16 November 2023

Re: Proposed shift from s100 to s85 scheduling for medicines used to treat chronic hepatitis B

Thank you for your engagement with the consultation led by ASHM and Hepatitis Australia to progress the proposed shift from Section 100 (s100) to Section 85 (s85) for medicines used to treat chronic hepatitis B. This consultation is being conducted to better understand the views and experience of key stakeholders, to support us to make informed recommendations and advocate effectively for all individuals affected by a change. Information collected will be used to inform advocacy by ASHM and Hepatitis Australia to progress this change, as well as identify further education and awareness needs. Currently, 74% of people living with hepatitis B in Australia are not engaged in care and are at risk of poorer health outcomes related to hepatitis B[1]. Increasing involvement of general practitioners in management of hepatitis B is a priority action to reduce existing barriers to treatment and care, particularly in regional and rural areas and for priority populations including Aboriginal and/or Torres Strait Islander peoples. The draft Fourth National Hepatitis B Strategy 2023-2030 prioritises the decentralisation of treatment to primary care and community settings. Adding the highly effective medications used to reduce the risk of liver disease and liver cancer to the PBS General Schedule (s85) will be an important step towards facilitating that.

Under current arrangements, hepatitis B medications entecavir and tenofovir are listed under s100 of the PBS, which allows only accredited community-based practitioners supported by a comprehensive prescriber program to prescribe hepatitis B medications without hospital affiliation. Further details on the scheduling of medications can be found here. Only 22.2% of people living with chronic hepatitis B who received treatment had at least one of their prescriptions written by a GP in 2021, which is no improvement from 22.8% in 2020[1]. Even lower is the percentage of those who received treatment exclusively from a GP in 2021 at 8.3%[1].

A move to s85, in conjunction with considered approaches to ongoing support and training would benefit the community and healthcare workforce in several ways including:

- Expected improved treatment access
  S85 listing for hepatitis B medicines is likely to facilitate increases in community access to medicines. Increased community prescribing will also improve equity of treatment access in regional and rural areas.

  The inclusion of S85 listing of direct-acting antivirals (DAAs) for the treatment of hepatitis C has. significantly benefited Australia's hepatitis C elimination efforts. This classification increased the availability of treatment options for patients and simplified the process, removing the administrative barriers associated with s100 prescriptions. This listing allowed individuals to access a vast range of services for treatment, including NSP services and AOD services, facilitating broader access to medication.

[1] MacLachlan J, Purcell I, Cowie B. Viral Hepatitis Mapping Project: Hepatitis B National Report 2021. ASHM; 2023
[2] The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 12). The Kirby Institute, UNSW Sydney, NSW, Australia, July 2020 (available online at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-12-july-2022).
[3] The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 11). The Kirby Institute, UNSW Sydney, NSW, Australia, July 2021 (available online at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-11-july-2021)
[4] Papatheodoridis, G., et al (2018) Eight-year survival in chronic hepatitis B patients under long-term entecavir or tenofovir therapy is similar to the general population. Journal of Hepatology. 68 (6), 1129 – 1136.
[4] Waziry, R., et al (2016) Trends in hepatocellular carcinoma among people with HBV or HCV notification in Australia 2000-2014. Journal of Hepatology. 65 (6), 1086-1093.
[6] Papatheodoridis, G., et al (2015) Risk of hepatocellular carcinoma in chronic hepatitis B: assessment and modification with current antiviral therapy. Journal of Hepatology. 62 (4), 956-967.

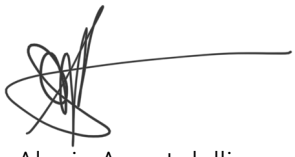
A notable success in Australia's hepatitis C treatment response has been the increase in treatment uptake among people who inject drugs. The proportion of people who inject drugs diagnosed with hepatitis C and subsequently treated rose from 3% in 2015 to 47% in 2019[2]. At a broader level, the proportion of individuals prescribed hepatitis C treatment by general practitioners (GPs) increased from 8% in March 2016 to 45% in December 2020[3], and it is estimated that 49% of individuals people living with hepatitis C in 2015 have initiated treatment at the end of 2020[3].

- Expected improved treatment adherence
  Interruptions to antiviral therapy can have serious consequences including viral rebound and hepatic flare. Adherence challenges are particularly acute in rural and remote areas (including in Aboriginal and Torres Strait Islander communities) due to limited availability and high turnover of accredited S100 treatment providers. This can limit access to scripts for treatment maintenance and exacerbate adherence challenges. Current arrangements can also limit access in urban areas, impacting treatment adherence if people cannot access their specialist or S100 GP for maintenance scripts. With General Schedule listing, any GP would be able to write maintenance scripts, thus removing this adherence barrier.

- Improved health outcomes for people living with hepatitis B due to improved treatment access.
  The drugs used for treatment of hepatitis B are usually lifelong, have few side effects and are highly effective for preventing liver cancer and cirrhosis – with an approximate 50-75% reduction in liver cancer incidence over 5 years following initiation of therapy.[4][5][6]

For these reasons, ASHM and Hepatitis Australia, as the peak bodies for healthcare professionals in hepatitis B and people living with hepatitis B are proposing to advocate for this change and are committed to ensuring all localised considerations are addressed. We would like to thank you for your feedback as part of this consultation process. If you require clarification on any of the points raised in this letter, or any further information, please contact ASHM CEO Alexis Apostolellis at alexis.apostolellis@ashm.org.au or Hepatitis Australia CEO Carrie Fowlie at carrie@hepatitisaustralia.com.

Regards,



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[1] MacLachlan J, Purcell I, Cowie B. Viral Hepatitis Mapping Project: Hepatitis B National Report 2021. ASHM; 2023
[2] The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 12). The Kirby Institute, UNSW Sydney, NSW, Australia, July 2020 (available online at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-12-july-2022).
[3] The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 11). The Kirby Institute, UNSW Sydney, NSW, Australia, July 2021 (available online at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-11-july-2021)
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