

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

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

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

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

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

1 Why the update is needed

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

The [scope for the current guideline](#) outlines the reasons why it is needed. Due to new evidence identified through the surveillance process, NICE may need to update the recommendations on:

- primary prophylaxis of oesophageal variceal haemorrhage
- the primary prevention of spontaneous bacterial peritonitis (SBP) in people with cirrhosis and ascites.

The guideline currently recommends endoscopic oesophageal variceal band ligation (also known as endoscopic variceal ligation [EVL]) as primary prophylaxis for preventing bleeding from medium-sized or large oesophageal varices. Evidence identified through surveillance shows that non-selective beta-blockers (NSBBs) may be an effective alternative to EVL for reducing bleeding or mortality. Feedback from

1 stakeholders suggests that healthcare professionals currently use NSBBs for this
2 purpose. New published evidence may also change the guideline's current cost-
3 effectiveness estimates for EVL, which could impact on the existing
4 recommendations.

5 Evidence indicates fluoroquinolones may no longer be the first choice of antibiotics
6 for the primary prevention of SBP in people with cirrhosis and ascites. New
7 published evidence suggests that rifaximin or co-trimoxazole, when compared with
8 fluoroquinolone antibiotics, may be as effective in reducing both SBP and mortality.
9 Along with an [MHRA Drug safety update on fluoroquinolones](#), this evidence could
10 impact on the current recommendations.

11 During surveillance, stakeholders also highlighted new published research about the
12 use of beta-blockers for the primary prevention of decompensation (for example,
13 ascites) in people with compensated cirrhosis. We will review this evidence and
14 consider making new recommendations in this area.

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

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

19 We will not be updating the recommendations on surveillance for HCC at this time
20 due to ongoing research (notably the [PEARL study](#)) in this area.

21 **2 Who the guideline is for**

22 This guideline is for:

- 23 • healthcare professionals caring for people with cirrhosis
- 24 • commissioners and providers of healthcare services
- 25 • people with cirrhosis, their families and carers, and the public.

1 NICE guidelines cover health and care in England. Decisions on how they apply in
2 other UK countries are made by ministers in the [Welsh Government](#), [Scottish](#)
3 [Government](#) and [Northern Ireland Executive](#).

4 **Equality considerations**

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

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

9 **3 What the updated guideline will cover**

10 **3.1 Who is the focus?**

11 **Groups that will be covered**

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

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

15 **3.2 Settings**

16 **Settings that will be covered**

17 Primary, secondary and tertiary NHS-commissioned care.

18 **3.3 Activities, services or aspects of care**

19 **Key areas that will be covered in this update**

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

23 1 Managing complications – primary prophylaxis of oesophageal variceal
24 haemorrhage

25 2 Managing complications – primary prevention of SBP in people with cirrhosis
26 and ascites.

1 3 Primary prevention of decompensation (for example, ascites) in people with
2 compensated cirrhosis.

3

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

9 **Proposed outline for the guideline**

10 The table below outlines all the areas that will be included in the guideline. It sets out
11 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 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 specific to 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 (this will be considered for update at
12 future surveillance due to ongoing research).
- 13 5 Management of hepatocellular carcinoma.
- 14 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 NSBBs, EVL or NSBBs
22 plus EVL compared to each other or no intervention for the primary
23 prevention of bleeding in people with oesophageal varices due to
24 cirrhosis?
- 25 2 Managing complications – primary prevention of SBP in people with cirrhosis
26 and ascites.
 - 27
28 2.1 What is the clinical and cost-effectiveness of different classes of
29 antibiotics compared with each other, placebo or usual care for the
30 primary prevention of SBP in people with cirrhosis and ascites?

1 3 Primary prevention of decompensation in people with compensated cirrhosis.

2

3 3.1 What is the clinical and cost-effectiveness of NSBBs to prevent

4 decompensation in people with compensated cirrhosis?

5 **3.6 Main outcomes**

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

8 1 Managing complications – primary prophylaxis of variceal haemorrhage

9 – Primary variceal bleeding

10 – Mortality (including mortality caused by bleeding)

11 – Adverse events

12 – Quality of life (using a validated scale)

13 – Liver transplant

14 – Number of decompensation episodes

15 – Hospitalisation

16 2 Managing complications – primary prevention of spontaneous bacterial peritonitis
17 in people with cirrhosis and ascites

18 – Occurrence of SBP

19 – Mortality (including mortality caused by SBP)

20 – Adverse events

21 – Quality of life (using a validated scale)

22 – Liver transplant

23 – Number of decompensation episodes

24 – Hospitalisation

25 3 Primary prevention of decompensation and ascites in people with
26 compensated cirrhosis

27 – Number of decompensation episodes

28 – Mortality

29 – Adverse events

30 – Quality of life (using a validated scale)

31 – Liver transplant

1 – Hospitalisation

2 **4 NICE quality standards**

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

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

6 **Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are to be confirmed.

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

You can follow progress of the [guideline update on the in development pages](#).

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

7 © NICE 2022. Subject to [Notice of rights](#).