

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

3 **Guideline scope**

4 **Myalgic encephalomyelitis (or**
5 **encephalopathy)/chronic fatigue syndrome:**
6 **diagnosis and management**

7 The Department of Health and Social Care in England has asked NICE to
8 develop guidance on diagnosing and managing myalgic encephalomyelitis (or
9 encephalopathy)/chronic fatigue syndrome (ME/CFS).

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

12 This guideline will replace the NICE guideline on chronic fatigue
13 syndrome/myalgic encephalomyelitis (or encephalopathy) (CG53).

14 **1 Why the guideline is needed**

15 This guideline scope uses the term 'ME/CFS' but this is one of a number of
16 names that have been used to describe this illness. It is recognised that there
17 are people who need care but who may not meet existing clinical or research
18 criteria.

19 ME/CFS is a disabling and distressing illness characterised by extreme and
20 debilitating fatigue, particularly after exertion. Clinically, ME/CFS is
21 heterogeneous and multifactorial and people experience the illness differently.
22 Common symptoms include chronic pain, disordered sleep, digestive
23 problems and cognitive difficulties. For most people with ME/CFS, everyday
24 life is severely disrupted and a complete recovery is unusual, although this
25 can vary depending on the age of onset.

26 The causes of ME/CFS are unknown but there are thought to be many
27 contributing factors. One commonly reported trigger is the onset of a viral

1 illness and post-viral malaise, although the reasons for this being a trigger for
2 ME/CFS are not understood. The lack of understanding of the aetiology of the
3 condition has contributed to a number of different symptom-based definitions
4 being used in research and in clinical care. Ongoing research into the causes
5 and pathological processes underlying the symptoms of ME/CFS includes
6 examination of immune function, autonomic function, neuroendocrine
7 disorders and gene expression.

8 The estimated minimum prevalence rate of ME/CFS in the UK was 0.2% for
9 people meeting either the Centers for Disease Control and Prevention (CDC)
10 or Canadian case definitions in a UK primary care cross-sectional study.
11 People with ME/CFS report delays in diagnosis, and research has highlighted
12 that many GPs lack the confidence and knowledge to diagnose and manage
13 ME/CFS. However, a review of diagnoses at a referral centre found that 40%
14 of people referred did not have CFS but had fatigue associated with another
15 chronic disease; a primary sleep disorder; a psychological or psychiatric
16 illness; or a cardiovascular disorder. In the same review, 5.2% of all the
17 people referred did not have a clear cause identified to explain their fatigue.

18 People with ME/CFS have reported a lack of understanding among health and
19 social care professionals about their illness and related problems. There are
20 added issues for children, young people and their carers when illness makes
21 school attendance difficult and families come to the attention of educational
22 and social care services.

23 The previous NICE guideline (CG53) made recommendations on the use of
24 cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The
25 evidence supporting these interventions has been challenged and some
26 people with ME/CFS report being pressured to participate in exercise
27 programmes, leading to a worsening of symptoms. There is therefore a need
28 to review the evidence for these and other interventions.

29 **2 Who the guideline is for**

30 This guideline is for:

- 1 • All health and social care professionals including those working or
- 2 providing input into educational and occupational health services
- 3 • Commissioners
- 4 • People with suspected or diagnosed ME/CFS, their families and carers and
- 5 the public

6 It may also be relevant for:

- 7 • education services
- 8 • occupational health services
- 9 • voluntary sector organisations

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

13 ***Equality considerations***

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

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

18 The guideline will look at inequalities relating to ethnic origin.

19 **3 What the guideline will cover**

20 **3.1 Who is the focus?**

21 **Groups that will be covered**

- 22 • People with suspected or diagnosed ME/CFS
- 23 • Specific consideration will be given to:
 - 24 – children and young people
 - 25 – people with severe symptoms.

1 **3.2 Settings**

2 **Settings that will be covered**

3 All settings where NHS or social care is provided or commissioned, including
4 health services related to education and occupational health.

5 **3.3 Activities, services or aspects of care**

6 **Key areas that will be covered**

7 We will look at evidence in the areas below when developing the guideline,
8 but it may not be possible to make recommendations in all the areas.

9 1 Identification and assessment before diagnosis

10 2 Diagnosis of ME/CFS

11 3 Management of ME/CFS

12 4 Monitoring and review

13 5 Information, education and support for people with suspected and
14 diagnosed ME/CFS, and their families and carers

15 6 Information, education and support for health and social care
16 professionals.

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

22 **Areas that will not be covered**

23 1 The specific management of symptoms where NICE guidance already
24 exists (see below for related NICE guidelines) and management is not
25 expected to be different in ME/CFS

26 **Related NICE guidance**

27 ***Published***

- 28 • [Lyme disease](#) (2018). NICE guideline NG95

- 1 • [Neuropathic pain in adults: pharmacological management in non-specialist settings](#) (2013). NICE guideline CG173
- 2
- 3 • [Headaches in over 12s: diagnosis and management](#) (2012). NICE
- 4 guideline CG150
- 5 • [Common mental health problems: identification and pathways to care](#)
- 6 (2011). NICE guideline CG123
- 7 • [Irritable bowel syndrome in adults: diagnosis and management](#) (2008).
- 8 NICE guideline CG61

9 ***In development***

- 10 • [Thyroid disease: assessment and management](#). NICE guideline.
- 11 Publication expected November 2019
- 12 • [Chronic pain: assessment and management](#). NICE guideline. Publication
- 13 expected January 2020

14 ***NICE guidance that will be replaced by this guideline***

- 15 • [Chronic fatigue syndrome/myalgic encephalomyelitis \(or encephalopathy\): diagnosis and management](#) (2007) NICE guideline CG53
- 16

17 **NICE guidance about the experience of people using NHS services**

18 NICE has produced the following guidance on the experience of people using
19 the NHS. This guideline will not include additional recommendations on these
20 topics unless there are specific issues related to ME/CFS:

- 21 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 22 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 23 • [Service user experience in adult mental health](#) (2011) NICE guideline
- 24 CG136
- 25 • [Medicines adherence](#) (2009) NICE guideline CG76

26 **3.4 Economic aspects**

27 We will take economic aspects into account when making recommendations.
28 We will develop an economic plan that states for each review question (or key
29 area in the scope) whether economic considerations are relevant, and if so

1 whether this is an area that should be prioritised for economic modelling and
2 analysis. We will review the economic evidence and carry out economic
3 analyses, using an NHS and Personal Social Services perspective.

4 **3.5 Key issues and draft questions**

5 While writing this scope, we have identified the following key issues and draft
6 question related to them:

- 7 1 Identification and assessment before diagnosis
 - 8 1.1 In whom should ME/CFS be suspected?
 - 9 1.2 What is the most clinically and cost effective method of assessing
10 people with suspected ME/CFS?
 - 11 1.3 Can disability or assessment scales aid the identification of people
12 with ME/CFS?
 - 13 1.4 What are the barriers and facilitators to the identification of ME/CFS?
 - 14 1.5 What are the precautionary management strategies that should be
15 adopted before diagnosis?
- 16 2 Diagnosis of ME/CFS
 - 17 2.1 What tests are clinically and cost effective in making a diagnosis of
18 ME/CFS?
 - 19 2.2 In people with suspected ME/CFS, what are the criteria used to
20 establish a diagnosis?
 - 21 2.3 What are the barriers and facilitators to the diagnosis of ME/CFS?
- 22 3 Management of ME/CFS
 - 23 3.1 What is the clinical and cost effectiveness of pharmacological
24 interventions for people with ME/CFS?
 - 25 3.2 What is the clinical and cost effectiveness of non-pharmacological
26 interventions for people with ME/CFS?
 - 27 3.3 What is the clinical and cost effectiveness of self-management
28 strategies for people with ME/CFS?
 - 29 3.4 In people with ME/CFS, what is the clinical and cost effectiveness of
30 different models of multidisciplinary team care, including team
31 composition?
- 32 4 Monitoring and review

1 4.1 What is the most clinically and cost effective method of monitoring
2 people with ME/CFS?

3 4.2 What is the most clinically and cost effective method of reviewing
4 people with ME/CFS?

5 4.3 What are the barriers and facilitators to the care of people with
6 ME/CFS?

7 5 Information, education and support for people with suspected and
8 diagnosed ME/CFS, and their families and carers

9 5.1 What information, education and support do people with ME/CFS
10 and their families and carers need?

11 6 Information, education and support for health and social care
12 professionals

13 6.1 What information, education and support do health and social care
14 professionals who provide care for people with ME/CFS need?

15 **3.6 Main outcomes**

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

18 1 Quality of life (for example, EQ-5D, SF-36)

19 2 Pain

20 3 Fatigue

21 4 Physical and cognitive functioning (a person's ability to do everyday
22 tasks and activities)

23 5 Psychological wellbeing

24 6 Care needs

25 7 Sleep

26 **4 NICE Pathways**

27 When this guideline is published, we will update the NICE Pathway on
28 [ME/CFS](#). NICE Pathways bring together everything we have said on a topic in
29 interactive flowcharts.

1 **5 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 21 June to 19 July 2018.

The guideline is expected to be published in October 2020.

You can follow progress of the guideline.

<https://www.nice.org.uk/guidance/indevelopment/gid-ng10091>

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

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