

## **5.16 PANCREATIC EXTRACT,**

**Capsule (containing enteric coated minimicrospheres)  
providing not less than 20,000 BP units of lipase  
activity,**

**Capsule (containing enteric coated minimicrospheres)  
providing not less than 35,000 BP units of lipase  
activity,**

**Creon<sup>®</sup>,**

**Mylan Health Pty Ltd**

### **1 Purpose of Application**

- 1.1 The minor submission sought a General Schedule listing for two new strengths of pancreatic extract (Creon<sup>®</sup>), 20,000 and 35,000 lipase BP units modified release capsules (herein referred to as Creon 20,000 and 35,000), under the same conditions as the currently PBS-listed Creon products.

### **2 Background**

#### ***Previous PBAC consideration***

- 2.1 Creon 20,000 and 35,000 have not been previously considered by the PBAC.

#### ***Current situation***

- 2.2 Creon Micro 5000 granules, Creon 10,000, 25,000 and 40,000 lipase BP units modified release capsules (herein referred to as Creon 10,000, 25,000 and 40,000) are listed on the PBS under the General Schedule as unrestricted benefits and restricted benefit for treatment of cystic fibrosis (which provides a higher number of repeats).

#### ***Registration status***

- 2.3 Creon 20,000 and 35,000 were TGA registered on 21 April 2020. The registered indication is the same as for the currently listed Creon products.
- 2.4 The current TGA indication for Creon is for pancreatic enzyme replacement in paediatric and adult patients with Pancreatic Exocrine Insufficiency (PEI). PEI is often associated with, but not limited to: cystic fibrosis; chronic pancreatitis; pancreatic surgery; gastrointestinal bypass surgery (e.g. Bilroth II gastroenterostomy); and ductal obstruction of the pancreas or common bile duct (e.g. from neoplasm).

### 3 Requested listing

3.1 The submission requested Creon 20,000 and 35,000 be made available through the PBS under the same circumstances as the currently PBS-listed Creon products.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PANCREATIC EXTRACT					
pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	5453B	3	3	10	Creon Micro
pancreatic extract 10 000 units modified release capsule, 100	8020D	5	500	10	Creon 10,000 Micro
pancreatic extract 20 000 units modified release capsule, 100	NEW	2	200	10	Creon 20,000
pancreatic extract 25 000 units modified release capsule, 100	8021E	2	200	10	Creon 25,000 Micro
pancreatic extract 35 000 units modified release capsule, 100	NEW	2	200	10	Creon 35,000
pancreatic extract 40 000 units modified release capsule, 100	9412J	2	200	10	Creon 40,000 Micro

**Benefit Type: 38023 – Unrestricted benefit**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners - CTO
<b>Restriction Type:</b> <input checked="" type="checkbox"/> Unrestricted benefit
<b>Prescribing Instructions:</b> <b>Continuing Therapy Only:</b>  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner Further information can be found in the Explanatory Notes for Nurse Practitioners.

Public Summary Document – November 2020 PBAC Meeting

Restriction Summary 5779 / Treatment of Concept: 5779

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PANCREATIC EXTRACT					
pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	5454C	3	3	21	Creon Micro
pancreatic extract 10 000 units modified release capsule, 100	9226N	5	500	21	Creon 10,000
pancreatic extract 20 000 units modified release capsule, 100	NEW	2	200	21	Creon 20,000
pancreatic extract 25 000 units modified release capsule, 100	9227P	2	200	21	Creon 25,000
pancreatic extract 35 000 units modified release capsule, 100	NEW	2	200	21	Creon 35,000
pancreatic extract 40 000 units modified release capsule, 100	9413K	2	200	21	Creon 40,000

Restriction Summary 5779 / Treatment of Concept: 5779

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
<b>Restriction Type:</b> <input checked="" type="checkbox"/> Restricted benefit
<b>Indication:</b> Cystic fibrosis
<b>Clinical criteria:</b>
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.
<b>Prescribing Instructions:</b> No increase in the maximum quantity or number of units may be authorised.
<b>Prescribing Instructions:</b> No increase in the maximum number of repeats may be authorised.

## 4 Comparator

- 4.1 The minor submission nominated Creon capsules as the comparator. This was appropriate.

## 5 Consideration of the evidence

### *Sponsor hearing*

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

### *Consumer comments*

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

### *Clinical trials*

- 5.3 No clinical trials were presented in the submission.

### *Economic analysis*

- 5.4 There was no economic evaluation presented.
- 5.5 The submission's proposed approved ex-manufacturer price is \$38.82 for Creon 20,000 and \$67.93 for Creon 35,000, resulting in a dispensed price for maximum quantity of \$94.68 and \$160.39, respectively. The proposed price is based on the price

per unit of the currently listed Creon 25,000 units and 40,000 units (\$0.00001941) which is cheaper than the price per unit of the currently listed Creon 10,000 units (\$0.00002435).

***Drug cost/patient/year: \$2726.63***

- 5.6 The estimated drug cost/patient/per year would be \$2726.63, based on a maximum dosage of 80,000 units lipase per meal for an adult who eats four meals a day. Such patients will require 17 prescriptions per year of Creon 35,000 (DPMQ of \$160.39) (i.e. 80,000 units/meal \* 4 meals \* 365 days divided by 35,000 units \* 200 packs).
- 5.7 The actual cost will vary due to individual patient needs.

***Estimated PBS usage & financial implications***

- 5.8 The minor submission used a market-share approach to estimate the usage of the two new strengths of Creon. The submission stated that Creon 20,000 is most likely to replace a portion of the currently listed Creon 10,000, and Creon 35,000 is most likely to replace a portion of the currently listed Creon 10,000 and 25,000 strengths.
- 5.9 The submission claimed that the proposed listings are not expected to grow the market size for Creon, given the maturity and size of the current market.
- 5.10 The minor submission estimated a net save to the PBS of \$0 to <\$10 million in Year 6 of listing, with a total net save to the PBS of \$0 to <\$10 million over the first 6 years of listing. The estimated use and financial implications are summarised in the table below.

Public Summary Document – November 2020 PBAC Meeting

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of scripts dispensed <sup>a</sup>	█ <sup>1</sup>	█ <sup>2</sup>	█ <sup>3</sup>	█ <sup>4</sup>	█ <sup>5</sup>	█ <sup>5</sup>
<b>Estimated financial implications of new strengths of pancreatic extract (i.e. Creon 20,000 and 35,000)</b>						
Cost to PBS/RPBS	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>
Copayments	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>
Cost to PBS/RPBS less copayments	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>
<b>Estimated financial implications for currently listed strengths of pancreatic extract capsules (i.e. Creon 10,000, 25,000 and 40,000)</b>						
Cost to PBS/RPBS	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>
Copayments	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>	\$█ <sup>6</sup>
Cost to PBS/RPBS less copayments	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>	-\$█ <sup>6</sup>

<sup>a</sup> As estimated by the submission in Section 4 Utilisation and Cost Workbook.

Source: Section 4 Utilisation and Cost Workbook (Sheet 3b. Impact – proposed (pub), Sheet 4b. Impact – affected (pub), Sheet 5. Impact – net)

The redacted values correspond to the following ranges:

<sup>1</sup>10,000 to <20,000

<sup>2</sup>20,000 to <30,000

<sup>3</sup>30,000 to <40,000

<sup>4</sup>40,000 to <50,000

<sup>5</sup>50,000 to <60,000

<sup>6</sup>\$0 to <\$10 million

5.11 As a minor submission, the financial estimates have not been independently evaluated.

### Quality use of medicines

5.12 The submission claimed that the additional strengths of Creon would allow greater dosing flexibility and reduce pill burden for patients, which will ultimately lead to greater adherence and therefore improve clinical outcomes.

5.13 The submission stated that these additional listings of Creon would ensure quality use of medicines, in line with Australia’s National Medicines Policy, allowing clinicians to prescribe the right dose for use at the right time.

For more detail on PBAC’s views, see section 6 PBAC outcome.

## 6 PBAC Outcome

6.1 The PBAC recommended the listing of two new strengths of pancreatic extract (Creon®), 20,000 and 35,000 lipase BP units modified release capsules, under the same conditions as the currently PBS listed Creon products.

- 6.2 The PBAC considered that the new listings may reduce pill burden and lead to greater adherence and improve clinical outcomes.
- 6.3 The PBAC considered the proposed pricing of pancreatic extract on a price per unit of the currently listed Creon 25,000 units and 40,000 units to be appropriate, calculated at the ex-manufacturer price. The PBAC noted that this was cheaper than the price per unit of the currently listed Creon 10,000 units.
- 6.4 The PBAC noted that the submission stated that Creon 20,000 is most likely to replace a portion of the currently listed Creon 10,000, and Creon 35,000 is most likely to replace a portion of the currently listed Creon 10,000 and 25,000 strengths. The PBAC considered that there may be savings to the Government associated with the listing of Creon 25,000 and 40,000 units, due to the lower price per unit of the new strengths compared with Creon 10,000.
- 6.5 The PBAC advised that, because pancreatic extract 20,000 and 35,000 lipase BP units are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over currently listed forms of pancreatic extract, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **7 Recommended listing**

- 7.1 Add 2 new strengths (20,000 units & 35,000 units) to the existing strengths as follows:

*Public Summary Document – November 2020 PBAC Meeting*

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pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	5453B	3	3	10	Creon Micro
pancreatic extract 10 000 units modified release capsule, 100	8020D	5	500	10	Creon 10,000 Micro
<i>pancreatic extract 20 000 units modified release capsule, 100</i>	<i>NEW</i>	2	200	10	<i>Creon 20,000</i>
pancreatic extract 25 000 units modified release capsule, 100	8021E	2	200	10	Creon 25,000 Micro
<i>pancreatic extract 35 000 units modified release capsule, 100</i>	<i>NEW</i>	2	200	10	<i>Creon 35,000</i>
pancreatic extract 40 000 units modified release capsule, 100	9412J	2	200	10	Creon 40,000 Micro
<b>Benefit Type: 38023 – Unrestricted benefit – NO CHANGES</b>					
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners - CTO					
<b>Restriction Type:</b> <input checked="" type="checkbox"/> Unrestricted benefit					
<b>Prescribing Instructions:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner Further information can be found in the Explanatory Notes for Nurse Practitioners.					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PANCREATIC EXTRACT					
pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	5454C	3	3	21	Creon Micro
pancreatic extract 10 000 units modified release capsule, 100	9226N	5	500	21	Creon 10,000
<i>pancreatic extract 20 000 units modified release capsule, 100</i>	<i>NEW</i>	2	200	21	<i>Creon 20,000</i>
pancreatic extract 25 000 units modified release capsule, 100	9227P	2	200	21	Creon 25,000
<i>pancreatic extract 35 000 units modified release capsule, 100</i>	<i>NEW</i>	2	200	21	<i>Creon 35,000</i>
pancreatic extract 40 000 units modified release capsule, 100	9413K	2	200	21	Creon 40,000
<b>Restriction Summary 5779 / Treatment of Concept: 5779 – NO CHANGES</b>					
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
<b>Restriction Type:</b> <input checked="" type="checkbox"/> Restricted benefit					
<b>Indication:</b> Cystic fibrosis					
<b>Clinical criteria:</b>					
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.					
<b>Prescribing Instructions:</b> No increase in the maximum quantity or number of units may be authorised.					
<b>Prescribing Instructions:</b> No increase in the maximum number of repeats may be authorised.					

*This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.*

## **8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **9 Sponsor's Comment**

The sponsor had no comment.