Information for Healthcare Professionals
Pharmaceutical Benefits Scheme - Biosimilar ADALIMUMAB

The following biosimilar brands of adalimumab are listed on the Pharmaceutical Benefits Scheme (PBS):

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Date of PBS Listing</th>
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<tbody>
<tr>
<td>Amgevita®</td>
<td>1 April 2021</td>
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<tr>
<td>Hadlima®</td>
<td></td>
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<tr>
<td>Hyrimoz®</td>
<td></td>
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<tr>
<td>Idacio®</td>
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These brands have been assessed by the Therapeutic Goods Administration on the basis of comparability and clinical studies to be highly similar to the reference brand, Humira®. This means that Amgevita®, Hadlima®, Hyrimoz® and Idacio® provide the same health outcomes and are as safe and effective as each other and the reference brand Humira®.

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

Further information for prescribers and dispensers about the PBS listing changes for adalimumab from 1 April 2021 is also available on the PBS website.

Who chooses whether the biosimilar brand is used?
Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. Adalimumab is primarily supplied through community pharmacies, where the choice of which brand (biosimilar or reference) is supplied may be discussed between pharmacist and patient, with reference to the prescriber’s stated preference on the prescription. However, in cases where adalimumab is supplied in the hospital setting, the choice of brand generally used may be based on medicine purchasing decisions made by a clinician-led committee. Specific patient requirements will be discussed with the patient.

Prescribers and pharmacists 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 Australian Government Department of Health website.
Can PBS brands of adalimumab be substituted?
The Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Amgevita®, Hadlima®, Hyrimoz® and Idacio® be listed on the PBS as substitutable biosimilars of Humira®, the reference brand of adalimumab.

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

What is adalimumab?
Adalimumab is a biological medicine that is used to treat a range of conditions such as rheumatoid arthritis, juvenile idiopathic arthritis, chronic plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn disease, ulcerative colitis and hidradenitis suppurativa.

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.

Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine. Biosimilars 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. There must also be no clinically meaningful differences identified in clinical studies comparing the biosimilar and reference products.

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 2019-20 were biological medicines with a combined cost of $2.01 billion. The cost to Government for adalimumab alone in 2019-20 was $318.7 million.

Increasing the use of biosimilar medicines is expected to deliver significant reductions in the cost of the PBS, due to price competition in the market. This can improve the Government’s capacity to fund expanded access to biological 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.
The biosimilars regulation page on the Therapeutic Goods Administration website.
The PBAC Public Summary Document for Amgevita® on the PBS website.
The PBAC Public Summary Document for Hadlima® on the PBS website.
The PBAC Public Summary Document for Hyrimoz® on the PBS website.
The PBAC Public Summary Document for Idacio® on the PBS website.
The Biosimilar Education Hub.