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. 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
   1. The submission requested the following changes to the existing listing:

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| **Name, Restriction,**  **Manner of administration and form** | | **Max.**  **Qty** | **№.of**  **Rpts** |  | **Proprietary 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:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | | |
| **Condition:** | Hypsarrhythmia | | | | | | |
| **PBS Indication:** | Hypsarrhythmia | | | | | | |
| **Restriction Level / Method:** | Restricted benefit | | | | | | |

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| **Name, Restriction,**  **Manner of administration and form** | | **Max.**  **Qty** | **№.of**  **Rpts** |  | **Proprietary Name and Manufacturer** | | | |
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|  | | | | | | |
| Category /  Program | GENERAL – General Schedule (Code GE) | | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | | |
| **Condition:** | Infantile spasms | | | | | | |
| **PBS Indication:** | Infantile spasms | | | | | | |
| **Restriction Level / Method:** | Restricted benefit | | | | | | |

1. Background
   1. Tetracosactrin is TGA registered for acute exacerbations in patients suffering from multiple sclerosis, and hypsarrhythmia, and or infantile spasms.
2. Current Situation
   1. Tetracosactrin is currently listed as an unrestricted PBS benefit on the General Schedule.
   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

* 1. The minor submission estimated there to be no financial implications to the PBS.

## Sponsor hearing

* 1. There was no hearing for this item as it was a minor submission.

## Consumer comments

* 1. The PBAC noted that no consumer comments were received for this item.

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

**Outcome:**

Recommended

1. **Recommended listing**
   1. Amend existing listing as follows:

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| **Name, Restriction,**  **Manner of administration and form** | | **Max.**  **Qty** | **№.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:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | | |
| **Condition:** | Hypsarrhythmia | | | | | | |
| **PBS Indication:** | Hypsarrhythmia | | | | | | |
| **Restriction Level / Method:** | Restricted benefit | | | | | | |

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| **Name, Restriction,**  **Manner of administration and form** | | **Max.**  **Qty** | **№.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 |  | | |
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| Category / Program | GENERAL – General Schedule (Code GE) | | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | | |
| **Condition:** | Infantile spasms | | | | | | |
| **PBS Indication:** | Infantile spasms | | | | | | |
| **Restriction Level / Method:** | Restricted benefit | | | | | | |

1. **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.

1. **Sponsor’s Comment**

The sponsor had no comment.