SCHEDULE OF PHARMACEUTICAL BENEFITS EFFECTIVE 1 SEPTEMBER 2024 ERRATA

(1) This Erratum corrects the clinical criteria for new Migalastat item 14573B in the 1 September 2024 Schedule.

General Pharmaceutical Benefits

▪ MIGALASTAT

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; OR
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; OR
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiepileptic medications for peripheral neuropathy; OR
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; OR
- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug, **AND**
- Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2 prior to commencing treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Migalastat 123mg capsule, 14

14573B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
MP	1	5		28076.45	31.60	Galafold, [Amicus Therapeutics]

(2) This Erratum corrects the DPMQ for CLAVULIN-125F (GlaxoSmithKline, Canada) brand of **Amoxicillin with clavulanic acid** in the 1 September 2024 Schedule.

▪ AMOXICILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

Note Pharmaceutical benefits that have the brand CLAVULIN-125F (GlaxoSmithKline, Canada) may be substituted for pharmaceutical benefits that have the brand Curam in the case of a shortage.

Restricted benefit
Infection where resistance to amoxicillin is suspected

Restricted benefit
Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

5009P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	#19.53	21.40	[a] Curam [SZ]

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL

14568R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $		Brand Name and Manufacturer
DP	‡1	..	..	#64.92	31.60	a	CLAVULIN-125F (GlaxoSmithKline, Canada) [DZ]

▪ AMOXICILLIN + CLAVULANIC ACID

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Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

1892N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $		Brand Name and Manufacturer
NP	‡1	1	..	#19.53	21.40	a	Curam [SZ]

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL

14569T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $		Brand Name and Manufacturer
NP	‡1	1	..	#64.92	31.60	a	CLAVULIN-125F (GlaxoSmithKline, Canada) [DZ]