**Recommendations made by the PBAC – July 2025 meeting**

**Nurse practitioners - oncology, haematology and Section 100 Highly Specialised Drugs Program medicines**

At its July 2025 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) considered a list of oncology and haematology medicines listed on the General Schedule, and medicines listed on the Section 100 Highly Specialised Drugs (S100 HSD) program that had been identified by stakeholders as being suitable for prescribing by nurse practitioners. The PBAC made its recommendations with reference to its four general principles for determining PBS prescriber eligibility.

For most of the identified oncology and haematology medicines (refer Table 1), the PBAC recommended that nurse practitioners be allowed to continue existing therapy where patient care is being shared with a medical practitioner. The PBAC considered that Principle 4 (‘Health condition specific considerations’) applied in this context, as these medicines are used to treat complex health conditions and management generally requires oversight by a medical specialist. The PBAC considered it would be reasonable to expect initial treatment for these complex conditions to be authorised by a medical practitioner. For a small number of identified oncology/haematology medicines, the PBAC recommended no changes to PBS prescriber type eligibility (refer Table 2).

The PBAC considered feedback indicating that many nurse practitioners are employed within medical oncology and haematology outpatient settings and that there are usually workplace prescribing protocols, clinician support and other safety and quality in healthcare measures in place that support the quality use of medicines.

**Table 1 – PBS General schedule oncology or haematology medicines that PBAC recommended amending to allow nurse practitioners to continue therapy where patient care is shared with a medical practitioner**

|  |
| --- |
| ***Pharmacological class:*** drug(s)  |
| 1 | ***Oral cytotoxic chemotherapy:***  capecitabine, cyclophosphamide, temozolomide, vinorelbine   |
| 2 | ***CDK4/6 inhibitors:*** abemaciclib, palbociclib, ribociclib   |
| 3 | ***Tyrosine kinase receptor inhibitors (TKIs):*** cabozantinib, lenvatinib, sunitinib   |
| 4 | ***EGFR TKIs:*** osimertinib, erlotinib, gefitinib  |
| 5 | ***PARP inhibitors:*** olaparib, niraparib, talazoparib   |
| 6 | ***ALK Inhibitors:*** alectinib, brigatinib, lorlatinib, crizotinib, ceritinib   |
| 7 | ***BRAF inhibitors:*** dabrafenib, vemurafenib, encorafenib   |
| 8 | ***MEK inhibitors:*** cobimetinib, trametinib, binimetinib  |
| 9 | ***Endocrine therapy for prostate cancer – other hormone antagonists and related ages:*** abiraterone, degarelix, abiraterone & methylprednisolone combination product  |
| 10 | ***Endocrine therapy for prostate cancer – anti-androgens:*** enzalutamide\*, apalutamide, darolutamide, cyproterone   |
| 11 | ***Gonadrotropin releasing hormone analogues:*** goserelin implant (both strengths), leuprorelin, goserelin & bicalutamide, leuprorelin & bicalutamide, triptorelin   |
| 12 | ***Other oncology medicines:*** medroxyprogesterone, fulvestrant, exemestane, hydroxycarbamide (hydroxyurea), mercaptopurine   |
| 13 | ***Tyrosine kinase inhibitors:*** dasatinib, imatinib, nilotinib, ponatinib, gilteritinib   |
| 14 | ***Bruton’s tyrosine kinase inhibitors:*** acalabrutinib, ibrutinib, zanubrutinib  |
| 15 | ***Phosphatidylinositol-3-kinase (Pi3K) inhibitors:*** idelalisib  |

\*include a Caution in the restriction to comply with any state or territory restrictions; CDK: Cyclin Dependent Kinase; EGFR: Epidermal Growth Factor Receptor; PARP: Poly ADP-Ribose Polymerase; ALK: Anaplastic Lymphoma Kinase; BRAF: B-Raf proto-oncogene; MEK: Mitogen-activated Extracellular signal-regulated Kinase

**Table 2 – PBS General Schedule oncology or haematology medicines which the PBAC did not support the addition of nurse practitioners as eligible prescribers**

| ***Drug***  | **Rationale**  |
| --- | --- |
| 1 | ***mycobacterium bovis BCG***  | Principle 3 (medicine specific considerations): Potential for difficult/incorrect administration resulting in serious complications |
| 2 | ***venetoclax*** | Principle 3 (medicine specific considerations): Difficult dose titration with high risk of toxicity |

BCG: Bacillus Calmette-Guérin

For most S100 HSD medicines that were cited by stakeholders, the PBAC supported nurse practitioners prescribing continuing treatment where there is agreement from the treating specialist medical practitioner. The PBAC acknowledged that in practice, it is likely that nurse practitioners would already be sharing patient care with medical practitioners, in the context of public hospital outpatient clinics or private hospitals. The PBAC considered it would be appropriate to require nurse practitioners to have agreement from the medical specialist to prescribe continuing treatment with S100 HSD medicines for consistency with existing requirements on non-specialist medical practitioners. In addition, the PBAC was supportive of nurse practitioners prescribing iron chelating medicines in the context of initial or continuing treatment where the patient’s care is shared with a medical practitioner:

* deferasirox tablets,
* deferiprone tablets/oral liquid,
* desferrioxamine injection.

The S100 HSD medicines that PBAC recommended as being suitable for prescribing by nurse practitioners (under certain conditions) are outlined in Table 3 below:

**Table 3 – S100 HSD (Public & Private hospital and CA) medicines for which PBAC recommended changes to include nurse practitioners as eligible prescribers under certain conditions**

|  |
| --- |
| ***Disease area:*** drug(s)  |
| **Continue therapy only with agreement from the treating specialist medical practitioner:**  |
| 1  | ***Neutropenia:*** filgrastim, pegfilgrastim  |
| 2  | ***Neuroendocrine cancer***: lanreotide (S100 HSD Public & Private Hospital and CA listings), octreotide (S100 HSD Public & Private and CA listings) |
| 3  | ***Acute myeloid leukaemia:*** midostaurin  |
| 4  | ***Breast cancer:*** zoledronic acid 4 mg/5 mL injection, 5 mL vial  |
| 5  | ***Psychosis:*** clozapine (S100 CA listings only – Continuing treatment)  |
| 6  | ***Cystic fibrosis:*** dornase alfa, mannitol  |
| 7  | ***Cystic fibrosis (CFTR modulators):*** ivacaftor, lumacaftor, elexacaftor, tezacaftor, combinations  |
| 8  | ***Transplant rejection:*** mycophenolate    |
| 9  | ***Transplant rejection (mTOR inhibitors):*** everolimus, sirolimus  |
| 10  | ***Transplant rejection (calcineurin inhibitors):*** ciclosporin, tacrolimus  |
| 11  | ***Cytomegalovirus (CMV) infection in transplants:*** valganciclovir  |
|   |
| **Initiate and/or continue therapy where patient care is shared with a medical practitioner:**  |
| 12  | ***Iron chelating agents:*** deferasirox, deferiprone, desferrioxamine  |

S100: Section 100, CA: Community Access, HSD: Highly Specialised Drugs; CFTR: Cystic Fibrosis Transmembrane conductance Regulator; mTOR: mammalian Target of Rapamycin

The PBAC was not supportive of nurse practitioner prescribing for some of the identified S100 HSD medicines (refer Table 4). This includes medicines where existing PBS restrictions limit prescribing to specialist medical practitioners only, and medicines with dual S100 HSD and General Schedule listings, where the General Schedule listing(s) already permit nurse practitioners to prescribe as continuing/maintenance therapy (i.e. sevelamer, lanthanum, sucroferric oxyhydroxide). The PBAC noted thalidomide and its analogues have further state/territory restrictions on prescriber types owing to the teratogenicity of these drugs.

**Table 4 – S100 HSD medicines which the PBAC did not support the addition of nurse practitioners as eligible prescribers:**

| ***Disease area:*** drug(s) | **Rationale**  |
| --- | --- |
| 1 | ***Multiple myeloma medicines:*** lenalidomide, thalidomide, pomalidomide | Principle 1: State/territory legislation considerations Principle 4: Complex condition where specialists are likely to diagnose/oversee treatment. |
| 2 | ***Biologics for severe asthma:***benralizumab, dupilumab, mepolizumab, omalizumab | Prescribing is currently limited to specialist medical practitioners onlyPrinciple 4: Complex condition where specialists are likely to diagnose/oversee treatment. |
| 3 | ***Schizophrenia:***clozapine (Initial treatment listing) | PBAC recommended nurse practitioners should be eligible to continue treatment only (see Table 3).Principle 4: Complex condition where specialists are likely to diagnose/oversee treatment. |
| 4 | ***Conditions arising from chronic kidney disease:***cinacalcet lanthanum, sevelamer, sucroferric oxyhydroxide | Nurse practitioners can already continue treatment of these medicines (under separate PBS listings). Principle 4: Complex condition where specialists are likely to diagnose/oversee treatment. |
| 5 | ***Multiple sclerosis:***alemtuzumab, natalizumab, ocrelizumab | Prescribing is currently limited to neurologists.Principle 4: Complex condition where specialists are likely to diagnose/oversee treatment. |
| 6 | ***Severe active rheumatoid arthritis:***rituximab | For consistency with other biological treatments where prescribing is limited to medical specialists.Principle 4: Complex condition where specialists are likely to diagnose/oversee treatment. |

In addition to the above recommendations, the PBAC considered the Department’s request toreview the nurse practitioner prescribing ‘Continuing therapy only’ (CTO) requirements that apply to recently (1 March 2025) PBS listed:

* estradiol 0.06% (750 microgram/actuation) gel, 64 actuations (Estrogel®)
* progesterone 100 mg capsule, 30 (Prometrium®)
* progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack (Estrogel Pro®)

The PBAC recommended removal of the CTO note for these three medicines, for consistency with its November 2024 consideration of listings with a nurse-practitioner CTO note.

The PBAC noted that this was the last tranche of medicines being considered through the PBS review. Whilst the PBAC recommendations to date have been made in the context of current experience and evidence, it noted that evidence will continue to evolve over time. The PBAC expressed its willingness to consider future requests to amend the eligible prescriber types, which according to the current PBAC submission guidelines would usually follow the format of a Category 4 submission.

**Implementation**

The PBAC’s recommendations are expected to be implemented in due course as part of routine monthly changes to the PBS schedule. The PBAC’s recommendations applied to PBS listings as of 1 July 2025. Some medicines are listed in more than one section of the Schedule or for more than one indication. PBS listings for the same medicine may have different conditions for prescribing. Medicines listed on the PBS are updated monthly and PBS prescribers should check the schedule regularly to ensure they prescribe in accordance with any restrictions specified in a listing. More information can be found by visiting ‘[Review of PBS items for prescribing by nurse practitioners and endorsed midwives](https://www.pbs.gov.au/info/reviews/review-pbs-items-prescribing-nurse-practitioners-endorsed-midwives)‘ on the PBS website.