

Agenda item 11.03

Palliative Care Schedule (PCS) review and outcomes of stakeholder consultation

1. Purpose of Item

- 1.1. To request that the PBAC consider proposals from the review of the Palliative Care Schedule (PCS), in relation to the retention, deletion and amendment of items on the PCS.

2. Context

- 2.1. In February 2020 the PBAC Executive noted that the Department, upon receiving a number of requests to review the PCS in recent years, tasked Emeritus Professor Lloyd Sansom to conduct a review of the PCS. At the May 2020 Intracycle meeting, the PBAC noted that Emeritus Professor Sansom had consulted a number of experts and made recommendations to retain, amend or remove each of the existing PCS items, as well as suggesting a number of additions to the PCS. The PBAC considered that further targeted consultation with key stakeholder organisations, the Royal College of General Practitioners (RACGP) and Palliative Care Australia (PCA), should be undertaken to seek their current views in relation to the PCS and the individual medicine listings it contains, given recent changes in the opioids environment.
- 1.1 Following the May 2020 PBAC Intracycle meeting, the Department undertook stakeholder consultations with the RACGP and PCA in relation to the current PCS listings.

3. Background

Establishment of the PCS

- 3.1. The PCS was established on 1 February 2004, following recommendation from the Palliative Care Medicines Working Group (PCMWG). The PCS is intended to complement the General Schedule, which also contains many medicines suitable for use in palliative care. Where medicines are included in both the General Schedule and the PCS, the benefit of the PCS is that items are often listed with larger quantities and numbers of repeats, suitable for palliative care use. This can reduce patient co-payment costs and the number of doctor visits required to obtain prescriptions for continuing therapy.

Revised Opioids PBS listings

- 3.2. A number of changes to opioid listings which were recommended by the PBAC in December 2019 were implemented on 1 June 2020. These changes were intended to align the opioid listings with regulatory measures undertaken by the TGA to reduce

the harms associated with prescription opioid dependence and inappropriate use, including overdose fatalities. The regulatory measures were based on the findings from the TGA's 2018 prescription opioid review, and advice received from the Opioid Regulatory Advisory Group (ORAG).

Perceived short falls of the PCS – requests to review the PCS

- 3.3. A range of concerns have been identified with the PCS over time such as:
- continued relevance with current clinical practice of specific listings on the PCS;
 - requests to add/amend/delete medicines from the list;
 - requests to increase maximum quantity and frequency of supply for items on the Prescriber Bag, as well as low utilisation of PCS items which may be related to incorrect use of the Prescriber Bag for palliative care patients;
 - the need to ensure evidence-based listing and use of medicines on the PCS and access needs for vulnerable patients; and
 - the ongoing need for a PCS.
- 3.4. Many of these concerns have been addressed over time through amendments to the list, work to improve education around use of the Prescriber Bag and the PCS, and the requirement for PBAC consideration of items listed on the PCS. Emeritus Professor Sansom's review of the PCS sought to consider the PCS broadly, including the continued need for a list.

4. Progress of the PCS Review

- 4.1. Professor Sansom's review took into account a range of factors:
- previous reviews and considerations of the PCS by the PBAC;
 - previous correspondence received about the PCS including requests for new and amended listings;
 - the outcome of consultation with clinicians in the palliative care sector;
 - consideration of the overlap of the PCS with the General Schedule of the PBS and the value gained by separate PCS listings; and
 - the need for new, amended and deletion of listings on the PCS.
- 4.2. The review considered there was still a need for the PCS with the retention of many items unchanged and some amendments.
- 4.3. Feedback was also sought from key stakeholder organisations, the RACGP and PCA, in relation to the current PCS.

5. PBAC Outcome

- 5.1. The PBAC considered the proposals from the review of the PCS, including input from the RACGP and PCA in relation to the retention, deletion and amendment of items on the PCS. Specific details of the PBAC recommended deletions, amendments and additions of items (outlined below) is in Section 6 Recommended Listing.
- 5.2. The PBAC considered there was an ongoing need for a PCS in addition to the General Schedule in order to provide palliative care patients with flexible access to medicines.
- 5.3. The PBAC considered that aligning PCS opioid listings with the recent changes to the General Schedule would support the appropriate prescribing and use of opioids. The PBAC maintained its intent to support quality use of opioids while not impacting appropriate supply of opioids to palliative patients.
- 5.4. The PBAC recommended PCS listings for a number of opioids for both short-term use (hydromorphone tablets, injections, oral liquid; morphine injections and oral liquid) and long term-use (morphine modified release tablets, capsules and granules; oxycodone modified release tablets, oxycodone with naloxone modified release tablets, fentanyl transdermal patches, hydromorphone modified release tablets, methadone tablets and injection).
- 5.5. For opioids for long-term use, the PBAC recommended Authority Required (telephone) listings which provide a maximum quantity for 4 weeks treatment, consistent with the current listings. For opioids for short-term use the PBAC recommended listings with a maximum quantity of 2 with 1 repeat noting that dosing would vary considerably between patients.
- 5.6. The PBAC considered that some of the restrictions applicable to authority requests for increased maximum quantities or repeats in the General Schedule opioid listings could be eased for the corresponding PCS listings.
- 5.7. The PBAC recommended removing the PCS listings for bisacodyl, diclofenac 100 mg suppository and indometacin as there are corresponding General Schedule listings for these medicines with similar maximum quantities and repeats.
- 5.8. The PBAC noted that clonazepam tablets and oral liquid have Authority Required (telephone) listings for myoclonus under the PCS. The PBAC acknowledged that in palliative care, clonazepam may have a broader use and considered it would be appropriate for the indication to read “For use in patients receiving palliative care.” The PBAC also recommended an Authority Required (STREAMLINED) PCS listing for clonazepam 1 mg injection with one additional repeat compared to the current listing.
- 5.9. The PBAC recommended a PCS listing for metoclopramide 10 mg tablets with a maximum quantity of 100 units and 5 repeats noting that the current Unrestricted Benefit listing provides only a maximum quantity of 25 units with no repeats. The PBAC also recommended amending the existing PCS listing of metoclopramide 10 mg injection to include two repeats.

5.10. The PBAC considered that the PCS should be reviewed in the future to ensure its listings remain appropriate in the palliative care setting.

6. Recommended Listing

6.1. Delete the following listings:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
BISACODYL bisacodyl 10 mg/5 mL enema, 25 x 5 mL	5302C	1	1	3	Bisalax
bisacodyl 10 mg suppository, 10	5303D	3	3	3	Petrus Bisacodyl Suppositories Dulcolax
bisacodyl 10 mg suppository, 12	5304E	3	3	3	Petrus Bisacodyl Suppositories
bisacodyl 5 mg enteric tablet, 200	5301B	1	200	3	Lax-Tab

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DICLOFENAC diclofenac sodium 100 mg suppository, 20	5363G	2	40	3	Voltaren 100
diclofenac 50 mg enteric tablet, 50	5362F	1	50	3	APO-Diclofenac Clonac 50 Diclofenac AN Diclofenac Amneal Diclofenac Sandoz Fenac Pharmacor Diclofenac 50 Voltaren 50
diclofenac sodium 25 mg enteric tablet, 50	5361E	2	100	3	APO-Diclofenac Clonac 25 Diclofenac AN Diclofenac Amneal Diclofenac Sandoz Fenac 25 Voltaren 25

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INDOMETACIN indometacin 100 mg suppository, 20	5378C	2	40	3	Indocid

6.2. Amend the existing listings as follows:

(i) Clonazepam

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
CLONAZEPAM clonazepam 500 microgram tablet, 50	11520H	2	100	3	Rivotril
clonazepam 500 microgram tablet, 100	5337	1	100	3	Paxam 0.5
clonazepam 2 mg tablet, 100	5338Y	1	100	3	Paxam 2
clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL	5339B	2	2	3	Rivotril

Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Authority Required – Streamlined <input checked="" type="checkbox"/> Restricted Benefit
Indication: Myelomus <i>For use in patients receiving palliative care</i>
Clinical criteria: The treatment must be for prophylaxis or prevention of the indication.
AND
Clinical criteria: Patient must be receiving palliative care.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

(ii) Metoclopramine

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METOCLOPRAMIDE metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	10762K	4	40	02	Maxolon

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(iii) Diclofenac

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DICLOFENAC diclofenac sodium 50 mg enteric tablet, 50	1300K	1	5	3	APO-Diclofenac Clonac 50 Diclofenac AN Diclofenac Amneal Diclofenac Sandoz Fenac Pharmacor Diclofenac 50 Voltaren 50
diclofenac sodium 25 mg enteric tablet, 50	1299J	2	100	3	APO-Diclofenac Clonac 25 Diclofenac AN Diclofenac Amneal Diclofenac Sandoz Fenac 25 Voltaren 50

Category / Program: GENERAL – General Schedule
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Restricted Benefit <input checked="" type="checkbox"/> Unrestricted
Indication: Chronic arthropathies (including osteoarthritis)
Clinical criteria: The condition must have an inflammatory component

Category / Program: GENERAL – General Schedule
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Restricted Benefit <input checked="" type="checkbox"/> Unrestricted
Indication: Bone pain
Clinical criteria: The condition must be due to malignant disease.

(iv) Buprenorphine

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
BUPRENORPHINE buprenorphine 5 microgram/hour patch, 2	10957Q	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 10 microgram/hour patch, 2	10948F	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 15 microgram/hour patch, 2	10953L	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 20 microgram/hour patch, 2	10970J	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 25 microgram/hour patch, 2	10964C	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 30 microgram/hour patch, 2	10949G	2	4	0	Bupredermal Buprenorphine Sandoz Norspan
buprenorphine 40 microgram/hour patch, 2	10959T	2	4	0	Bupredermal Buprenorphine Sandoz Norspan

Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type/Method: <input checked="" type="checkbox"/> Authority Required – immediate/real time assessment by Medicare (telephone)
Indication: Chronic severe disabling pain
Clinical criteria: Patient must be receiving palliative care.
AND
Clinical criteria: The condition must be unresponsive to non-opioid analgesics. Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; or Patient must be unable to use non-opioid analgesics due to contraindications or intolerance
Prescribing Instructions: Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
Administrative Advice: This treatment is not suitable for 'as-required' pain relief.
Administrative Advice: Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos). Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333. Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857 [Your capital city]
Telephone approvals are limited to 1 month's therapy.
Caution: The risk of drug dependence is high.

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(i) Morphine

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MORPHINE morphine sulfate pentahydrate 200 mg modified release tablet, 28	5391R	2	56	0	MS Contin

Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction Level: <input checked="" type="checkbox"/> Authority required - immediate/real time assessment by Medicare (telephone)
Caution: The risk of drug dependence is high.
Administrative Advice: <i>This treatment is not suitable for 'as-required' pain relief.</i>
Administrative Advice: <i>Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</i>
Administrative Advice: <i>Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos). Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333. Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857 [Your capital city]</i>
PBS Indication: Severe disabling pain
Clinical criteria: <i>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid OR other opioid analgesics; or Patient must be unable to use non-opioid OR other opioid analgesics due to contraindications or intolerance</i>
Treatment criteria <i>Patient must be undergoing palliative care</i>
Prescribing instruction: <i>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</i>

6.3. Add new items:

(i) Non-opioid items

(a) Clonazepam

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
CLONAZEPAM clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (& inert substance diluent [5 x 1 mL ampoules], 1 pack	NEW	1	5	1

Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Restricted Benefit
Indication: For use in patients receiving palliative care

(b) Haloperidol

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
HALOPERIDOL haloperidol 5 mg/mL injection, 10 x 1 mL ampoules	NEW	1	10	2

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Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Restricted Benefit
Indication: For use in patients receiving palliative care
Administrative Advice:
Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

(c) Metoclopramide

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
METOCLOPRAMIDE metoclopramide hydrochloride 10 mg tablet, 25	NEW	4	100	5

Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners
Restriction type / Method: <input checked="" type="checkbox"/> Restricted Benefit
Indication: For use in patients receiving palliative care

(ii) Opioid items

Restrictions for these items are to be finalised.

(a) Fentanyl

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
FENTANYL fentanyl 12 microgram/hour patch, 5	NEW	2	10	0
fentanyl 25 microgram/hour patch, 5	NEW	2	10	0
fentanyl 50 microgram/hour patch, 5	NEW	2	10	0
fentanyl 75 microgram/hour patch, 5	NEW	2	10	0
fentanyl 100 microgram/hour patch, 5	NEW	2	10	0

(b) Hydromorphone

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
HYDROMORPHONE hydromorphone hydrochloride 2 mg tablet, 20	NEW	2	40	1
hydromorphone hydrochloride 4 mg tablet, 20	NEW	2	40	1
hydromorphone hydrochloride 8 mg tablet, 20	NEW	2	40	1
hydromorphone hydrochloride 4 mg modified release tablet, 14	NEW	2	28	0
hydromorphone hydrochloride 8 mg modified release tablet, 14	NEW	2	28	0
hydromorphone hydrochloride 16 mg modified release tablet, 14	NEW	2	28	0
hydromorphone hydrochloride 32 mg modified release tablet, 14	NEW	2	28	0
hydromorphone hydrochloride 64 mg modified release tablet, 14	NEW	2	28	0
hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL	NEW	2	2	1
hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1

(c) Methadone

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
METHADONE methadone hydrochloride 10 mg tablet, 20	NEW	6	120	0
methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	NEW	24	120	0

(d) Morphine

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
MORPHINE morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine hydrochloride trihydrate 50 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine hydrochloride trihydrate 100 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL	NEW	2	2	1
morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL	NEW	2	2	1

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules	NEW	2	10	1
morphine sulfate pentahydrate 5 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 10 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 15 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 30 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 60 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 100 mg modified release tablet, 28	NEW	2	56	0
morphine sulfate pentahydrate 10 mg modified release capsule, 28	NEW	2	56	0
morphine sulfate pentahydrate 20 mg modified release capsule, 28	NEW	2	56	0
morphine sulfate pentahydrate 30 mg modified release capsule, 14	NEW	2	28	0
morphine sulfate pentahydrate 50 mg modified release capsule, 28	NEW	2	56	0
morphine sulfate pentahydrate 60 mg modified release capsule, 14	NEW	2	28	0
morphine sulfate pentahydrate 90 mg modified release capsule, 14	NEW	2	28	0
morphine sulfate pentahydrate 100 mg modified release capsule, 28	NEW	2	56	0
morphine sulfate pentahydrate 120 mg modified release capsule, 14	NEW	2	28	0
morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets	NEW	2	56	0
morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets	NEW	2	56	0
morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets	NEW	2	56	0
morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets	NEW	2	56	0
morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets	NEW	2	56	0

(e) Oxycodone

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
OXYCODONE	NEW	2	56	0
oxycodone hydrochloride 10 mg modified release tablet, 28				
oxycodone hydrochloride 15 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 20 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 30 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 40 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 80 mg modified release tablet, 28	NEW	2	56	0

(f) Oxycodone with naloxone

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts
OXYCODONE + NALOXONE	NEW	2	56	0
oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28				
oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28	NEW	2	56	0
oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28	NEW	2	56	0

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

7. 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.