

6.21 TETRACOSACTRIN

Compound depot injection 1 mg in 1 mL, Synacthen Depot 1 mg/1 mL[®], Link Medical Products Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requests to amend the current unrestricted benefit to a Restricted Benefit for use in patients with hypsarrhythmia and/or infantile spasms.

2 Requested listing

- 2.1 The submission requested the following changes to the existing listing:

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Proprietary Manufacturer	Name and Manufacturer
TETRACOSACTRIN tetracosactrin 1 mg/mL modified released injection, 1 mL ampoule	5	5	Synacthen Depot 1 mg/1 mL	Link Healthcare Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Hypsarrhythmia
PBS Indication:	Hypsarrhythmia
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

Name, Restriction, Manner of administration and form	Max. Qty	Nº. of Rpts	Proprietary Name and Manufacturer
TETRACOSACTRIN tetracosactrin 1 mg/mL modified released injection, 1 mL ampoule	5	5	Synacthen Link Healthcare Depot 1 Pty Ltd mg/1 mL

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Infantile spasms
PBS Indication:	Infantile spasms
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

3 Background

- 3.1 Tetracosactrin is TGA registered for acute exacerbations in patients suffering from multiple sclerosis, and hysarrhythmia, and or infantile spasms.

4 Current Situation

- 4.1 Tetracosactrin is currently listed as an unrestricted PBS benefit on the General Schedule.
- 4.2 Tetracosactrin is a low volume product with an average of five PBS prescriptions per month (Source: PBS data 1 July 2015 to 30 June 2017)

Estimated PBS usage & financial implications

- 4.3 The minor submission estimated there to be no financial implications to the PBS.

Sponsor hearing

- 4.4 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.5 The PBAC noted that no consumer comments were received for this item.

5 PBAC Outcome

- 5.1 The PBAC recommended the amendment of the current unrestricted benefit to a Restricted Benefit for use in patients with hysarrhythmia and/or infantile spasms, noting this is a small patient group.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name	Manufacturer
TETRACOSACTRIN tetracosactrin 1 mg/mL modified released injection, 1 mL ampoule	5	5	Synacthen Depot 1 mg/1 mL	Link Healthcare Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Hypsarrhythmia
PBS Indication:	Hypsarrhythmia
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name	Manufacturer
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Condition:	Infantile spasms
PBS Indication:	Infantile spasms
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.