

9.04b Drugs for the treatment of hepatitis C

Stakeholder meeting outcomes

December 2018

1 Purpose of Item

- 1.1 To seek PBAC's advice on changes to the listings of direct-acting antiviral (DAA) regimens and the associated General Statement for drugs used for the treatment of hepatitis C, raised at the Hepatitis C clinical stakeholder meeting held on 13 December 2018.

2 Background

- 2.1 The first DAA regimens (not requiring co-administration of interferon) were listed on the PBS in March 2016 for the treatment of CHC infection. The first pan-genotypic regimen was listed in August 2017.
- 2.2 Since the first listings, the number of patient initiations per month has declined from approximately 4,400 patients per month during the first four months of listing to an average of 1,280 patients per month by December 2017.

3 Stakeholder meeting outcomes & requested PBAC advice

- 3.1 The clinical stakeholders considered that at current prescribing levels, Australia may achieve World Health Organization (WHO) hepatitis C virus (HCV) elimination targets by 2030, however also stated that higher initiation rates (approximately 19,000 patients per year) would be required to meet National Hepatitis C strategy targets for 2022.
- 3.2 Stakeholders broadly agreed on a number of changes to the listings that were desirable to simplify prescribing and drive uptake, and that some elements of current listings were serving as barriers to treatment. Stakeholders broadly agreed the following changes to listings were desirable and requested the PBAC consider:
 - Removal of the requirement for patient genotype to be reported prior to commencing therapy. Stakeholders considered that without the mandatory requirement most patients would still have genotyping done. However, for some patients, awaiting the results of genotype testing may delay initiation of therapy and increase the risk of loss to follow up. Stakeholders highlighted that this was of particular concern in the corrective services setting where any delay to treatment may be a barrier as patients often move between settings at frequent and unexpected intervals. Stakeholders indicated that in this setting there may also be barriers to undertaking genotyping at the same time as HCV RNA testing due to cost constraints.
 - Implementing a streamlined authority listing for most regimens to simply patient

care. Stakeholders considered it important to incorporate cirrhotic status into any Authority Required (STREAMLINED) listing for DAA regimens. Stakeholders suggested that any such amendments could be modelled on the current Authority Required (STREAMLINED) listings for medicines for the treatment of chronic hepatitis B infection. Stakeholders generally agreed special conditions should be considered for salvage regimens for patients who had previously failed DAA therapy.

- Nurse Practitioner prescribing of S100 listings. Stakeholders raised concerns regarding the Section 100 Highly Specialised Drugs Program prescribing of DAAs, which is required for patients treated in hospital care or in corrective services. Concerns raised related to the inability of nurse practitioners to prescribe in these settings under current Section 100 arrangements, with stakeholders considering this a barrier to treatment.
- Removal of age restrictions from the listings.
- Consideration of use of the term 'chronic' in the listing, which stakeholders suggested may be a potential barrier to prescribing.
- Removal of interferon-containing regimens. Stakeholders agreed that since non-interferon containing regimens were available for all genotypes, these could be removed from the General Statement.

4 PBAC Outcome

- 4.1 The PBAC provided specific advice on the changes requested by clinical stakeholders as outlined below.
- 4.2 The PBAC recommended the removal of the requirement for mandatory pre-treatment determination of patient genotype. In making this recommendation, the PBAC considered that with the listing of pan-genotypic treatments, the risks associated with not knowing patient genotype prior to initiating therapy were reduced, and acknowledged that awaiting the results of genotyping may delay initiation of therapy or increase the risk of loss to follow-up. The PBAC also noted there may be rare extenuating circumstances where genotyping is not possible or not practical. The PBAC agreed that while the requirement is informative for monitoring and data collection purposes, it is counter-productive if this requirement is a barrier to treatment.
- 4.3 The PBAC agreed with stakeholders to maintain a requirement for clinicians to obtain patients cirrhotic status prior to commencing treatment, as cirrhotic status is directly associated with patient outcomes and treatment duration is sometimes affected by patients' cirrhotic status. The PBAC agreed this assessment was most appropriately a matter of clinical judgment and should be noted in patient records as part of prescribing criteria.

- 4.4 The PBAC deferred making a recommendation on implementing streamlined authority listings for DAA regimens to undertake further investigation as to the feasibility of such a change. The PBAC noted stakeholders supported this move, at minimum, for patients naïve to DAA therapy, however considered aspects such as the risk of prescribers selecting incorrect prescribing codes and matters relating to administration of current risk share arrangements predicated the need for further investigation of the potential implications.
- 4.5 The PBAC recommended the removal of the remaining peg-interferon alfa-2a containing regimen options from the General Statement, and noted that interferon-free options are now available on the PBS for all genotypes.
- 4.6 The PBAC agreed it may be reasonable to remove the PBS age restrictions from the General Statement and authority requirements and considered that age criteria for these treatments were adequately outlined in the approved Product Information documents.
- 4.7 The PBAC noted other issues raised by stakeholders, including the inability for nurse practitioners to prescribe under the Section 100 listings, and agreed this may have implications for patients in some settings, such as custodial or corrective services. The PBAC noted legislative amendments would be required to facilitate any such changes and requested the Department explore this issue further.
- 4.8 The PBAC also noted the request to remove the term ‘chronic’ from the PBS listings of the DAA regimens, and considered this would introduce a new population of patients with acute infection where cost-effectiveness has not been established. The PBAC agreed such a change would require a major submission to be brought forward by one or more sponsors with clinical evidence and economic evaluation to establish cost-effectiveness in this population.

Outcome: Advice provided