Factsheet for Healthcare Professionals
Pharmaceutical Benefits Scheme – New Biosimilar INSULIN GLARGINE

Semglee® is a new brand of insulin glargine listed on the Pharmaceutical Benefits Scheme (PBS) on 1 October 2019. It is biosimilar to the reference biological medicine Lantus®, and is regarded as equivalent on the PBS (‘a’-flagged) to the Lantus SoloStar® brand presentation for the purposes of pharmacy substitution.

Semglee® has been assessed by the Therapeutic Goods Administration (TGA) on the basis of comparability and clinical studies to be highly similar to Lantus®. This means Semglee® and Lantus® provide the same health outcomes and are as safe and effective as each other.

What is insulin glargine?
Insulin glargine is a long-acting insulin used to treat diabetes mellitus. It is a recombinant human insulin analogue produced by DNA technology.

Insulin glargine is supplied on the PBS under the General Schedule (s85).

Semglee® and Lantus SoloStar® are dosed the same and are available as a pre-filled disposable pen presentation (100 units per mL).

Refer to the Schedule of Pharmaceutical Benefits, available online, in PDF and in prescribing software, for detailed information on the PBS prescribing restrictions.

What is a biological medicine?
Biological medicines, including biosimilars, contain active substances derived from living cells or organisms. Compared to synthetic chemical medicines, biological medicines are more complex and have an inherent degree of minor variability in the production process. This means no two batches of a biological medicine (even from the same manufacturer) are ever exactly the same.

What is a biosimilar medicine?
Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine.

Biosimilar medicines are designed and engineered to be as similar as possible to the reference biological medicine. There may be minor differences (known as molecular microheterogeneity) due to natural variability and the more complex manufacturing processes required for biological medicines. Importantly, these minor differences do not affect the safety, quality or effectiveness of the biosimilar medicine.

For a biosimilar medicine to be approved, the structural variability of the biosimilar medicine and the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar.

Insulin glargine and PBS brand substitution
The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Semglee® be listed on the PBS as a substitutable biosimilar of the Lantus SoloStar®
brand of insulin glargine, which is related to the reference brand Lantus®. Both Semglee® and Lantus SoloStar® are available as pre-filled disposable pen devices.

When PBS brands are listed as substitutable with each other, the pharmacist may dispense either brand, provided the prescriber has not indicated ‘brand substitution not permitted’, and they have consulted with and have permission from the patient.

**Who chooses whether the biosimilar brand is used?**
The choice of brand is with the prescriber in consultation with the patient. Specific patient requirements will remain for discussion between a patient and treating clinician.

Prescribers are encouraged to discuss biosimilar medicines with patients. See “How do I talk to patients about biosimilar medicines?” in the ‘Information for health care professionals’ FAQs on the Department of Health website.

**Why are biosimilar medicines important?**
The PBS is a key element of Australia’s National Medicines Policy which aims to deliver timely access to medicines at a cost that individuals and the community can afford.

Increasing costs associated with very expensive new health technologies, and the increasing prevalence of chronic conditions, is putting pressure on the sustainability of the PBS. Seven of the ten most expensive medicines subsidised by the PBS in 2017-18 were biological medicines with a combined cost of $1.53 billion.

Increasing use of biosimilar medicines is expected to deliver significant savings, due to price competition in the market. These savings can be reinvested into other areas of the Australian health system, expand access to biologic medicines as they become more affordable, and reduce the risk of medicine shortages.

**Where can I find more Information?**
The biosimilars page on the [Australian Government Department of Health website](https://www.gov.au)
The biosimilars regulation page on the [Therapeutic Goods Administration website](https://www.tga.gov.au)
The PBAC Public Summary Document for Semglee® on the [PBS website](https://www.pbs.gov.au)
The [Biosimilar Education Hub](https://www.biosimilareducationhub.org.au)