Joint BASL and BSG Statement: Information regarding new monoclonal antibody drugs against Covid-19

Dear BASL and BSG Liver Section members,

With the rapid rise in cases of the Omicron variant of COVID-19 in the UK the NHS potentially faces another surge in hospital admissions and we are all facing familiar uncertainty and drawing on our resilience mechanisms again. The uncertainty is compounded by not yet knowing the severity or otherwise compared to the Delta variant, the moderating effect of vaccination and whether enough of the population are either vaccinated or boosted to exert this effect, and how the new monoclonal antibody drugs for symptomatic mild to moderate disease in the community will impact on admissions. Below is a summary from the relevant policies, with links, for your information.

These new monocolonals now have conditional marketing authorisation for use in non-hospitalised patients in the UK https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103186 .

- Sotrovimab is given by single intravenous infusion and is reported to reduce the relative risk of hospitalisation or death by 85%.

- Molnupiravir is given orally by capsules for 5 days and is reported to reduce the relative risk of hospitalisation or death by 30%.

Patients must meet all of the eligibility criteria and none of the exclusion criteria. Prehospitalised patients are eligible for treatment if:

• SARS-CoV-2 infection is confirmed by polymerase chain reaction (PCR) testing within the last 5 days
AND
• Onset of symptoms of COVID-193 4 within the last 5 days
AND
• A member of a ‘highest’ risk group (as defined in Appendix 1).

Symptoms listed are: feverish, chills, sore throat, cough, shortness of breath or difficulty breathing, nausea, vomiting, diarrhoea, headache, red or watery eyes, body aches, loss of taste or smell, fatigue, loss of appetite, confusion, dizziness, pressure or tight chest, chest pain, stomach ache, rash, sneezing, sputum or phlegm, runny nose.

Appendix 1 includes liver disease in the following categories:

• Patients with cirrhosis Child’s-Pugh class B and C (decompensated liver disease).
• Patients with a liver transplant
• Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis)
• Patients with cirrhosis Child’s-Pugh class A who are not on immune suppressive therapy (compensated liver disease)

Patients will be anxious, and as clinicians we may be contacted for advice. How the delivery of these drugs is to be organised is being worked out at local operational levels. Members are advised to make enquiries within their Trusts for local arrangements. The Liverpool COVID-19 interactions checker is a useful resource https://www.covid19-druginteractions.org/checker . We checked these drugs against the more commonly used immunosuppressants and, for those not familiar with this tool, it is easy to use (no expected interactions for tacrolimus, ciclosprin, azathioprine, mycophenolate, prednisolone).

Members will no doubt be aware that casirivumab and imdevimab (Ronapreve®) has authorisation in hospitalised patients admitted with acute COVID-19. This seems to be less effective in patients with the Omicron variant. Thus where Omicron accounts for more than 50% of the local hospital prevalence, Ronapreve is only recommended where genotyping results are available and confirm infection with a non-Omicron variant. Where genotyping is not available or genotyping confirms infection with the Omicron variant, the December 2021 rapid policy statement advises nMABs can only be offered as part of a formal trial.

Nosocomial acquisition is a bit different. Ronapreve can be used in non-Omicron cases where known, meeting high risk criteria and Sotrovimab has also now been authorised for hospitalised patients who acquire Omicron variant COVID-19 during their hospital stay and meet high risk criteria - for our patients with liver disease, these are the same as those listed above.
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103187

Again, members are advised to check their local Trust policies, but nosocomial acquisition of COVID-19 in patients with liver disease may well meet criteria for the use of these drugs so we thought we would draw your attention to this.

Hepatologists and gastroenterologists have faced very challenging changes to practice over the last two years and rising numbers of patients with liver disease. We know the changing Covid-19 landscape continues to bring new challenges. We hope you all stay safe and well during this period.

Rebecca Jones
President BASL

John Dillon
Vice President Hepatology, BSG