NCCP Guidance on the Provision of Parenteral Systemic Anti-Cancer Therapy (SACT) and Supportive Care in SACT Outreach and Community Services

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1	21/10/2020		NCCP Executive
2	09/02/2024	Update to title. Updated the terminology to align with SACT Model of Care 2022. Addition of patient eligibility and suggested SACT and supportive care.	NCCP National Medical Oncology and Haemato-oncology Clinical Leads Groups

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

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Glossary

Term	Explanation
Aseptic Compounding Unit	An aseptic compounding unit is a specialised suite of graded rooms with engineering controls such as high efficiency particulate air (HEPA) filtration that contains specialised equipment such as isolators
Physical Separator Device	This includes an isolator in an ACU or other devices where there is a barrier between the operator and product.
Systemic Anti-Cancer Therapy	For the purpose of this document, SACT involves parenteral systemic treatment for cancer, including but not limited to chemotherapy, targeted therapies and immunotherapies.
Type 1-3 SACT Outreach	Type 1-3 SACT outreach are defined as an extension of Type 1-3 hospitals from an off-site location. SACT outreach services are resourced by the Type 1-3 SACT hospital, including staffing, medicines and other supplies. SACT outreach must be managed by a clinical nurse manager 2 (CNM2) or equivalent at a minimum.
Type 4 SACT Community Services	Type 4 SACT community services include providing SACT and supportive care in locations such as primary care centres, community infusion clinics, community hospitals and health centres, GPs as well as patients' homes.

Abbreviations

Abbreviation	Detail
ACU	Aseptic Compounding Unit
BSA	Body Surface Area
CAYA	Children Adolescent and Young Adult
HEPA	High efficiency particulate air
HPSC	Health Protection Surveillance Centre
IM	Intramuscular
IV	Intravenous
mAbs	Monoclonal Antibodies
OAMs	Oral anti-cancer medicines
PPPGs	Policies, procedures, protocols and guidelines
SACT	Systemic Anti-Cancer Therapy
SC	Subcutaneous
SPC	Summary of Product Characteristics

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1 Introduction

The practice of systemic anti-cancer therapy (SACT) has changed in recent years, with many new advances in treatments, resulting in improved outcomes and increased survival for many patients with cancer. Coupled with this, the method of delivery of SACT has developed, with many medical oncology and haemato-oncology treatments now suitable for administration in the community (1). In addition, many aspects of supportive care for patients receiving SACT are well suited for provision in the community[1].

In Ireland, as in many other developed countries, the number of cancer patients is projected to increase, and there is also a projected increase[2] in the volume of SACT activity, to 2045 (2).

Delivering SACT closer to the patient's home and away from the acute hospital setting is acknowledged internationally as important for both the patient experience during their cancer treatment as well as for relieving capacity issues in hospital-based day wards (1, 3).

A key focus of the National Cancer Strategy 2017-2026 is the achievement of an integrated continuum of care for patients through primary, secondary and tertiary care (4). Central to this is the provision of appropriate cancer care services in the community, including SACT. The provision of clinically appropriate care as close to home as possible is also consistent with the objectives of Sláintecare Implementation Strategy and the NCCP SACT Model of Care (5, 6).

There are a number of SACT outreach and community services available in Ireland. Stakeholders identified the need for an overarching guidance document on the establishment and provision of these services. This document aims to provide this guidance and is also underpinned by the SACT Model of Care 2022. (6)

1.1 Models of service delivery

A number of different service models have been considered internationally to meet the objective of providing SACT outside of acute hospital settings (1, 7). These include services provided in community

[1] Supportive care for patients receiving SACT includes, but is not limited to, bisphosphonates, phlebotomy, pump disconnections, intravenous access flushes and dressings.

[2] The 2019 National Cancer Registry Ireland (NCRI) report "Cancer incidence projections for Ireland 2020-2045" projects an increase of 81% in the number of male patients undergoing chemotherapy and a 58% increase in females undergoing chemotherapy within one year of their diagnosis, up to 2045

clinics, mobile units, or directly to patients in their homes. There are a number of common themes outlined internationally to direct the provision of safe and high quality SACT services in the community. These include:

- Patient choice (8, 9)
- Clear governance structures (8, 10)
- Policies and procedures for the management of referrals to the community (9-11)
- Patient selection criteria based on treatments and care appropriate to community settings (9, 10)
- The management of side effects, including acute oncology pathways (1, 3, 8, 10, 11)

In Ireland, as defined in the SACT Model of Care, Type 1-3 SACT hospitals may establish SACT outreach clinics (6). The NCCP Community Oncology Nursing Education programme has enabled community nurses to deliver some aspects of care to oncology patients in the community. A number of Type 4 SACT community services (6) are already in place with a number of further services in development. These include;

- Community infusion clinics providing services for patients with cancer such as low-risk infusions, pre-SACT blood tests and supportive care for SACT patients
- The provision of SACT directly to patients by third party/private providers under contract with the hospitals/HSE.

2 Purpose and scope of this document

The purpose of this document is to provide guidance on the provision of adult SACT services to medical oncology/haemato-oncology patients in SACT outreach and community services in Ireland.

2.1 Scope

For the purposes of this document, SACT outreach and community services include Type 1-3 SACT outreach as well as Type 4 SACT community services. Please refer to the Glossary for definitions.

In each of these settings, it is possible that services may be operated and provided by the HSE or through a third party provider under contract to the HSE.

This guidance document covers services such as parenteral SACT and supportive care. It is expected that these services will be locally identified[3] following a risk assessment and that these will include treatments that are deemed to be clinically appropriate for community administration.

The content of this Guidance document aligns with existing National HSE guidance including Health Protection Surveillance Centre (HSPC)[4].

Areas that are outside the scope of this document include:

- Children, Adolescent and Young Adult (CAYA) systemic therapy
  - A National Model of Care for Paediatric Healthcare Services in Ireland is in place.
  - A National Model of Care for CAYA Cancer Services is in the process of being developed by the NCCP CAYA Programme. (12)
- Oral Anti-Cancer Medications (OAMs) or medications self-administered by patients are outside the scope of this document[5].

2.2 Intended audience

The intended audience for this document is:

- Managers and clinical leads in hospital and community services that have developed or are considering establishing SACT outreach and community services.
- Third party providers who are delivering SACT on behalf of the HSE[6].

3 General principles for SACT outreach and community services

1. **Regional/Networked:** SACT outreach and community services should be developed and provided as part of a regional or a network approach to SACT services and should be integrated with overall SACT service delivery. For Type 4 SACT community services, formal links between community SACT services and SACT hospitals should be in place to ensure clear governance structure and alignment of clinical pathways, as well as clear communication channels between health professionals.

[3] This may be further informed by National Guidance

[4] https://www.hpsc.ie/

[5] Refer to the Oral Anti-Cancer Medications Recommendations. NCCP HSE 2018.

[6] While OAMs are outside the scope of this document, in cases where OAMs are delivered through third party providers, this document may be used to provide guidance for the service.

2. **Integrated/Seamless:** A seamless pathway between hospital and community services should be established, which should include transitions from hospital services. This must be underpinned by communications policies including access to relevant electronic systems where available, such as Healthmail. For the duration of treatment in SACT outreach or community services the SACT hospital and relevant medical oncologist or haematologist will retain overall responsibility for the patient until the patient is discharged from the SACT service.
3. **Quality Service:** The patient's treatment pathway should remain the same, with any clinician reviews, scans, phlebotomy appointments occurring as would be the case had the patient opted for treatment in a hospital setting.
4. **Referrals/Access:** Patient referrals should consider clinical suitability and patient choice. Patients should be able to access out of hours' services and patient supports (e.g. dietetics and other therapies) as required and on the same basis as those patients receiving SACT in a hospital.

3.1 Policies, procedures, protocols and guidelines (PPPGs)

Agreed policies, procedures, protocols and guidelines (PPPGs) must be in place in all SACT outreach and community services. These PPPGs should align to national advice, guidelines and regimens where available. The PPPGs put in place locally should include the following at a minimum:

1. Patient selection criteria relevant to the particular service (See Section 3.3 and Appendix 1)
2. The management of patients during their SACT treatment, including discharge or onward referral
3. The range of services, including treatments, that can be safely and appropriately provided in the specific community setting. See Appendix 2 for further guidance in relation to SACT and supportive care medication selection for preparation and administration in SACT outreach or community services
4. The roles and responsibilities for staff, including staff in the community and hospital settings
5. The education and training requirements of staff
6. Communication pathways between health professionals in the community, as well as with the acute referring hospital
7. Information and education to be provided to the patient and carer as required
8. Contact details to be provided to patients and/or carer, including phone numbers for advice and emergencies such as the Acute Oncology Service (AOS)
9. Management of patient data on paper and electronic systems, as appropriate to the service
10. Risk and incident management in line with relevant HSE policies
11. Referral to medical oncology/haematology services or AOS, including out of hours' services, when necessary

12. Waste management, including the collection and disposal of clinical and cytotoxic waste products and the management of cytotoxic spillages
13. Sites should consider cohorting patients to maximise capacity.

3.2 Governance

All SACT outreach and community services must operate in line with the governance structure as outlined in the SACT Model of Care 2022 and have a responsibility to abide by legislative requirements and national PPPGs governing SACT. The governance arrangements will include funding and procurement arrangements including the supply and dispensing of medication.

As outlined in Section 2, the overall responsibility for the patient remains with the medical oncologist or haematologist.

All services that are subcontracted to third party providers will have clearly defined service level agreements (SLAs) in place with the HSE. The SLA will detail the governance structures, which should be in line with this guidance document.

3.3 Patient eligibility criteria

The patient eligibility criteria for treatment in SACT outreach and community services should be detailed in the local PPPGs. These should align to National Advice, Guidelines and Regimens where available. The service specific criteria should take into account a range of factors, including:

- The type and range of services as set out in the PPPG, including the services that are clinically appropriate for each service location
- Patient specific factors, including patient condition and suitability for treatment in SACT outreach and community services. See Appendix 1 for more detail.
- Patient preferences and other personal perspectives such as proximity to a SACT outreach or community service

4 Performance and evaluation

The monitoring of SACT outreach and community services will be the responsibility in the first instance of the relevant SACT hospital / Health Regions or HSE community services as outlined in the governance arrangement for the service. This may include metrics such as:

- Patient experience
- Patient activity numbers
- Expenditure data
- Target access times

The service will also support education and research activities as required, as well as data to facilitate audit.

Appendix 1

Eligibility criteria for referral to a SACT outreach or community service

Decisions to provide a patient's treatment in a lower acuity setting needs to consider each patient's individual clinical condition as well as the patient's wishes. Selection criteria for the referral of a patient for administration of SACT or supportive care in SACT outreach and community services should be detailed in local policy, procedures, protocols and guidelines.

Factors to consider: Patient specific factors, including but not limited to patient performance status, disease status, co-morbidities, and suitability for treatment in SACT outreach and community services

Inclusion criteria:

1. Patients must have the ability to make informed decisions and consent to treatment in SACT outreach or community services
2. Patients must be receiving a SACT or supportive care medication which has been agreed locally as suitable for preparation / administration in a SACT outreach or community service (See Appendix 2 for suggested SACT and supportive care which may be suitable for preparation and administration in a SACT outreach and community services
3. Patients must be clinically stable, e.g. ECOG[7] 0-2; performance status must be agreed locally
4. Patients must have received a minimum of three doses in the Type 1-3 hospital setting without any adverse reactions or toxicities above Grade 1 CTCAE[8] or as advised by primary consultant
5. Patients must be able to comply with attending clinical reviews and blood testing as required

[7] Eastern Cooperative Oncology Group Performance Status scale

[8] Common Terminology Criteria for Adverse Events. Grade refers to the severity of the adverse event. Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_8.5x11.pdf

6. Patients must have a Type 1-3 hospital-based review at an interval specified by their consultant and appropriate to their particular treatment and disease status. This interval must be clearly stated in the local PPPGs

Exclusion criteria:

1. Previous history of sensitivity / anaphylaxis to the SACT or supportive care
2. Treatment deferred more than twice due to toxicities
3. History of previous non-attendance as required for bloods, clinical reviews, test or scans

Appendix 2

SACT and supportive care medication selection for preparation and administration in SACT outreach and community services

The following points were considered in the development of the suggested list of SACT and supportive care medications which may be suitable for preparation and administration in SACT outreach and community services.

1. Suitability of medications:
    a. Non-cytotoxic medications are preferred unless a cytotoxic medication is available in a ready to use format. This is due to the occupational exposure associated with preparation outside of a physical separator device which is not recommended (13)[9]
    b. Medications with flat or fixed dosing are preferred. Medications which are dosed based on body surface area (BSA) or weight should only be considered if there is no financial losses with respect to cost savings usually gained through vial sharing when prepared in an aseptic compounding unit (ACU) environment
    c. Non-vesicant medications are preferred

2. Route of administration:
    a. Only subcutaneous (SC), intramuscular (IM) and intravenous (IV) routes are included

3. Treatment regimen:
    a. Some of the medications listed in Table 1 are given in combination with cytotoxic chemotherapy in specific sections of regimens. It is suggested that these medications will only be suitable for preparation and administration in SACT outreach and

[9] The 1996 DoH published document "Guidelines for the safe administration of cytotoxic medical preparations in the treatment of patients with cancer" advised that all cytotoxic drugs should be prepared by trained pharmacy personnel in a contained environment (e.g. isolator units, bubble units or laminar airflow cabinets) to improve patient safety in addition to minimising risk of exposure.

community services on days when the cytotoxic chemotherapy is not due. An exception to this is if the cytotoxic component is available in a ready to use format, e.g. bortezomib

4. Complexity of reconstitution:
    a. Only medications which are categorised as Complexity Band 0, Band 1 or Band 2 are included as being suitable for preparation in SACT outreach and community services (14)
        i. Medications in higher complexity bands may be included in local lists provided they are available in ready to use format (this would automatically reduce their classification to Band 0)

5. Summary of Product Characteristic (SPC) information:
    a. The information relating to posology and method of administration information within each SPC was considered
    b. Products requiring full resuscitation facilities during administration are not included

Table 1 is not an exhaustive list; local capacity, experience and the service being provided will influence which SACT and supportive care medications can be relocated to SACT outreach and community services. Correspondingly, each site must determine the local list of suitable medications to be used in that specific location.

Additionally, the following documents also contain relevant information and should be used to inform local decisions about which medications are suitable for preparation outside of an ACU.

- NCCP Guidance: Pharmacy bench top preparation of monoclonal antibodies (mAbs) used in the treatment of cancer[10]

[10] https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/nccp-guidance-benchtop-preparation-mabs-v1.pdf

- NCCP Template SOP 105 Pharmacy Bench Top Preparation of Monoclonal Antibodies (mAbs) used in the treatment of cancer[11]

Although the Pharmacy bench top preparation guidance and SOP are intended to be used in the pharmacy setting, the principles of risk assessment and other considerations will be applicable to SACT hospital wards, day units as well as outreach and community services where non pharmacy staff may also be involved.

Hormonal agents such as degarelix, fluvestrant, goserelin, leuprorelin and triptorelin are not included in Table 1 since these are not routinely given on their own in a day ward setting and so transfer of administration of these agents to a SACT outreach or community services is unlikely to increase day ward capacity.

Pre-medications required for each medication listed below are outlined in the individual NCCP National SACT regimens, therefore no details regarding pre-medications have been included in Table 1.

[11] https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/nccp-temp-acu-sop105-for-bench-top-preparation-of-monoclonal-antibodies-v1a-copy.docx

The list in Table 1 is not an exhaustive list; local capacity, experience and the service being provided will influence which SACT and supportive care medications can be relocated to SACT outreach and community services.

Table 1: Medications which may be suitable for preparation and administration in SACT outreach and community services

Drug	Route of Admin	Medicine type	Presented as solution in vial / syringe	Complexity Band[12]	Flat/ fixed dose
Atezolizumab	IV	Monoclonal (Humanised)	Yes	Band 2	Yes
Avelumab	IV	Monoclonal (Humanised)	Yes	Band 2	Yes
Bortezomib	IV / SC	Cytotoxic	N/ A[13]	Band 0 (must be available in ready to use format)	No[14]
Daratumumab[15]	SC	Monoclonal (Humanised)	Yes	Band 1	Yes
Denosumab[16]	SC	Other	Yes	Band 1	Yes
Durvalumab	IV	Monoclonal (Humanised)	Yes	Band 2	Yes[17]
Intravenous Immunoglobulin	IV	Other	Yes	Band 0	No
Nivolumab	IV	Monoclonal (Humanised)	Yes	Band 2	Yes
Pamidronate	IV	Bisphosphonate	Yes	Band 2	Yes
Pembrolizumab	IV	Monoclonal (Humanised)	Yes	Band 2	Yes
Trastuzumab	SC	Monoclonal (Humanised)	Yes	Band 1	Yes
Zoledronic acid	IV	Bisphosphonate	Yes	Band 0	Yes

[12] Defined as per NCCP Capacity Planning Toolkit User Manual. https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/aseptic unit capacity planning user manual.pdf

[13] As a cytotoxic agent, bortezomib will only be suitable for administration in the community setting if available in ready to use format.

[14] NCCP has developed a dose banding table for bortezomib which may reduce wastage due to individualised patient dosing.

[15] The Darazalex SC SPC states that DARZALEX should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available. The suggested patient eligibility criteria above rules out first dose administration of any agent in SACT outreach and community services

[16] As Xgeva®

[17] Individual patient weight based dosing (14 day schedule) excluded

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14. NCCP. NCCP Capacity Planning for Parenteral SACT. 2017.