or SMC approved SACT, or SACT included in the Cancer Drug Fund (CDF) must have a cost per case application (CPC) submitted by their consultant prior to commencing treatment.

4.2 Routes for access to non-approved SACT

4.2.1. There are a number of routes available within NI including

- EAMS
- compassionate use programmes
- individual patient funding requests
- top-up payments and self-funding via a private funding route (see below)

4.2.2. Governance arrangements for use of medicines via these routes will be in place locally. In terms of SACT verification, processes should be in place to enable verifying staff to identify non-approved treatments and ensure that checks are made to confirm approval has been given before verifying cycle 1 of any new treatment.

5. Clinical Trials

5.1 Many organisations across the four Nations will provide access to clinical trials for eligible patients. Funding arrangements and local clinical trials governance arrangements will be in place prior to patients being enrolled in a clinical trial.

6. Top-Up and Private Healthcare Funded in Addition to NHS Care

6.1 There are Department of Health, and Scottish Government Health Department

policies in place for this situation. Refer to local guidelines and governance arrangements.

7. Independent Sector

7.1 Within private healthcare, there are two methods of payments, Private Medical Insurance (PMI) and self-pay.

7.2 All medicines are available if licensed for the indication required providing the patient's policy covers the treatment required (this is individual by patient and policy). For medicines without MHRA license, if there are clinical trials to support use, it is a recognised gold standard of care, or is licensed in another country then this is likely to be approved for use, providing the patient's policy covers the treatment required (this is individual by patient and policy). In addition, these treatments should be approved by the internal clinical governance group.

7.3 Deviation from standard of care treatment can be sought sometimes with patient's individual clinical circumstances. These deviations must be evidence-based, and multi-disciplinary discussion clearly documented. An individualised treatment protocol is subject to approval by the internal clinical governance group, and a specific protocol must be created and labelled for the individual patients' use only. PMI cover is individual by patient and policy.

7.4 Each patient is approved on a case-by-case basis.