DECEMBER 2022 PBAC OUTCOMES-OTHER MATTERS

| **DRUG TYPE AND USE** | **PURPOSE** | **PBAC OUTCOME** |
| --- | --- | --- |
| Pharmaceutical Benefits Scheme (PBS) medicines used to treat chronic stable conditions. These are listed by World Health Organisation Anatomical Therapeutic Classification (ATC) Index, referred to as “Body Systems”, on the PBS.   * Alimentary (ATC-A): diabetes, inflammatory bowel disease, laxatives, digestive enzymes * Antineoplastic and immunomodulatory (ATC-L) – immunosuppressants, breast cancer, rheumatoid arthritis * Anti-infectives (ATC-J): acne, bronchiectasis, rheumatic fever * Blood (ATC-B): platelet inhibitors, thrombin inhibitors * Cardiovascular (ATC-C1- C10, high cholesterol, hypertension, angina, heart failure * Dermatological (ATC-D)- psoriasis, acne * Genitourinary (ATC-G): hormone replacement therapy, urinary incontinence * Musculoskeletal (ATC-M): gout, osteoporosis * Nervous (ATC-N)– antidepressants, epilepsy, migraine prevention, Parkinson disease * Respiratory (ATC-R) – asthma, chronic obstructive pulmonary disease * Sensory (ATC-S): glaucoma, dry eyes * Systemic hormonal preparations (ATC-H): endometriosis, thyroid, parathyroid * Various (ATC-V) – hypercalcemia, hyperkalaemia, hyperphosphatemia | The Delegate requested the Pharmaceutical Benefits Advisory Committee provide advice on the following matter under section 101(3) of the National Health Act, 1953 (the Act).  The clinical safety and suitability of each medicine for the treatment of chronic conditions for PBS listing under the following circumstances:  • Increase the maximum dispensed quantities (MDQ) on selected PBS items from one months’ supply to up to three months’ supply per dispensing, allowing up to 12 months’ supply in total per prescription. | In [August 2018](https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/recommendations-made-pbac-august-2018), the PBAC considered the clinical safety and suitability of selected PBS medicines for chronic conditions for PBS listing with increased dispensed quantities i.e. from one months’ supply to two months’ supply per dispensing, allowing up to 12 months’ supply in total.  In December 2022, the PBAC reconsidered an updated list of PBS medicines that are indicated for the treatment of chronic conditions for their suitability for listing with increased MDQs per dispensing, from one months’ supply to up to three months’ supply per dispensing.  The PBAC accepted the updated guidance for exclusion of a medicine/medicine group from the increased MDQ proposal.  Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that 304 medicines (895 PBS items)\* were suitable for listing with increased MDQs of either two or three months’ supply per dispensing.  The PBAC also recommended amending the 12 month repeat listings (21 medicines/43 PBS item codes)\* for digestive enzymes, lipid lowering medicines, ulcerative colitis and ocular lubricants to include increased MDQs. The 12 month repeat PBS items currently allow a MDQ of approximately one months’ supply and 11 repeats and will be amended to allow up to three months’ supply per dispensing with sufficient repeats to provide 12 months’ supply.  The [list of medicines](https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/recommendations-made-by-the-pbac-december-2022-intracycle) accepted by the PBAC as suitable for additional PBS items with increased MDQ is available on the PBS website.  The PBAC confirmed that the recommendations for PBS items with the increased MDQ would be in addition to the current PBS items with one months’ supply and five repeats for the corresponding medicine. This would ensure prescriber choice; such that smaller quantities could still be prescribed for patients as clinically appropriate to avoid medicine wastage and to support closer clinical monitoring of patients where required.  The PBAC recommended that the following standard criterion be included in the PBS restrictions for PBS medicines with increased MDQ:   * Clinical criterion: *Patient’s condition must be stable and suitable for the increased Maximum Dispensed Quantity measure*   The PBAC recommended that the approved prescribers for each recommended PBS medicine would remain consistent for the increased MDQ listing for the same medicine.  The PBAC accepted that the Department will specify the appropriate number of repeats for any medicine the PBAC recommended for inclusion in the increased MDQ proposal to allow 12 months’ supply (at the dosage recommended in the Product Information), except where the PBAC specifically recommended increased quantities for shorter prescription durations. |

\*These numbers were correct at the time of PBAC consideration in December 2022 but due to ongoing updates to the PBS schedule these numbers may vary over time.