NATIONAL BLOOD AUTHORITY
AUSTRALIA

Frequently Asked Questions: Subcutaneous Immunoglobulin

For Patients and Support Team

What is subcutaneous immunoglobulin (SCIg)?

Immunoglobulin (Ig) products are blood-derived treatments used for various medical conditions. They contain antibodies that your body's immune system naturally produces to fight infections and diseases.

Immunoglobulin can be given in two ways:

- **Intravenously (IVIg)** - through a vein
- **Subcutaneously (SCIg)** - under the skin

If SCIg is suitable for your condition, you'll receive training to administer this treatment yourself at home. This approach gives you greater independence and flexibility in managing your treatment.

How do I get access to SCIg?

Immunoglobulin is a valuable blood product that provides significant therapeutic benefits to many patients. However, due to its high cost and limited supply in Australia, access to government-funded Ig is carefully managed through strict governance processes.

The approval process:

- The National Blood Authority (NBA) manages the National Ig Governance Program
- Your condition must meet the criteria outlined in "The Criteria for the clinical use of immunoglobulin in Australia"
- These criteria are available at https://www.criteria.blood.gov.au/

Getting started:

- Your specialist doctor will determine if your diagnosis qualifies under the Criteria
- They will arrange approvals and product access through the online blood sector system
- You and your specialist doctor will decide together if this treatment is right for you
- Your specialist doctor will refer you to a SCIg program for training and ongoing support

How do I use SCIg?

SCIg is administered by infusing the medication into subcutaneous tissue (the layer just beneath your skin) using a small needle.

Training and support:

- A SCIg nurse will provide comprehensive training on the administration process
- You'll join a SCIg program that offers ongoing education and support
- Once you've mastered the technique, you can perform treatments in the comfort of your home

Will my SCIg treatment change?

Your specialist doctor will schedule regular appointments to monitor your treatment progress.

Possible changes may include:

- **Temporary discontinuation** - to assess treatment effectiveness
- **Permanent discontinuation** - if treatment is no longer necessary
- **Switch to hospital-based IVIg** - if you experience difficulties with self-administration

It's important to discuss any concerns with your specialist doctor to determine the best treatment approach for your specific situation.

How much SCIg can I collect?

- **Initial supply:** One month of SCIg medication
- **Ongoing supply:** Up to two months' supply, as per national policy

If clinically appropriate, you may receive repeat prescriptions without seeing your specialist doctor between regular review appointments. However, your specialist doctor will conduct periodic reviews to assess your response to treatment, which may result in prescription adjustments.

Where will I collect my SCIg?

SCIg will be available for collection at one of these locations:

- Hospital pathology department
- Hospital pharmacy
- Participating community pharmacy

Your SCIg nurse and specialist doctor will advise which options are available to you.

How do I keep track of my treatments?

Each SCIg program provides documentation methods to record your infusion details. This may include:

- Treatment diaries
- Mobile phone apps
- Other tracking systems

Your SCIg nurse will teach you the specific documentation process used by your program.

What if I cannot use the SCIg (e.g., breakage/not suitable)?

Before each infusion:

- Your SCIg nurse will teach you how to inspect the medication
- Always check the product before administration

If the product cannot be used:

- Record the reason in your provided documentation
- Contact your SCIg nurse immediately
- They will help resolve the issue and arrange a replacement

How do I store my SCIg product?

Each SCIg product comes with specific storage instructions in the Product Information sheet. Always refer to this documentation for proper storage requirements.

What happens if my SCIg product is left out of the fridge or my fridge breaks down?

Different SCIg products respond differently to temperature changes. Always consult the Product Information sheet included with your specific medication for guidance on what to do if refrigeration is interrupted.

After infusion, what do I do with my needles, used vials and other waste?

Discard needles and used vials into a sharps bin. Any general rubbish can go in the household bin. Your SCIg nurse or program will provide you with additional guidance on waste disposal.

For Health Professionals

Which patients can access SCIg under the National Blood Supply arrangements?

Patients must meet eligibility criteria as detailed in "The Criteria for the clinical use of immunoglobulin in Australia," available at https://www.criteria.blood.gov.au/

How do I gain access to SCIg for my patients?

Access to SCIg products under the National Blood Agreement is provided through a structured assurance framework.

Patient eligibility requirements:

- Medical condition with SCIg support cited in the Criteria (see current list at https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig)
- Patient must be under the care of a clinical medical specialist within a healthcare facility participating in the National SCIg Program

Healthcare facility requirements:

- Must establish capability and capacity to manage a SCIg program
- Must provide access to necessary resources
- Must take full accountability to use the product within the governing requirements
- No cost to patients

For detailed requirements, visit: https://www.blood.gov.au/blood-products/immunoglobulin-products/subcutaneous-immunoglobulin-scig#accessing-scig

Authorisation process: All patient-specific authorisation requests must be submitted through the blood sector systems (BloodSTAR), clearly stating that it is a SCIg product.

How do I order and dispense SCIg?

Designated Dispensers: Designated areas (e.g. pharmacy and pathology) within a healthcare facility or a community pharmacy who have ordering and inventory management responsibility for Ig can order and dispense these products. In BloodSTAR, this is referred to as the "Dispenser."

Dispenser requirements:

- Management competencies appropriate for high-cost blood-derived products
- Appropriate facilities and endorsement
- Compliance with local legislation such as Schedule 4 poisons regulations related to the product
- Compliance with the requirements of Lifeblood, healthcare facility pathology and pharmacy policies and procedures

Dispenser responsibilities:

- Product ordering through BloodNET (stock orders or transfers between facilities)
- Dispensing in accordance with access arrangements
- Following guidelines in Module 2: Managing Intravenous and Subcutaneous Immunoglobulin Inventory of the National policy: Access to government funded Ig products in Australia

Key requirements:

- inventory must not exceed one month's supply of IVIg or two months' supply of SCIg
- only issue government-funded Ig products with approved BloodSTAR authorisation
- regularly reconcile dispense records with authorisations
- record all dispenses in BloodNET within 14 days
- failure to record appropriately may result in direct invoicing for full product cost.

Is this treatment limited to public institutions?

No. Both public and private healthcare facilities with SCIg programs can order SCIg for their patients.

What products are available? What vial sizes are available?

The current list of available products, including vial sizes and supplier information, is available at: https://www.blood.gov.au/blood-products/national-product-price-list