Governing requirements for a hospital based SCIg program

Quality Assurance

The hospital must have in place policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards, particularly Standards 1 and 7.

Clinical oversight

The hospital must have a recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist.

The hospital based SCIg program must provide ongoing clinical oversight and support for participating patients. This may include community nursing, hospital in the home or contact persons for both routine and emergency support as required.

The responsible clinician must consider patient suitability for the self-management and administration of SCIg to ensure appropriate management and use of SCIg product.

Equipment and facilities

The hospital based SCIg program must ensure that patients have access to all necessary equipment and consumables to administer the product, at no additional cost to patients.

Education and training

The hospital based SCIg program must provide education and training for staff and patients to ensure the appropriate management and use of SCIg, including for transport, storage, use of equipment and infusion techniques.

Regular review

Regular review to assess clinical benefit of treatment for ongoing therapy should be conducted at periods specified by the responsible clinician in line with the *Criteria for Use*. Patients should be encouraged to maintain a diary to record SCIg product use and any adverse reactions, as well as collection and management of product as an aid for the clinician at the assessment.

Supply of product

During this initial phase of implementation, orders for SCIg for authorised patients must be patient-specific orders through BloodNet (or alternative arrangement if necessary). The amount of SCIg supplied to a patient should not exceed more than is required for treatment for one month with a number of repeats up to 6 months, as determined by the prescriber. Dispensing of SCIg product to patients must be in accordance with relevant state/territory legal requirements.

Reporting unused, discarded, spoilt/broken product

Patients supplied with SCIg will be expected to report details of unused, discarded or spoilt/broken product to the hospital, to be reported by the hospital through BloodNet (or alternative arrangement if necessary). This, and other information relevant for authorisation of requests collected by the Blood Service, will be reported to the NBA to assist with supply reconciliation and planning.