

5.06 OPICAPONE, Capsule 50 mg, Ongentys[®], MAXX Pharma Pty Ltd.

1 Purpose of submission

- 1.1 The Category 2 submission requested a General Schedule Restricted Benefit listing for Parkinson disease as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.
- 1.2 Listing was requested on the basis of a cost-minimisation analysis versus entacapone.

Table 1: Key components of the clinical issue addressed by the submission (as stated in the submission)

Component	Description
Population	Levodopa-treated patients with Parkinson disease experiencing fluctuations in motor function due to end-of-dose effects
Intervention	Opicapone 50 mg capsules once daily
Comparator	Entacapone – 200 mg given with every dose of levodopa, 5 times per day
Outcomes	The primary efficacy outcome in the Phase III studies was the change in absolute OFF-time from baseline to the end of the Double-blind (DB) period.
Clinical claim	Opicapone met the non-inferiority criteria to Entacapone in absolute OFF-time reduction and achieved the minimal clinically important difference. The opicapone safety and tolerability profile was favourable compared to entacapone.

Source: Table 1.1, p11 of the submission.

2 Background

Registration status

- 2.1 Opicapone was TGA registered on 23 September 2020 for use as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson disease (PD) and end-of-dose motor fluctuations who cannot be stabilised on those combinations.
- 2.2 Opicapone is a peripheral, selective, and reversible catechol-o-methyl transferase (COMT) inhibitor that increases levodopa plasma levels when co-administered with levodopa.

For more detail on PBAC's view, see section 7 PBAC outcome.

3 Requested listing

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
Opicapone Capsules, 50mg, 30	1	5	\$171.67	Ongentys® Maxx Pharma Pty Ltd
Category/Program:	General Schedule			
Prescriber types	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners			
PBS indication:	Parkinson disease			
Treatment phase:	Initial and continuing			
Restriction:	<input checked="" type="checkbox"/> Restricted benefit			
Clinical criteria:	The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND Patient must be experiencing fluctuations in motor function due to end of dose effect			
Administrative advice	Continuing Therapy Only: 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.			

- 3.1 The requested restriction was identical to that for entacapone. Opicapone would be the second COMT-inhibitor on the PBS. The proposed restriction would not prevent simultaneous use of opicapone and entacapone. The proposed place in therapy of opicapone was to be an alternative therapy to entacapone where a COMT-inhibitor is indicated. The PBAC considered the simultaneous use of opicapone and entacapone was unlikely in practice.

4 Population and disease

- 4.1 The submission provided a summary of the burden of disease due to PD, including the impact on quality of life and on carers, as well as the economic burden. For Australia, this information is primarily based on a study published by Deloitte from 2014. More recent data from the Australian Institute of Health and Welfare (AIHW) was not available. It was conservatively estimated in the Deloitte study that in 2014 there were 69,208 Australians living with PD, of whom 53% were male and 47% were female. This equates to 294 per 100,000 of the total Australian population, and 867 per 100,000 among the population aged over 50. Based on these estimates, approximately one in every 340 people in Australia lives with PD.
- 4.2 The last new product in this class listed on the PBS for management of PD was the fixed dose combination of levodopa + carbidopa + entacapone, listed in 2005. A review of prescription data for entacapone and the combination shows that the FDC now dominates the market. Other products for PD considered by the PBAC include safinamide (in combination with L-dopa, 2019), rotigotine dermal patch (2013), and rasagiline (2012).

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Comparator

- 5.1 The submission appropriately nominated entacapone as the comparator as it is the only other COMT inhibitor available on the PBS.

For more detail on PBAC’s view, see section 7 PBAC outcome.

6 Consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from Parkinson’s Australia that noted the convenience and possible adherence benefits of a once-daily COMT inhibitor option for patients to help control end-of-dose motor function symptoms associated with treatment with L-dopa.

Clinical trials

- 6.3 The submission was based on one head-to-head trial comparing 3 different doses of opicapone to entacapone and to placebo (n=599), BIPARK I [BIA-91067-301].
- 6.4 The table below provides details of the trial presented in the submission.

Table 2: Trials and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
Study 301 (BIPARK I)	Clinical Trials.gov Identifier: NCT01568073: Efficacy and Safety of BIA 9-1067 in Idiopathic Parkinson’s Disease Patients With “Wearing-off Phenomenon”. Ferreira JJ, Lees A, Rocha JF Poewe W, Rascol O, Soares-da-Silva P; Bi-Park 1 investigators. Opicapone as an adjunct to levodopa in patients with Parkinson’s disease and end-of-dose motor fluctuations: a randomised, double-blind, controlled trial. Ferreira JJ, Lees A, Rocha JF, Poewe W, Rascol O, Rocha JF, Keller B, Soares-da-Silva P; Effectiveness of opicapone and switching from entacapone in fluctuating Parkinson disease. Korlipara P, Ferreira J, Gama H, Santos A, Ikedo F, Arbe E, Rocha J, Soares-da-Silva P; Baseline OFF-time influence in Opicapone’s efficacy outcomes in Parkinson’s disease patients with motor fluctuations: the BIPARK-1 double-blind data.	Lancet Neurol. 2016 Feb;15(2):154-165. doi: 10.1016/S1474-4422(15)00336-1. Epub 2015 Dec 23. Neurology. 90 (21) (pp E1849-E1857), 2018. European Journal of Neurology, 2019 Sept; 26(09):649.
Study 302 (BIPARK II)	ClinicalTrials.gov Identifier: NCT01227655: Efficacy and Safety of BIA 9-1067 in Idiopathic Parkinson’s Disease Patients. (BIPARKII) Lees AJ, Ferreira J, Rascol O, Poewe W, Rocha JF, McCrory M, Soares-da-Silva P; BIPARK-2 Study Investigators. Opicapone as Adjunct to Levodopa Therapy in Patients With Parkinson Disease and Motor Fluctuations: A Randomized Clinical Trial	JAMA Neurol. 2017 Feb 1; 74(2):197-206. doi: 10.1001/jamaneurol.2016.4703.

Source: Table 2.3, p34 of the submission.

- 6.5 The key features of the direct randomised trial are summarised in the table below.

Table 3: Key features of the included evidence

Trial	N	Design/ duration	Risk of bias	Patient population	Outcome(s)
BIPARK I [BIA-91067-301]	599	R, DB 15 weeks	Low	Parkinson Disease	Absolute off time, on time, with and without dyskinesia, quality of life

Source: constructed during the evaluation

DB = double blind; MC = multi-centre; R = randomised.

- 6.6 The trial compared three doses of opicapone (5 mg, 25 mg and 50 mg daily) with entacapone (200 mg with each dose of levodopa) and placebo. As the only registered dose of opicapone is 50 mg per day, without the possibility of down titrating due to the formulation, this advice concentrates on the data from the 50 mg arm of the trial.
- 6.7 In the trial, patients had to have been on a stable dose of L-dopa + DDCI for 4 weeks before screening (CSR). The number of daily doses of L-dopa + DDCI could be between three and eight. The entacapone dose was therefore determined by the baseline frequency of L-dopa doses and could be between 600 mg and 1,600 mg. The numbers of patients receiving each dose frequency were not reported. However, the median dose of entacapone was 800 mg = 4 tablets daily, the 25th centile was approximately 600 mg = three tablets daily and the 75th centile was approximately 1,000 mg = five tablets.
- 6.8 The highest individual mean daily dose of entacapone in the trial was reported as 7,069 mg. The methods for calculation of the mean dose of entacapone were not provided in the submission or CSR and the evaluation was unable to replicate the estimates provided using standard methods for calculating means. The submission used the mean dose of 906.1 mg based on the safety population; the mean dose for the full population set was reported as 913.5 mg. The DDD for entacapone is 1,000 mg/day. The maximum recommended daily dose of entacapone in the Australian PI is 2,000 mg/day. It was not clear therefore how a subject could have a maximum mean daily dose of 7,069 mg/day, which would potentially significantly inflate the overall calculation of the mean daily dose in the trial.
- 6.9 The Pre-PBAC Response clarified how the resultant highest daily dose of 7,069 mg/day was derived and PBAC considered this was explanation was reasonable.

Comparative effectiveness

- 6.10 The tables below present the results for the key outcomes, on and off time, as dichotomous and continuous data.

Table 4: Dichotomous outcomes: OFF-time responders and ON-time responders

	Opicapone 50mg n/N (%)	Entacapone n/N (%)	Placebo n/N (%)	Odds Ratio Opicapone 50mg vs Entacapone (95% CI)	P-value Opicapone 50mg vs Entacapone
Proportion of OFF-time responders	80/115 (69.6%)	70/120 (58.3%)	57/120 (47.5%)	1.63 (0.95, 2.80)	0.063
Proportion of ON-time responders	75/115 (65.2%)	69/120 (57.5%)	55/120 (45.8%)	1.39 (0.82, 2.35)	0.1479

Source: Table 19, CSR; Table 14.11.1.1

CI = confidence interval; n = number of participants with event; N = total participants in group.

Table 5: Absolute OFF-TIME

Opicapone 50mg			Entacapone			Placebo			LS mean difference (95% CI) Opicapone 50mg - Entacapone	ANCOVA P-value Opicapone 50mg vs Entacapone
Baseline Mean (SD), minutes N=115	Endpoint Mean (SD), minutes N=115	LS mean difference (95% CI)	Baseline Mean (SD), minutes N=120	Endpoint Mean (SD), minutes N=120	LS mean difference (95% CI)	Baseline Mean (SD), minutes N=120	Endpoint Mean (SD), minutes N=120	LS mean difference (95%CI)		
372.2 (107.0)	265.4 (142.5)	117.6 (147.2, 88.0)	387.6 (130.5)	294.1 (165.6)	92.6 (120.7, 64.5)	370.1 (106.7)	325.2 (166.2)	61.8 (89.5, 34.4)	25.0 (64.6, -14.6)	0.215

Source: Table 14.9.12 et seq; 14.10.1

ANCOVA = analysis of covariance; CI = confidence interval; SD = standard deviation

Comparative harms

6.11 Adverse events as reported in the trial are summarised below. The main adverse events were those that would be expected based on the mechanism of action of the drug, similar to the adverse effects profile of entacapone.

Table 6: Summary of key adverse events in the trials

	Placebo n with event/N (%)	Opicapone all doses n with event/N (%)	Opicapone 50mg n with event/N (%)	Entacapone n with event/N (%)
Participants with any TEAE	60/121 (49.6%)	190/356 (53.4%)	62/115 (53.9%)	69/122 (56.6%)
Participants with any SAE	6/121 (5.0%)	9/356 (2.5%)	4/115 (3.5%)	9/122 (7.4%)
Discontinuation of study drug due to TEAE	8/121 (6.6%)	20/356 (5.6%)	5/115 (4.3%)	8/122 (6.6%)
Dyskinesia	5/121 (4.1%)	44/356 (12.4%)	18/115 (15.7%)	10/122 (8.2%)
Insomnia	1/121 (0.8%)	16/356 (4.5%)	7/115 (6.1%)	7/122 (5.7%)
Constipation	3/121 (2.5%)	11/356 (3.1%)	7/115 (6.1%)	5/122 (4.1%)
Buying Disorder	7/121 (5.8%)	30/356 (8.4%)	11/115 (9.6%)	12/122 (9.8%)
Compulsive Sexual Behaviour	3/121 (2.5%)	5/356 (1.4%)	0/115 (0%)	3/122 (2.5%)
Hallucinations	1/121 (0.8%)	8/356 (2.2%)	1/115 (0.9%)	1/122 (0.8%)
ALT > 3xULN	6/121	2/356	0/115 (0%)	0/122 (0%)
AST > 3xULN	4/121	1/356	0/115 (0%)	0/122 (0%)

Source: Table 25; Table 14.12.2; Table 14.17.4a,

TEAE = Treatment Emergent Adverse Event; SAE = Serious Adverse Event; CI = confidence interval; n = number of participants reporting data; N = total participants in group; ALT = alanine aminotransferase; AST = aspartate aminotransferase; ULN = Upper Limit of Normal

Clinical claim

- 6.12 The submission described opicapone as non-inferior in terms of effectiveness compared to entacapone. The ESC and PBAC considered the claim was adequately supported.
- 6.13 The submission described opicapone as non-inferior in terms of safety compared to entacapone. The ESC and PBAC considered this claim was adequately supported.

Economic analysis

- 6.14 The submission appropriately presented a cost-minimisation analysis compared to entacapone.
- 6.15 The equi-effective doses were estimated as opicapone 50mg daily and entacapone 1,000mg per day in 5 divided doses. This equivalence was based on rounding up the mean dose of entacapone from the trial (906 or 913 mg/day) to the 1,000mg/day DDD. As noted in paragraph 6.5, the dose of entacapone in the trial was determined for each patient according to the number of daily doses of levodopa, but the submission did not report the proportions of patients taking the different doses.
- 6.16 No additional costs or cost offsets were included in the cost-minimisation analysis.
- 6.17 Given the uncertainty about the estimate of the mean dose of entacapone as described in paragraph 6.6, the equivalence might be more reliably estimated using the median dose of 800 mg entacapone vs 50 mg opicapone. If the actual mean (913 mg/day) or median dose (800 mg/day) was used for the cost-minimisation analysis, the price for opicapone is lower than that requested in the submission.
- 6.18 A sensitivity analysis of the cost-minimisation analysis based on median entacapone doses (compared to be base case) in the clinical trials, is presented in the table below.

Table 7: Base case cost-minimisation and sensitivity analysis based on median entacapone dose

	Entacapone 1,000mg daily [base case]	Entacapone 800mg daily [median dose]
AEMP of entacapone 200 mg, 200 tablets	\$194.46	\$194.46
Days of therapy provided per prescription	40	50
Entacapone cost per day (AEMP)	\$4.84	\$3.89
Entacapone prescriptions per year	9.13	7.31
Annual entacapone AEMP cost ^a	\$1,775.66	\$1,420.53
30 days' opicapone cost AEMP [1 pack]	\$145.85	\$116.68
Annual opicapone cost [AEMP]	\$1,775.72	\$1,420.58
Opicapone DPMQ	\$171.68	\$138.74

Source: Base case – Table 3.3 of the submission. Sensitivity analysis calculated during the evaluation

^aAssumes 365.25 days

- 6.19 The Pre-Sub-Committee Response (PSCR) argued that the proposed equi-effective doses were reasonable on the basis that the (i) World Health Organization (WHO) defined daily dose of entacapone was 1,000 mg daily, (ii) studies which have showed 20% of patients have required doses greater than 800 mg within 12 months of

commencing levodopa (Bodel et al 2012¹) and, (iii) patients with advanced disease will require doses in excess of 2,000 mg of entacapone per day (Zadikoff et al 2020²). The ESC agreed with the commentary and considered that equi-effective doses based on either the median or an adjusted mean daily dose, excluding the outlier dose of 7,069 mg, were the most reasonable bases upon which to determine the equi-effective doses of opicapone and entacapone.

- 6.20 In its Pre-PBAC Response, the Sponsor advised the mean dose of entacapone in the pivotal trial when the outlier dose was removed was 856 mg per day. Using equi-effective doses based on the mean doses of both opicapone and outlier-adjusted entacapone, defined as opicapone 49.2 mg daily = entacapone 856 mg daily, the Pre-PBAC Response proposed a cost-minimised AEMP for opicapone of \$126.87. The PBAC considered the revised equi-effective doses were reasonable.

Drug cost/patient/year: \$1,830.05

- 6.21 The cost-minimisation analysis was undertaken using the daily equi-effective doses noted in paragraph 6.20 above, on a cost-per-day basis for drug costs only, based on the cost minimised DPMQ of opicapone proposed in the Pre-PBAC Response (\$150.25) and 12.18 prescriptions (365.25/30) per year.

Estimated PBS usage & financial implications

- 6.22 This submission was not considered by DUSC.
- 6.23 The submission presented a market-share approach, based on the current prescription data for entacapone alone. The submission did not include any consideration of the FDC market size. The key inputs used in the financial estimates are summarised below.

¹ Brodell, D. W., Stanford, N. T., Jacobson, C. E., Schmidt, P., & Okun, M. S. (2012). Carbidopa/levodopa dose elevation and safety concerns in Parkinson's patients: A cross-sectional and cohort design. *BMJ Open*, 2(6), 1–6. <https://doi.org/10.1136/bmjopen-2012-001971>

² Zadikoff, C., Poewe, W., Boyd, J. T., Bergmann, L., Ijacu, H., Kukreja, P., ... Antonini, A. (2020). Safety of Levodopa-Carbidopa Intestinal Gel Treatment in Patients with Advanced Parkinson's Disease Receiving ≥ 2000 mg Daily Dose of Levodopa. *Parkinson's Disease*, 2020. <https://doi.org/10.1155/2020/9716317>

Table 8: Key inputs for financial estimates

Data	Value	Source	Comment
Treatment utilisation			
Uptake rate	Yr 1: 25% Yr 2: 30% Yr 3: 35% Yr 4: 40% Yr 5: 45% Yr 6: 50%	Sponsor assumptions	May be reasonable
Scripts dispensed	Yr 1: [redacted] ¹ Yr 2: [redacted] ¹ Yr 3: [redacted] ¹ Yr 4: [redacted] ¹ Yr 5: [redacted] ¹ Yr 6: [redacted] ¹	Applies proportion to existing services with a small annual growth rate (up to 1.46%) included	Assumes that opicapone will not replace any of FDC market
Costs			
Proposed medicine	\$171.67	DPMQ Requested price	
Comparator	\$226.56	8367J	
Patient co-payment	\$9.74	Table 4.5 of the submission	

Source: Excel Workbook, Section 4 Attachment of the submission.

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

6.24 The estimated use and net cost of opicapone are shown in the tables below.

Table 9: Estimated use of opicapone

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
A	Number treated with entacapone in 2019	█ ¹					
B	Annual growth rate	-	-1.13%	-1.20%	-1.28%	-1.37%	-1.46%
C	Predicted number of patients treated with entacapone	-	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
D	Uptake rate	-	25%	30%	35%	40%	50%
E	Total script numbers	-	█ ²	█ ²	█ ²	█ ²	█ ²

Source: Table 4.4 and Attachment 4 Workbook of the submission.

Table 10: Estimated net cost of opicapone to the PBS/RPBS

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed ^a	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Number of entacapone scripts replaced ^b	-█ ²	-█ ²	-█ ²	-█ ²	-█ ²	-█ ²
Drug costs						
Cost of opicapone to PBS/RPBS (excl. patient copayments)	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³
Less patient co-payments	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³
Cost to PBS/RPBS ^c	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³
Change to other PBS/RPBS medicines inc. co-payments ^d	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³
Estimated net financial implications						
Net cost to PBS/RPBS	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³

Source: Section 4 Attachment spreadsheet

^a Sourced from tab 3a. Scripts – proposed; ^b Sourced from tab 2d. Scripts – market; ^c Sourced from tab 3b. Impact – proposed (pub); ^d Sourced from tab 4b. Impact – affected (pub)

The redacted values correspond to the following ranges:

¹ 5,000 to < 10,000

² 500 to < 5,000

³ \$0 to < \$10 million

- 6.25 The total net cost to the PBS/RPBS of listing opicapone (accounting for changes in entacapone use) was estimated to be less than \$0 to < \$10 million per year in all of years 1-6.
- 6.26 The submission did not consider that the overall market for entacapone is dominated by the FDC of levodopa/carbidopa/entacapone. Based on PBS prescription data, the total number of prescriptions for the FDC with entacapone is close to 60,000 to < 70,000 in 2020. Although clinically it is unlikely that there would be a straight substitution of opicapone plus levodopa for the entacapone FDC for a large proportion of this market, it is certainly possible that for some patients, opicapone may be seen as a reasonable and useful alternative. It is therefore likely that the market for opicapone will be larger than estimated by the submission, although it is difficult to predict the size of the difference.
- 6.27 The PSCR stated that while it was difficult to predict the extent to which an opicapone-based regimen may replace the FDC, the extent of switching was likely to be impacted by the PBS eligibility requirements for the FDC which require patients to be stable on

a concomitant regimen prior to initiation. Further, the PSCR also argued it is unlikely that switching a patient who is stable on the FDC away from a simple regimen was likely to occur widely in practice. The ESC considered these arguments were reasonable, however noted there was also a portion of patients with Parkinson Disease who are entacapone resistant (approximately 20%, per the TGA CER) who may be untreated with entacapone and not captured in the market-share analysis. Therefore, the ESC considered the utilisation of opicapone may be underestimated. The Pre-PBAC Response acknowledged these uncertainties with the utilisation and financial estimates, however reiterated the sponsor's view that these are unlikely to have a major impact on the utilisation of opicapone on the PBS.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

- 7.1 The PBAC recommended listing opicapone as a General Schedule Restricted Benefit for Parkinson disease, with the same circumstances of use as entacapone, on a cost-minimisation basis with entacapone.
- 7.2 The PBAC advised the equi-effective doses are opicapone 49.2 mg once daily = entacapone 856 mg daily (given as divided doses with each L-dopa dose).
- 7.3 The Committee acknowledged there was a moderate clinical need for additional therapeutic options to manage end-of-dose motor fluctuations, as entacapone is the only catechol-o-methyl transferase (COMT) inhibitor currently on the PBS for this indication and there is a cohort of patients who are resistant to entacapone therapy.
- 7.4 The PBAC considered the nominated comparator of entacapone was reasonable.
- 7.5 The PBAC noted the BIPARK I study was a small, well conducted study comparing opicapone (5 mg, 25 mg and 50 mg daily) to entacapone and placebo and also noted PBS listing was only being sought for the 50 mg dose of opicapone. Based on the evidence presented, the PBAC was satisfied that opicapone 50 mg once daily was of non-inferior comparative safety and efficacy to entacapone 200 mg given with each L-dopa dose.
- 7.6 The Committee considered structure of the cost-minimisation analysis was reasonable, however agreed with the ESC and considered the equi-effective doses should be based on the mean doses in the BIPARK I trial, with an adjustment to remove the outlier dose of 7,069 mg daily from the mean calculation in the entacapone arm. The Committee noted the adjusted mean dose of entacapone was 856 mg daily and considered this was reasonable.
- 7.7 The PBAC agreed with the ESC and considered the likely utilisation of opicapone was uncertain due to the market dominance of the L-dopa/carbidopa/entacapone fixed dose combination (FDC) and it was unclear what proportion of the FDC market opicapone may capture. Furthermore, the PBAC also noted that a proportion of the

population is resistant to entacapone and considered some patients may also be treated with opicapone. However, overall, the PBAC considered the utilisation and financial risks associated with these uncertainties was likely to be low.

- 7.8 The PBAC advised that, under Section 101(3BA) of the *National Health Act 1953*, that opicapone should be treated as interchangeable on an individual patient basis with entacapone.
- 7.9 The PBAC advised that opicapone is suitable for prescribing by nurse practitioners, consistent with the listing of entacapone.
- 7.10 The PBAC recommended that the Early Supply Rule should apply.
- 7.11 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, as opicapone is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over entacapone, 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.
- 7.12 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

8.1 Add new medicinal product as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OPICAPONE					
opicapone 50 mg capsule, 30	NEW	1	30	5	Ongentys
Restriction Summary / Treatment of Concept: 5133 (as per entacapone 8367J as at 1 July 2021)					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners - CTO					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Parkinson disease					
Clinical criteria:					
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination					
AND					
Clinical criteria:					
Patient must be experiencing fluctuations in motor function due to end-of-dose effect					
Administrative Advice:					
Continuing Therapy Only:					
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.					

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.