



New arrangements for migalastat (Galafold®) for treatment of Fabry Disease – Information for patients

Migalastat (Galafold®) for Fabry disease is moving to the Pharmaceutical Benefits Scheme (PBS)

From 1 September 2024, following a recommendation by the Pharmaceutical Benefits Advisory Committee, migalastat (Galafold®) will be available through the PBS, rather than the Life Saving Drugs Program (LSDP).

What does this mean for patients?

If you are an existing LSDP patient, you can continue to receive your treatment through the LSDP until you transition to the PBS.

You will need to arrange an appointment with your treating physician to discuss transitioning to the PBS from 1 September 2024. Transitional arrangements will be in place until 30 November 2024.

This means that there should be no disruption to your treatment.

The eligibility criteria for the PBS are similar to the eligibility criteria for the LSDP with some differences. If you are already receiving migalastat (Galafold®) through the LSDP, you will be eligible to keep accessing it through the PBS.

If you are a current LSDP patient receiving enzyme replacement therapy (ERT) for Fabry disease and wish to transition to migalastat (Galafold®), you should discuss this with your treating physician.

Who is eligible to be prescribed migalastat (Galafold®) through the PBS?

To be eligible for access to PBS-subsidised migalastat (Galafold®), you must:

- be an Australian resident and eligible for a Medicare card
- be under appropriate specialist medical care, and
- meet the required PBS criteria.

The PBS access criteria are similar to the previous LSDP access criteria, but patients will no longer be required to complete 12 months of ERT before being eligible for PBS-subsidised access to migalastat (Galafold®).

How do I access migalastat (Galafold®) through the PBS?

Migalastat (Galafold®) will be listed on the PBS as an Authority Required benefit. This means that your treating physician will need to have your prescription approved by Services Australia. Generally, it takes 1 to 2 weeks for this process and for you to receive your approved Authority prescription.

How often do I need to get a prescription?

If you are being treated with migalastat (Galafold®) through the PBS, your treating physician can request quantity and repeats to allow up to 6 months treatment per prescription. However, this may vary from patient to patient depending on how often your treating physician may wish to review your treatment.

Will this change affect my access to treatment?

There should be no impact to your access to treatment. However, to ensure a smooth transition from LSDP to PBS supply, you should schedule an appointment with your treating physician as soon as possible on or after 1 September 2024. If you are an existing LSDP patient, we will continue to supply your treatment through the LSDP for up to 3 months (to 30 November 2024) until you transition to the PBS.

If you are a new patient seeking access to migalastat (Galafold®), you should discuss this with your treating physician. If you are eligible, your treating physician can arrange a PBS prescription for you on or after 1 September 2024.

I'm a current migalastat (Galafold®) patient. When does my LSDP supply cease?

If you are currently accessing migalastat (Galafold®) for Fabry disease through the LSDP, you will have 3 months (from 1 September to 30 November 2024) to arrange your transition to the PBS through your treating physician. Supply through the LSDP will cease from 1 December 2024 (or from the date of your transition to the PBS arrangements, whichever comes first).

Is there a change to the cost?

Yes. If you are prescribed migalastat (Galafold®) through the PBS, you will be required to pay a co-payment each time your prescription is dispensed. Current co-payments (in 2024) are \$31.60 for general patients, or \$7.70 if you have a concession card. This also means that your PBS prescriptions for migalastat (Galafold®) will be counted towards your or your family's [PBS Safety Net](#).

When you reach the Safety Net threshold, you may pay the concessional co-payment for your medicines under the PBS for the rest of that calendar year if you are a general patient. Also, if you are a concessional patient, you may receive your medicines under the PBS free of charge for the rest of that calendar year.

Will my local pharmacy stock these medicines?

Yes. Approved pharmacists are able to dispense and supply all pharmaceutical benefits including migalastat (Galafold®).

Some pharmacies may only stock certain medicines as needed or on an individual patient basis. Your pharmacy may need to order migalastat (Galafold®) for you. We recommend that you contact your chosen pharmacy to confirm availability and ongoing supply arrangements.

I currently receive enzyme replacement therapy for Fabry disease through the LSDP. Are these medicines also moving to the PBS?

There are no changes to arrangements for accessing other Fabry disease medicines on the LSDP. Agalsidase alfa (Replagal®) and agalsidase beta (Fabrazyme®) will remain available through normal LSDP arrangements.