

1                   **NATIONAL INSTITUTE FOR HEALTH AND CARE**  
2                   **EXCELLENCE**

3                   **Guideline scope**

4                   **Cirrhosis in over 16s: assessment and management**  
5                   **(update)**

6                   This guideline will update the NICE guideline on cirrhosis in over 16s: assessment  
7                   and management (NG50).

8                   The guideline will be developed using the methods and processes outlined in  
9                   [developing NICE guidelines: the manual](#).

10                  This guideline may also be used to update the [NICE quality standard for liver](#)  
11                  [disease](#).

12                  **1                   Why the update is needed**

13                  New evidence that could affect recommendations was identified through the  
14                  surveillance process. Topic experts, including those who helped to develop the  
15                  existing guideline, advised NICE on whether areas should be updated or new areas  
16                  added. Full details are set out in the [surveillance review decision](#).

17                  The [scope for the current guideline](#) outlines the reasons why it was needed. Due to  
18                  new evidence, NICE may need to update the recommendations on:

- 19                  • primary prevention of oesophageal variceal haemorrhage  
20                  • primary prevention of spontaneous bacterial peritonitis (SBP) in people with  
21                  cirrhosis and ascites.

22                  The guideline currently recommends endoscopic oesophageal variceal band ligation  
23                  (also known as endoscopic variceal ligation [EVL]) to prevent bleeding from medium-  
24                  sized or large oesophageal varices. Evidence shows that non-selective beta-  
25                  blockers (NSBBs) may be a cost-effective alternative to EVL for reducing bleeding or  
26                  mortality. Feedback from stakeholders suggests that healthcare professionals  
27                  currently use NSBBs.

FINAL

1 We are aware that the UK-based [BOPPP](#) and [CALIBRE](#) trials may be relevant to  
2 these recommendations, but results are unlikely to be available within the  
3 development time of this update (the BOPPP trial is due to end in December 2026  
4 and CALIBRE in February 2024). We will monitor outputs from these trials and  
5 assess whether they have an impact on recommendations.

6 Fluoroquinolones may no longer be the first choice of antibiotics for preventing SBP  
7 in people with cirrhosis. Evidence suggests that rifaximin or co-trimoxazole may be  
8 as effective. Along with an [MHRA Drug safety update on fluoroquinolones](#), this  
9 evidence could impact on the current recommendations.

10 We are aware that ongoing UK-based research (the [ASEPTIC](#) trial) may be relevant  
11 to these recommendations, but is unlikely to publish its results within the  
12 development time of this update (the trial is due to end in August 2025). We will  
13 monitor outputs from that trial and assess whether they have an impact on  
14 recommendations.

15 During surveillance, stakeholders highlighted new published research about the use  
16 of beta-blockers for the primary prevention of decompensation in people with  
17 compensated cirrhosis (the [PREDESCI](#) trial). We will review this evidence and  
18 consider making new recommendations in this area.

19 Stakeholders also highlighted that ultrasound is no longer suitable for surveillance for  
20 hepatocellular carcinoma (HCC) in all populations. This is because of:

- 21 • the rising proportion of cirrhosis related to obesity or alcohol misuse
- 22 • new processes and techniques (both molecular and imaging) for surveillance.

23 We are not updating the recommendations on surveillance for HCC at this time  
24 because of ongoing research (the [PEARL study](#)) in this area.

## 25 **2 Who the guideline is for**

26 This guideline is for:

- 27 • healthcare professionals caring for people with cirrhosis
- 28 • commissioners and providers of healthcare services

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- 1 • people with cirrhosis, their families and carers, and the public.
- 2 NICE guidelines cover health and care in England. Decisions on how they apply in  
3 other UK countries are made by ministers in the [Welsh Government](#), [Scottish](#)  
4 [Government](#) and [Northern Ireland Executive](#).

## 5 **Equality considerations**

6 NICE has carried out an [equality impact assessment](#) during scoping. The  
7 assessment:

- 8 • lists equality issues identified, and how they have been addressed  
9 • explains why any groups are excluded from the scope.

## 10 **3 What the updated guideline will cover**

### 11 **3.1 Who is the focus?**

#### 12 **Groups that will be covered**

- 13 • People with cirrhosis that is suspected or confirmed when they are 16 years or  
14 older.

15 No subgroups of people have been identified as needing specific consideration.

### 16 **3.2 Settings**

#### 17 **Settings that will be covered**

- 18 • Primary, secondary and tertiary NHS-commissioned care.

### 19 **3.3 Activities, services or aspects of care**

#### 20 **Key areas that will be covered in this update**

21 We will look at evidence in the areas below when developing this update. We will  
22 consider making new recommendations or updating existing recommendations in  
23 these areas only.

- 24 1 Managing complications – primary prophylaxis of oesophageal variceal  
25 haemorrhage.

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- 1 2 Managing complications – primary prevention of spontaneous bacterial
- 2 peritonitis (SBP) in people with cirrhosis and ascites.
- 3 3 Primary prevention of decompensation (for example, ascites) in people with
- 4 compensated cirrhosis.

5 Note that guideline recommendations for medicines will normally fall within licensed  
6 indications; exceptionally, and only if clearly supported by evidence, use outside a  
7 licensed indication may be recommended. The guideline will assume that prescribers  
8 will use a medicine's summary of product characteristics to inform decisions made  
9 with individual patients.

### 10 **Proposed outline for the guideline**

11 The table below outlines all the areas that will be included in the guideline. It sets out  
12 what NICE plans to do for each area in this update.

## 1 Proposed outline for the guideline

Area in the guideline	What NICE plans to do
1.1 Diagnosis	No evidence review: retain recommendations from existing guideline.
1.2 Monitoring	No evidence review: retain recommendations from existing guideline.
1.3 Managing complications	<p>Review evidence for primary prophylaxis of variceal haemorrhage: update existing recommendations as needed.</p> <p>Review evidence for primary prevention of spontaneous bacterial peritonitis (SBP) in people with cirrhosis and ascites: update existing recommendations as needed.</p> <p>Retain remaining recommendations from existing guideline.</p>
1.4 Primary prevention of decompensation	<p>New area of guideline.</p> <p>Review evidence on primary prevention of decompensation in people with compensated cirrhosis.</p>

2  
3 Recommendations in areas that are being retained from the existing guideline may  
4 be edited to ensure that they meet current editorial standards, and reflect the current  
5 policy and practice context.

## 6 Areas that will not be covered by the guideline

- 7 1 Diagnosis, investigation and management of the underlying cause of cirrhosis.
- 8 2 Complications because of the underlying cause of cirrhosis.
- 9 3 Liver transplantation (other than the criteria for referral for assessment for liver  
10 transplantation).
- 11 4 Diagnosis of hepatocellular carcinoma.
- 12 5 Management of hepatocellular carcinoma.
- 13 6 Management of variceal haemorrhage.

## 1 **NICE guidance about the experience of people using NHS services**

2 NICE has produced the following guidance on the experience of people using the  
3 NHS. This guideline will not include additional recommendations on these topics  
4 unless there are specific issues related to cirrhosis:

- 5 • [Shared decision making](#) (2021) NICE guideline NG197
- 6 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 7 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 8 • [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- 9 • [Medicines adherence](#) (2009) NICE guideline CG76

### 10 **3.4 Economic aspects**

11 We will take economic aspects into account when making recommendations. We will  
12 develop an economic plan that states for each review question (or key area in the  
13 scope) whether economic considerations are relevant, and if so whether this is an  
14 area that should be prioritised for economic modelling and analysis. We will review  
15 the economic evidence and carry out economic analyses, using an NHS and  
16 personal social services (PSS) perspective, as appropriate.

### 17 **3.5 Key issues and draft questions**

18 While writing the scope for this updated guideline, we have identified the following  
19 key issues and draft questions related to them:

- 20 1 Managing complications – primary prophylaxis of variceal haemorrhage.
  - 21 1.1 What is the clinical and cost-effectiveness of non-selective beta-  
22 blockers (NSBBs), endoscopic variceal ligation (EVL) or NSBBs plus EVL  
23 compared to each other or no intervention for the primary prevention of  
24 bleeding in people with medium to large oesophageal varices due to  
25 cirrhosis?
- 26 2 Managing complications – primary prevention of spontaneous bacterial  
27 peritonitis (SBP) in people with cirrhosis and ascites.
  - 28 2.1 What is the clinical and cost-effectiveness of different antibiotics  
29 compared with each other, placebo or usual care for the primary  
30 prevention of SBP in people with cirrhosis and ascites?

FINAL

- 1 3 Primary prevention of decompensation in people with compensated cirrhosis.  
2 3.1 What is the clinical and cost-effectiveness of NSBBs to prevent  
3 decompensation in people with compensated cirrhosis?

### 4 **3.6 Main outcomes**

5 The main outcomes that may be considered when searching for and assessing the  
6 evidence are:

- 7 • primary variceal bleeding (for question 1.1 only)  
8 • occurrence of spontaneous bacterial peritonitis (for question 2.1 only)  
9 • decompensation episodes  
10 • mortality (including mortality caused by bleeding)  
11 • quality of life (using a validated scale)  
12 • liver transplant  
13 • hospitalisation  
14 • other adverse events

## 15 **4 NICE quality standards**

16 **NICE quality standards that may need to be revised or updated when this**  
17 **guideline is published**

- 18 • [Liver disease](#) (2017) NICE quality standard QS152.

## 19 **Further information**

The guideline update is expected to be published in February 2024.

You can follow progress of the [guideline update](#).

Our website has information about how [NICE guidelines](#) are developed.

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