Fact Sheet

Single Patient Use (SPU) Protocol Requests

In certain circumstances, a clinician may wish to use a systemic cancer therapy protocol that has not been approved by the SA Health Cancer Drug Committee (SAHCDC) for use in SA Health hospitals and therefore is not listed on the SA Health Approved Cancer Therapy Protocol Register.

In these circumstances a clinician must complete a Single Patient Use* (SPU) Form to obtain approval to use a non-standard protocol. SPU pathway requests are used to ensure appropriate cancer therapy governance and inform protocol development requests to tumour streams.

*Note: An Individual Patient Use Form (IPU) submission to DTC's may also be required for some individual high-cost drugs. An SPU cannot be used in place of an IPU and vice versa.)

When is a Single Patient Use protocol request form required?

A duly completed SPU protocol request form is required prior to prescribing a non-standard treatment. A non-standard treatment protocol can be either a new protocol or a modification of an existing approved protocol – otherwise known as a "protocol variation". A protocol variation may be clinically required when:

- Treatment of a rare cancer where evidence for 'standard' systemic cancer therapy is very limited or non-existent.
- Where new evidence for a cancer therapy protocol becomes available prior to submission to SAHCDC for consideration of adding to the SA Health Cancer Therapy Approved Protocol Register
- Where a patient is unable to tolerate 'standard' systemic cancer therapy and the chosen alternative is not a recognised standard
- Where one systemic cancer therapy in an approved protocol is to be substituted for another in the therapeutic class
- Upfront omission of a systemic cancer therapy from approved protocol
    - Unless the intent is to withhold a medication for initial cycle(s) while a patient regains fitness to proceed e.g. recovers from surgery (no SPU required)
- Additional cycles of treatment beyond the number of cycles listed in the approved protocol.
- Patient has already received maximum number of lines of standard systemic cancer therapy or has not responded to standard treatment.

What is the process for accessing non-standard cancer therapy protocols?

If the required protocol or desensitisation schedule is not listed on the SA Health Approved Cancer Therapy Protocol Register, then a Single Patient Use protocol request form must be completed and submitted.

The clinicians

- Complete a Single Patient Use (SPU) protocol request form
    - If the application is completed by a clinician other than the treating consultant, the form and supporting evidence for protocol use (e.g. abstract, conference papers, and published articles) must be forwarded to the treating consultant.

- Treating consultant
    - Completes the SPU application or reviews the SPU form detail and supporting evidence for protocol use (e.g. abstract, conference papers, and published articles)
    - Signs and dates the form to indicate their approval of the SPU protocol details.
    - Forwards the form to a nominated consultant(s) with expertise in the therapeutic area, as well as a clinician that is a SAHCDC member.
- The consultant with tumour expertise
    - Reviews the SPU form and evidence.
    - If in agreement that the protocol is suitable, completes and signs the authorisation section of the form or e-mails the clinician of their approval.
    - Once all authorisation sections of the form have been completed, the patient may be treated.
    - The SAHCDC consultant
        - Reviews the SPU form and evidence.
        - If in agreement that the protocol is suitable, completes and signs the authorisation section of the form or e-mails the clinician of their approval.
        - Once all authorisation sections of the form have been completed, the patient may be treated.

- Forward the completed ‘Single Patient Use’ protocol request from, supporting evidence and any email authorisation to: SAHCDC generic email

The SAHCDC pharmacist:

- Reviews the request for completeness and provides the authorised SPU protocol request form to the SA Pharmacy Cancer Medication Management Team (iQemo Clinical Support Team) for building into a prescribing tool (within 1 business day).
- Records the SPU protocol details including evidence provided and authorising clinicians.
- Provides a monthly report to SAHCDC on SPU requests and protocols recommended for development, noting:
    - Any prescriber indication of likely further use or changes to medication availability (e.g. PBAC recommendations)
    - Previous SPU requests for the same non-standard protocol within a 12-month period

The SAHCDC members:

- Consider the need for new protocol development or addition of a variation to an existing protocol on the SA Health Approved Cancer Therapy Protocol Register to align with recent evidence or to support local practice.
- If members agree that a protocol or a protocol variation are required, the tumour group will be contacted and requested to progress the development of a new protocol/variation

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When is a Single patient Use (SPU) form not required?

A SPU form is not required to be completed in the following circumstances:

- When the protocol or desensitisation schedule is listed on the SA Health Approved Cancer Therapy Protocol Register
    - All dose and schedule options included in the approved protocol are SAHCDC endorsed for use in SA Health Hospitals
    - If the prescription is not/not yet available for prescribing in iQemo
- When a prescriber wishes to alter only pre- or supportive medications in an approved protocol
- When the protocol is included in an SAHCDC or SA Health guideline detailing exemptions (e.g. scheduling changes due to COVID-19 pandemic)
- When an individual patient requires a dose reduction of one or more drugs in a standard protocol due to clinical reasons, e.g. reduced renal/liver function, drug toxicity, previous treatment, co-morbidities.
- When an individual patient requires complete removal of a drug from a standard protocol for subsequent cycles due to clinical reasons.

What if a protocol is not available in the iQemo prescribing system?

- If the protocol or desensitisation schedule is available on the register
    - Contact the iQemo Clinical Support Team for urgent build (streamline process under development)
- If the protocol or desensitisation schedule is NOT available on the register
    - Clinician is to submit a Single Patient Use request form

What if a non-standard protocol is required for multiple patients?

Should a clinician wish to make protocol changes on a routine basis (i.e. not single patient use), then a systemic cancer therapy protocol should be developed and submitted through the New or Revised Systemic Cancer Therapy Protocol Registration – Application Form

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Examples of protocol variations

Variation sought	Classification	Escalation pathway
Dose rounding (e.g. <5% to nearest measurable dose per SA Pharmacy Manufacturing Service)	Operational requirement	> SPU form not required.
Dose reduction due to patient's clinical condition / organ function e.g. 25% reduction due to reduced creatinine clearance	Permitted within protocol intent. Note: clinically appropriate dose reduction may vary from the % dose reduction listed on the approved protocol	> SPU form not required. > Site based process to be followed e.g. peer review for curative intent. > Rationale must be documented in patient medical record and in electronic prescribing system (iQemo)
Substitution of supportive care medication or anti-emetics e.g. change from palonosetron IV to netupitant/palonosetron PO (Akynzeo®)	Permitted within protocol intent	> SPU form not required. > See SA Medicines Formulary and local guidelines. > Supportive therapies e.g. antiemetics, premedications, etc can be substituted to reflect SA Medicines Formulary listings. > Antiemetics in eviQ protocols are based on national and international guidelines. These are defaults only and may be substituted to reflect local guidelines and SA Medicines Formulary listings
Delay of subsequent cycle or extension of cycle duration due to patient's clinical condition/response to previous cycle e.g. azacitidine with venetoclax changing from 28-day cycle to 35-day cycle	Permitted within protocol intent	> SPU form not required. > Clinician to complete streamline process for iQemo build (under development) > Rationale must be documented in patient medical record and in electronic prescribing system (iQemo)
Increased number of cycles e.g. carboplatin / etoposide continued beyond 4 cycles	**Minor Variation**	> SPU form not required. > Clinician to complete streamline process for iQemo build (under development) > Rationale must be documented in patient medical record and in electronic prescribing system

Upfront dose reduction for patient clinical factors e.g. frailty (or other clinical condition not described in treatment plan or dose modification section of protocol)	**Minor Variation**	> SPU form not required. > Rationale must be documented in patient medical record and in electronic prescribing system (iQemo) > Scheduled monthly report to be built in iQemo for SAHCDC
Upfront withholding of a cancer therapy due temporary patient factors with intention to start drug at a later cycle e.g. withholding bevacizumab in FOLFOX bevacizumab protocol for initial cycles	**Minor variation**	> SPU form not required. > Rationale must be documented in patient medical record and in electronic prescribing system (iQemo) > Scheduled monthly report to be built in iQemo for SAHCDC
Upfront removal of a cancer therapy agent from a protocol	**Variation - New or unapproved protocol**	> Clinician to complete SPU Form > Rationale to be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation
Dose reduction without individual patient rationale e.g. consultant choice	**Variation - New or unapproved protocol**	> Clinician to complete SPU Form > Rationale must be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with monthly report of variation
Change of route of administration of cancer therapy	**Variation - New or unapproved protocol**	> Clinician to complete SPU Form > Confirm product availability with pharmacy service. > Rationale must be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation

Addition of extra systemic cancer therapy agent e.g. addition of targeted therapy to an approved chemotherapy protocol	**Variation - New or unapproved protocol**	> Clinician to complete SPU Form > Rationale to be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation
Compressed dosing frequency to intensify therapy e.g. changing cycle frequency from 21 days to every 14 days	**Variation - new or unapproved protocol**	> Clinician to complete SPU Form > Rationale to be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation
Upfront change in dose frequency to de-intensify therapy e.g. upfront change in dose frequency from 14 days to every 21 days	**Variation - new or unapproved protocol**	> Clinician to complete SPU Form > Rationale must be documented in patient medical record and in electronic prescribing system > iQemo to provide SAHCDC with regular report of variation
Substitution of systemic cancer therapy agent e.g. vincristine changed to vinblastine	**Variation - new or unapproved protocol**	> Clinician to complete SPU Form > Rationale must be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation
Upfront changes to treatment days e.g. Carboplatin + Gemcitabine (Day 8 Carboplatin)	**Variation - new or unapproved protocol**	> Clinician to complete SPU Form > Rationale must be documented in patient medical record and in electronic prescribing system. > iQemo to provide SAHCDC with regular report of variation

For more information

Single Patient Use (SPU) Protocol Requests FAQ
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