NSW Medicines Formulary Information 02/23

Issue date: 02/08/2023

Biologic and biosimilar medicines

Summary

The NSW Medicines Formulary Committee supports the use of biosimilars and recognises that their use supports better value healthcare.

The use of biosimilar medicines is expected to deliver significant savings, which can be reinvested into other areas of the NSW Health system and expand access to biologic medicines as they become more cost-effective.

What are biologic and biosimilar medicines?

A biologic is a medicine whose active substance has a large, complex, molecular structure, which can only be made or derived from a living organism (e.g., bacterium, yeast, human/animal cell line).[1,2] Because of the variability of biological systems in the manufacturing process, no two batches of a biological medicine, are ever exactly the same (even from the same manufacturer).[1]

Biologic medicines vary in complexity from small, highly purified proteins to more complex structures such as monoclonal antibodies.[2] Biologic medicines include:

- peptide hormones and glycoproteins (e.g., insulin, human growth hormone, follitropin, filgrastim)
- immunological medicines (e.g., monoclonal antibodies and vaccines)
- other biological products, including polysaccharides (e.g. low molecular weight heparins).[2]

The first registered brand of a biologic medicine is often referred to as the 'reference biologic'. It may also be referred to as the reference brand or the originator/innovator biologic.[1,2]

Biosimilar medicines are highly similar versions of the reference biologic. They have no clinically meaningful differences and are considered therapeutically equivalent to the reference biologic medicine.[1] Biosimilar medicines are approved by Therapeutic Goods Administration (TGA) after assessment of:

- physicochemical, biological, and immunological characteristics
- efficacy
- safety.

The TGA website provides a list of biosimilar medicines approved and their reference biologic. The Pharmaceutical Benefits Scheme (PBS) website provides a list of biologic medicines that are subsidised and the approved biosimilars for supply.

What are the benefits of biosimilar medicines?

The availability of biosimilars in Australia has significantly decreased the cost of individual biologic medicines and consequently has the potential to:

- improve cost-effectiveness
- improve economic efficiencies
- expand access to medicines via broader patient eligibility criteria or broadening of approved and/or subsidised indications.[2]

Are biologics and biosimilars included on the NSW Medicines Formulary?

The Formulary lists medicines approved for initiation in NSW Health inpatients and restrictions for their use (such as approved indications, patient criteria or prescriber requirements). Biologic medicines are included on the Formulary and are listed by their generic medicine name. The Formulary does not specify a specific biosimilar brand for use unless there is a clinical or safety need.

Initiation of biologics in NSW public hospitals and health services.

Treatment naïve patients are to be initiated with biosimilars that are listed on HealthShare NSW pharmaceutical contracts. Where no biosimilar medicine is contracted, local sites are responsible for determining the most cost-effective biosimilar(s) to stock and use.

Where the contracted biosimilar has been deemed clinically inappropriate for an individual patient, the use of an alternative biosimilar may be considered. Initiation of an alternative biosimilar is to be approved by the Drugs and Therapeutics Committee (DTC).

Patients on existing biologics in NSW Public hospitals and health services.

For patients that are receiving treatment with a non-contracted biosimilar, the local DTC can consider switching patients to a cost-effective biosimilar brand where:

- the biosimilar is deemed suitable for substitution by the TGA and/or PBS
- in consultation with the clinical teams, decision makers and other stakeholders
- the potential impact on medication safety and patients on long-term therapy has been considered
- there is a management plan for the switch to occur.[2]

This information has been developed based on information available from the Department of Health and Aged Care and/or Council of Australian Therapeutic Advisory Group websites.

References:

1. Australian Government Department of Health and Aged Care. Biosimilar Medicines Information Collection. Australian Government Department of Health and Aged Care, 2022.

2. Council of Australian Therapeutic Advisory Groups. Biologics and biosimilars best practice: Guiding principles for the governance of biologics and their biosimilars in Australian hospitals. CATAG, 2021.

Clinical Excellence Commission

Tel: 02 9269 5500 **Email:** CEC-MedicineFormulary@health.nsw.gov.au

Website: www.cec.health.nsw.gov.au

Review date: 08/24