| **DRUG, SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE OR USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
| --- | --- | --- | --- |
| Direct-acting antivirals (DAA) for hepatitis C | Chronic hepatitis C  | To update the PBAC on the use of DAA regimens to treat hepatitis C and their cost-effectiveness based on health outcomes from real-world data.  | The PBAC noted the data that was used to inform the economic evaluation and considered that these data sources were well established and appropriate.The PBAC recalled its consideration from the March 2015 meeting that the cost for an entire treatment course with a DAA regimen should be within an ICER of $15,000 per QALY.The PBAC considered that overall, the economic evaluation based on real-world data demonstrated that the DAA listings were likely to be cost-effective in practice, including for patients with decompensated cirrhosis. The PBAC did not recommend any further changes to the listings for DAA treatment for hepatitis C at this time. |
| Nurse Practitioners as secondary reviewers for ongoing treatment with opioid medications  | Chronic pain  | To consider the request from the Australian College of Nurse Practitioners to allow Nurse Practitioners to conduct the secondary annual review required for non-palliative patients to access ongoing treatment with PBS subsidised opioid medications.  | The PBAC did not support the request from the Australian College of Nurse Practitioners that Nurse Practitioners be able to perform the secondary annual review on non-palliative patients with chronic pain requiring more than 12 months of opioid treatment. The PBAC recalled that the changes to opioid listings (implemented on 1 June 2020) were intended to reduce the harms associated with prescription opioid dependence and inappropriate use, including overdose fatalities. In this context, the PBAC considered the request did not identify barriers to appropriate opioid access that the requested change would overcome.  |
| Digital Submission and Assessment for Authority Required PBS Listings | N/A | For the PBAC to endorse the proposal from Services Australia for digital submission of authority requests for Authority Required (written) PBS items and to consider and advise of any implications of these changes for existing PBS items. | The PBAC endorsed the implementation of digital submission authority requests for Authority Required (written) PBS items. The PBAC recognised that the availability of the current system allowing an upload functionality has been advantageous for prescribers and considered the move to a more integrated digital platform would provide further benefit.The PBAC noted that listing changes may be required for the transition to the digital platform and recommended that where appropriate in relation to policy matters (e.g., biosimilar uptake drivers), and where particular therapeutic groups or medicines may not be suitable for immediate digital assessment, the Department should seek PBAC advice prior to implementation. The PBAC noted that legislative changes, including those being considered for the purposes of prescriber compliance, may be required to implement this recommendation.  The PBAC perceived that this system may provide opportunities to undermine the purpose of the current authority system, with the digital channel potentially achieving the same barrier as a written authority. Therefore, the PBAC supported plans to utilise data to monitor and audit compliance with PBS listings and for legislative and policy changes to be subsequently investigated and employed to improve adherence. The PBAC recognised that implementation of these changes would be a medium to long term project and considered that there are still significant barriers in practice, e.g., in the public hospital setting. Further, integration into prescribing software, while supported, is outside the scope of the PBAC. |