Cirrhosis in over 16s: assessment and management
Consultation on draft scope
Stakeholder comments table

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1	SH	Stanningley Pharma Ltd	General	General	It is disappointing that no mention is made of the importance of appropriate nutritional support for patients with cirrhosis. Such patients have very specific dietary requirements and dietary support is an integral part of patient management. Protein loss, catabolism and issues with protein synthesis contribute to patients with cirrhosis have far greater protein requirements than many other patient groups. Similarly, patients may have problems managing fat in their diet rendering many dietary supplements unsuitable. I have added a couple of review papers which list the full supporting references.	Thank you for your comment. The update of NICE guideline NG50 will focus on some very specific areas which were identified as having new evidence to support an update (See the surveillance review decision). Nutritional support for people with cirrhosis has not been prioritised for inclusion in the scope of this update, however your comments will be passed to our Surveillance team. NICE has made recommendations in other related guidelines which may be of interest. For example, the original guideline NG50 cross refers to NICE guideline NG49 Non-alcoholic fatty liver disease: assessment and management and this includes recommendations on lifestyle modifications.
2	SH	British Society of Gastroenterology	General	General	The scope seems appropriate and reasonable but we feel this is probably not the right time to embark on writing new guidelines as we are awaiting the results of several large, UK based, multi-centre trials on cirrhosis; CALIBRE and BOPPP, looking at primary prophylaxis of variceal bleeding; PEARL looking at outcomes in HCC surveillance; and ASEPTIC, looking at use of prophylactic anitbiotics to prevent first episode of SBP. Some of these trials will be reporting in the next 12-24 months and we will then have better	Thank you for highlighting these trials to us. As noted in the surveillance review decision, we are monitoring CALIBRE, BOPPP and ASEPTIC and have been in contact with the investigators regarding the anticipated completion dates of these trials The investigators have advised that none of

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					evidence on which to base the recommendations. We therefore suggest delaying the development of the guidelines for 6- 12 months at least so that this evidence can be incorporated.	the trials are expected to report during the lifetime of this update or shortly afterwards. The surveillance review has identified that there is new published evidence to support an update at this time, of recommendation 1.3.1 which focuses on the primary prophylaxis of bleeding from medium to large oesophageal varices. According to the protocol for BOPPP, the focus of that trial is on the primary prophylaxis of bleeding from small varices. The surveillance review also identified that there is new published evidence to support an update at this time of recommendation 1.3.5 on the prophylactic use of antibiotics for the primary prevention of spontaneous bacterial peritonitis in people with cirrhosis and ascites. In addition, the existing recommendation focuses on the use of ciprofloxacin and norfloxacin. The MHRA has issued restrictions and precautions for the use of fluoroquinolone antibiotics and norfloxacin has been withdrawn in the UK.

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						For these reasons it is important that this recommendation is updated at this time. Regarding the recommendations on surveillance for hepatocellular carcinoma, the surveillance review did not identify a body of new evidence which would support an update of this area of the guideline at this time. We are aware that the PEARL study is in progress and the committee agreed prior to consultation on the draft scope, that the recommendations on surveillance for hepatocellular carcinoma would not be updated at this time. We will however continue to monitor all of these trials and when they publish their findings, we will consider any implications for our recommendations.
3	SH	British Society of Gastroenterology	General	General	'Why the disparity with PEARL and BOPPP/ASEPTIC? Could the committee be deferred for 6-12 months so evidence from UK studies can be included in the review?'	Thank you. We understand from the trial investigators that BOPPP has a trial end date of December 2026 and ASEPTIC has an end date of August 2025 This means we would need to delay this update by more than a year to include their results. The decision was made internally at NICE that we should go ahead with this update but

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						continue to monitor these trials and when they publish, we will consider any implications for our recommendations. The apparent disparity is because the surveillance review conducted by NICE identified studies to update the recommendations about SBP and EVL, but did not identify evidence to update the recommendations on surveillance for HCC.
4	SH	British Society of Gastroenterology	General	General	'The consensus in the liver section that now is probably not the best time for NICE to be producing these guidelines, with some major UK multi-centre trials in progress and outputs expected shortly after the time of likely publication. We would suggest delaying 6-12 months to allow the initial results of these trials to be available.'	Thank you. We understand from the trial investigators that BOPPP has a trial end date of December 2026 and ASEPTIC has an end date of August 2025 This means we would need to delay this update by more than a year to include their results. The decision was made internally at NICE that we should go ahead with this update but continue to monitor these trials and when they publish, we will consider any implications for our recommendations.
5	SH	British Association for the Study of the Liver (BASL)	General	General	The scope needs to explore the role of non-invasive tests in ruling patient in-or out of endoscopic surveillance	Thank you for your comment. During surveillance, evidence was sought to determine if an update is needed of recommendations 1.27 and 1.28 which focus on endoscopic detection of, and surveillance for, oesophageal varices in

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						people who have been diagnosed with cirrhosis. This is summarised on pages 15-18 of Appendix A of the surveillance decision report. In summary, in response to experts who suggested that not everyone should automatically undergo endoscopy for this purpose, evidence was sought on the accuracy of non-invasive tests to help identify people who should undergo endoscopy. The surveillance report found that there is some uncertainty in the ability of non-invasive tests to rule out oesophageal varices and there is a lack of evidence on the long-term follow-up outcomes of related strategies. Stakeholders were asked during the surveillance consultation, how often and why non-invasive tests are used in the UK as an alternative to endoscopy and if there is evidence on long-term outcomes. However, the consensus was that non-invasive approaches are not used in this way and that the existing guideline position that endoscopy should be used remains sound. This area of the guideline was not therefore identified for update.

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6	SH	British Association for the Study of the Liver (BASL)	General	General	The scope needs to be careful of duplicating national organisation guidelines-but at the same time as also changing them slightly which leads to confusion amongst clinicians and patients. BSG has guidelines that perhaps should now be updated. Baveno has also published recently-but that is a very opinion heavy organisation. NICE previously published on the management of GI bleeding and the guidelines were poor (actually) and were out of date immediately as it recommended banding ahead of beta blockers, whilst the BSG guidelines correctly recommended beta blockers as primary and secondary prophylaxis of choice. So I have a huge concern re these guidelines which is similar to my concern when they were originally published. The most data in the management of cirrhosis is from portal hypertension-and therefore this group will re-write/review what has already been written and I think as far as the management of portal hypertension is concerned should defer to the national organisation guidelines (BSG/BASL) and if it feels these need re-writing, charge those organisations with doing just that. For instance, it is likely that the NICE group will recommend the use of Terlipressin in the management of variceal bleeding. Because Baveno	Thank you for your comment. During the surveillance process, it was highlighted by experts that practitioners currently use non-selective beta blockers for the primary prevention of bleeding from medium to large oesophageal varices. This is in keeping with guidelines from the British Society of Gastroenterology. New evidence in this area, this change in practice and awareness that there is different advice from other organisations, are all contributory factors in making the decision to update NICE guidance in this area. The evidence will be reviewed according to NICE methods and processes by an independent multi-disciplinary committee of experts in the field and as such it is not possible to pre-empt the recommendations which will be made.

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					has, and so did BSG/BASL. But we are having a very active debate currently as to whether that recommendation is based on out of date information. Yet if NICE recommends its use, then we could end up with a very confusing message to patients and other organisations	
7	SH	Alpha-1 UK Support Group	General	General	Alpha-1 antitrypsin deficiency (AATD) is a known cause of liver disease in adults. There is currently no reference to AATD in the Cirrhosis in over 16s: assessment and management guideline. We feel the scope and guideline should address AATDs potential association with liver cirrhosis and that the guideline should also include signposting regarding testing for this genetic condition.	Thank you for your comment. The diagnosis, investigation and management of the underlying causes of cirrhosis is however out of scope for the original guideline and for this update.
8	SH	NHS England	General	General	*Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline?* The cost and availability differential between proposed antibiotics in question 2.1 is significant and may warrant consideration.	Thank you for this helpful information, which will be passed to our health economics advisors.
9	SH	NHS England	General	General	We note that interventions to support medication adherence (for example from the Primary Care	Thank you for your comment. As is noted in the Equality Impact Assessment, the committee are mindful that for some groups support in medication adherence may be

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					Network pharmacist or health coach) may be helpful for some of these patients	helpful. This is part of a broader issue and it may not be possible to directly address it within this guideline update. However, keeping this in mind when the committee make their recommendations may help to ensure that these issues are highlighted in the guideline and taken into account when implementing it.
10	SH	NHS England	General	General	There are numerous mentions of primary prevention but no mention on the role of primary care in primary prevention of SBP, decompensation and ascites.	Thank you for your comment. Please see section 3.2 of the Draft Scope which states that primary care is a setting which will be included within the guideline.
11	SH	United Kingdom Clinical Pharmacy Association	002	007	If mentioning rifaximin for SBP – this would be off label and would be difficult to access due to high cost and would need robust commissioning advice.	Thank you for your comment. Guideline recommendations for medicines will normally fall within licensed indications. Exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.
14	SH	NHS England	006	024	Adherence to NSBB is a key consideration in answering this question since it is a drug group often not well tolerated	Thank you for your comment. Adverse events and quality of life are included in the outcomes for this question and so factors such as this should be taken into

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						consideration by the committee when making their recommendations. There is also information in the EIA document about adherence, especially in people who may have chaotic lifestyles that make regular tablet taking challenging.
15	SH	NHS England	007	011	Should this be adverse events and adverse effects, recognising that some untoward outcomes may not manifest as an event?	Thank you for your comment. Adverse events includes adverse effects.
16	SH	NHS England	007	020	Ditto - Should this be adverse events and adverse effects, recognising that some untoward outcomes may not manifest as an event?	Thank you for your comment. Adverse events includes adverse effects.
17	SH	NHS England	007	029	Ditto - Should this be adverse events and adverse effects, recognising that some untoward outcomes may not manifest as an event?	Thank you for your comment. Adverse events includes adverse effects.