

Pharmaceutical Benefits Scheme (PBS) OPIOID CHANGES– PRESCRIBER INFORMATION

Why have changes been made?

Over the past decade, Australians have experienced a significant increase in the level of harm and deaths arising from the inappropriate use of prescription opioid medicines. Every day in Australia, nearly 150 hospitalisations and 14 emergency department admissions involve issues relating to opioid use, and three people die from the harm that results. The Pharmaceutical Benefits Advisory Committee (the independent body responsible for advising the Australian Government about what medicines should be subsidised under the PBS) in consultation with the Therapeutic Goods Administration (TGA), recommended a number of amendments to be made to the listings of opioid medications to ensure safe and appropriate access through the PBS. For information on why these changes have occurred and information on further regulatory changes affecting opioid medicines, please refer to the [TGA's Prescription opioids hub](#).

What are the new PBS requirements?

Prescribers should refer to the PBS schedule for the restriction/authority level. Across all PBS listings for opioids, patients must meet at least one of the following clinical criteria depending on the PBS listing (not all options are available for all listings):

- The patient's pain is attributable to cancer; OR
- The maximum tolerated doses of non-opioid (or/and other opioid) analgesics do not, or will not provide, adequate pain management; OR
- The maximum tolerated doses of non-opioid (or/and other opioid) analgesics are contraindicated, or unable to be taken; OR
- The treatment must be for post-operative pain following a major operative procedure; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Where increased quantities and/or repeats are required:

- Most PBS listings require a secondary review of the patient's pain management with a second doctor if opioid treatment will exceed or has exceeded 12 months duration. This is an annual requirement.
- Further changes to the PBS listings will be implemented shortly which allow a palliative care nurse practitioner to perform the secondary review for palliative care patients. As above, this is a requirement for palliative patients who have been receiving or are expected to receive treatment with opioids for more than 12 months, unless their clinical condition is such that a secondary review is not possible.
- Secondary reviews may be conducted by phone or telehealth consultation.
- It is not mandatory to consult a pain specialist as part of the secondary review requirement. Any doctor registered in Australia may conduct this review.
- Updated restrictions that will be implemented shortly will no longer require the date of the review and name of the medical practitioner consulted to be provided when requesting authority approval. However, prescribers need to ensure they keep this information for compliance purposes. Prescribers will also need to confirm if the patient has received an authority approval for the same medicine..
- Restrictions will also be split into initial and continuing treatment phases to minimise the requirements for prescribers to provide information repetitively. Prescribers will need to indicate if the patient has received initial authority approval for the drug after 1 June 2020.

How do I apply for authorities for increased quantities or repeats?

Prescribers may request real-time authority approval through the [Online PBS Authorities system \(OPA\)](#) for quantities and/or repeats that provide up to 3 months' treatment. This removes the need for prescribers to call or submit a written application to Services Australia.

Alternatively, prescribers can request up to 1 months' treatment via telephone and up to 3 months' treatment in writing (via mail or Health Professional Online Services (HPOS) form upload). (Telephone authority requests seeking treatment beyond 1 month requests will not be approved).

To assist in streamlining this process, it is important to familiarise yourself with the relevant PBS restriction.

What if my patient does not meet the PBS restriction criteria?

Stopping or reducing opioid medications too quickly poses risks, and may result in harmful effects. Where patients do not meet the new PBS criteria, suitable pain management strategies, including slow opioid weaning, with negotiation about when to start, rate of reduction and use of self-management strategies should be discussed with the patient. To aid in the weaning process, non-PBS (private) prescriptions may be written in accordance with State and Territory law. Further, the [National Pain Services Directory](#) lists over 200 pain specialist services across Australia and can assist in finding a multidisciplinary pain management program that may be beneficial for your patient.

What products are available?

All **standard quantities for immediate release opioid formulations** remain available on the PBS in addition to their reduced listed quantities. These listings are Restricted Benefits for the treatment of severe pain, meaning no authority approval is required before prescribing listed quantities.

Reduced quantities for immediate release opioid formulations are intended for use when other medications are not enough to manage pain, but ongoing pain management is unlikely to be required beyond 2-3 days. These listings are Restricted Benefits meaning no authority approval is required before prescribing.

Standard quantities for modified release products are available for the treatment of patients with chronic severe pain, requiring daily, continuous long-term therapy. These listings are predominantly Authority Required (STREAMLINED) listings meaning no authority approval is required before prescribing listed quantities. However, prescribers must include the correct streamlined code on the prescription. Streamlined codes are provided on the PBS website against the relevant PBS item code and restriction.

Where can I get more information on these changes?

The NPS MedicineWise has a [RADAR article](#) summarising the June 2020 PBS changes. In addition a [summary table](#) of individual changes to PBS listings, can be viewed on the PBS website. All new and amended restrictions will be updated on the [PBS website](#) from 1 October 2020.

How do I stay up to date with PBS changes?

The best way to keep informed of all PBS changes is by signing up for PBS alerts on the [PBS website](#).

It is important for Prescribers to update the prescribing software on the first of every month. This is to ensure correct prescribing under the correct PBS schedule requirements.