Information for Consumers and Carers
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>
</tr>
</thead>
<tbody>
<tr>
<td>Amgevita®</td>
<td>1 April 2021</td>
</tr>
<tr>
<td>Hadlima®</td>
<td></td>
</tr>
<tr>
<td>Hyrimoz®</td>
<td></td>
</tr>
<tr>
<td>Idacio®</td>
<td></td>
</tr>
</tbody>
</table>

These brands have been assessed by the Therapeutic Goods Administration (TGA) 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®.

Medicines listed on the PBS are subsidised by the Commonwealth of Australia where they are priced above the PBS co-payment amount.

**Adalimumab and PBS brand substitution**

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Amgevita®, Hadlima®, Hyrimoz® and Idacio® be listed on the PBS as substitutable with Humira®, the reference brand of adalimumab.

When PBS brands are listed as substitutable the pharmacist can dispense any brand, with permission from the patient, unless otherwise directed by the prescriber.

**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. Your doctor can discuss with you the detailed requirements around prescribing adalimumab under the PBS.

Adalimumab is prescribed by specialists.

More information about this medicine is available by entering ‘adalimumab’ at the NPS MedicineWise Medicine Finder.

**What are biological and biosimilar medicines?**

Biological medicines, including biosimilars, contain substances made by living cells or organisms. They are more complex to make than synthetic chemical medicines.
A biosimilar medicine is a highly similar version of a reference biological medicine, which is invariably the first brand to market. Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines.

Biosimilar medicines have been tested and shown to be as safe and effective as the reference biological medicines.

Who chooses the brand?
In Australia, injections of adalimumab are given subcutaneously and can be given by the patient or carer.

It is up to you and your doctor to choose which biological medicine to use. You should discuss with your doctor which medicine is right for you.

Your doctor may decide to prescribe a particular brand of medicine. Your pharmacist might offer you the choice of brands – choosing a biosimilar brand is likely to contribute to competition that can drive the price of medicines down. However, your doctor can tick a box on the script to say that brand substitution is not permitted, if they think you should only take a particular brand.

In some cases adalimumab is supplied in the hospital setting. The choice of brand generally used in a hospital or clinic may be based on medicine purchasing decisions made by a doctor-led committee. Specific patient requirements will be discussed between a patient and their doctor.

Will I have the same health outcome no matter which brand of adalimumab I use?
Yes. The TGA approved the biosimilars Amgevita®, Hadlima®, Hyrimoz® and Idacio® because they were determined to be as safe and effective as the reference brand Humira® and to provide the same health outcomes.

Why are biosimilar medicines important?
The growing cost of new and innovative medicines, including biological medicines, continues to put pressure on the financial 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. The introduction of biosimilar medicines encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, improving the Government’s capacity to subsidise access to new and innovative treatments for seriously ill patients.

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 PBAC webpage of the PBS website.
The PBAC Public Summary Document for Hadlima® on the PBAC webpage of the PBS website.
The PBAC Public Summary Document for Hyrimoz® on the PBAC webpage of the PBS website.
The PBAC Public Summary Document for Idacio® on the PBAC webpage of the PBS website.
The Biosimilar Education Hub (for consumers and carers)