GESA
Gastroenterological Society of Australia

POSITION STATEMENT

GESA-ALA Recommendations for the Prescribing of Interferon-Free Treatment Regimens for Chronic HCV Infection

Chronic hepatitis C (CHC) is a major medical issue in Australia (1):

1. **CHC is a physical, mental and social disease,** affecting the individual, their family, and society as a whole.

2. The number of Australians living with CHC is **more than 230,000** (1).

3. **CHC is a leading cause for cirrhosis, liver failure, liver cancer and liver transplant in Australia**. In 2013, it was estimated that there are 14,000 people living with CHC-related cirrhosis in Australia. As a consequence of CHC, 1430 individuals developed liver failure; 590 individuals developed primary liver cancer; 540 people died a liver-related death, and 140 people received a liver transplant as a direct result of CHC, all of whom developed post-transplant HCV recurrence. HCV-related liver disease is the most common indication for liver transplant in Australia, and much of the Western world. If the current treatment paradigm does not change, then the burden of HCV-related liver disease will rise such that in 2030 there will be 38,130 individuals living with HCV-related cirrhosis, 4170 cases of decompensated liver disease, 2040 new diagnoses of HCC and 1740 HCV-related deaths (1).

4. Hepatitis C infection is **curable**. In people with CHC, **cure of HCV infection can prevent cirrhosis, liver failure and liver cancer, improve quality of life, and prevent transmission of HCV**. Current interferon-based treatment regimens are effective in those with early liver disease, with treatment responses ranging from 70%-80%. However, current interferon-based treatment regimens are less effective in those with more advanced liver fibrosis (F3 and F4), and are contra-indicated in people with liver failure. Therefore, those people who require treatment urgently have few, or no, treatment options currently.

5. Current treatment regimens are poorly tolerated and are associated with significant toxicity, including severe constitutional symptoms, depression and bone marrow suppression. Many people are ineligible or intolerant of therapy. Many people choose not to receive the current treatment regimens due to perceived risk of severe side effects.

Treatments for people living with CHC are undergoing a revolution. In the near future, the Australian pharmaceutical benefits scheme will list a number of new interferon-free treatment regimens that are highly effective, short duration, and have few side-effects. **All people living with chronic hepatitis C** are treatment candidates, including those with liver failure, as well as those who are interferon intolerant/ineligible. These patients currently have no treatment options.

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A major challenge will be to deliver these treatments safely and efficiently to a broad range of Australians living with chronic hepatitis C, with a view to treating all people with CHC.

New models of care will be important. It will be important to develop models of care for the **primary care setting**. At the same time, it will be necessary to ensure that people living with CHC undergo a comprehensive **assessment for liver disease** prior to undergoing treatment, such that those that people who require long-term specialist care are identified. ^

There are two critical issues:

1. The identification of people who have **cirrhosis**. This is important due to the ongoing risk of liver disease progression and liver cancer development in patients with liver cirrhosis**.**

2. The identification of **co-existent liver disease**, in particular alcoholic liver disease and non-alcoholic fatty liver disease. These co-existent liver diseases require specific management.

There will also continue to be specific issues related to **patient selection, side-effect management* and drug-drug interactions.**

GESA therefore supports the proposal by the PBAC for new treatments to be listed on the general schedule of drugs of the pharmaceutical benefits scheme (S85).

We support the development of models of care whereby treatment of people with CHC and who **DO NOT have cirrhosis** can be treated in the community. **Community based treatment of CHC should occur in consultation with a clinician experienced in prescribing treatment for chronic hepatitis C,** such as a hepatologist, gastroenterologist or infectious disease physician.

Assessment of severity of liver disease, in particular the presence or absence of liver cirrhosis*, will be essential before commencing treatment as it identifies patients who will require long term specialist follow up, even after achieving viral clearance. This is important due to the ongoing risk of liver disease progression and liver cancer development in patients with liver cirrhosis.

**** Notes***

- Patients with liver cirrhosis should be managed by a specialist in liver disease. These patients require long-term screening for liver cancer and other complications related to liver decompensation. The presence or absence of cirrhosis should be determined by serum markers, liver imaging, transient elastography (or equivalent method) or liver biopsy.

- Treatment regimens containing Ribavirin should have a safety note. Ribavirin is a teratogenic drug (pregnancy Category X) and commonly leads to hemolytic anemia. Pre-treatment counseling, close monitoring and follow up are essential with these regimens.

- Prisoners are a special population. We recommend treatment for prisoners to be listed as highly specialized drugs under Section 100 of the National Health Act. Medical practitioners must be formally associated with specialist hospitals to prescribe these drugs as pharmaceutical benefit items for prisoners.

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