

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management

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

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

This guideline replaces CG53.

1 Why the guideline is needed

The guideline scope is using the term ME/CFS to indicate the condition the guideline is addressing. It is recognised that the term is an umbrella term and that those who need care may not meet existing clinical or research criteria.

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS) are terms used for conditions characterized by extreme fatigue (particularly after exertion) and other debilitating symptoms such as malaise, chronic pain, and cognitive difficulties. Research is ongoing into the causes and pathological processes underlying these symptoms and includes examination of immune function, autonomic function, neuroendocrine disorders and gene expression.

The lack of understanding of the aetiology of the condition has contributed to a number of different symptom based definitions used in research and/or clinical care. The Centre for Disease Control and Prevention (CDC) case definition has been widely used for research purposes. It includes the

1 requirement for symptoms to be present for six months before a diagnosis can
2 be made which can be unhelpful in clinical practice.

3 The estimated minimum prevalence rate of ME/CFS was 0.2% for people
4 meeting one of the case definitions used in a UK primary care cross-sectional
5 study. People with ME/CFS report delays in diagnosis and research has
6 highlighted that many GPs lack the confidence and knowledge to diagnose
7 and manage ME/CFS. Conversely a review of diagnoses at a referral centre
8 found that 40% of people referred did not have CFS but had fatigue
9 associated with either another chronic disease, primary sleep disorders,
10 psychological/psychiatric illnesses or a cardiovascular disorder. In the same
11 review 5.2% of the total referrals did not have a clear cause identified to
12 explain the fatigue.

13 People with ME/CFS commonly report a lack of understanding among health
14 and social care professionals about their illness and related problems. There
15 are added issues for children, young people and their carers when illness
16 makes school attendance difficult and families come to the attention of
17 educational and social care services.

18 NICE guideline CG53 made recommendations for use of cognitive
19 behavioural therapy (CBT) and graded exercise therapy (GET). The evidence
20 supporting these interventions has been challenged and some people report
21 having been pressured to participate in exercise programmes. There is a need
22 to review the evidence for these and other interventions.

23 **2 Who the guideline is for**

24 This guideline is for:

- 25 • people using services, their families and carers and the public
- 26 • all health and social care professionals

27 It may also be relevant for:

- 28 • education services

- 1 • occupational health services
- 2 • voluntary sector organisations

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

6 ***Equality considerations***

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

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

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

12 **3 What the guideline will cover**

13 ***3.1 Who is the focus?***

14 **Groups that will be covered**

- 15 • Children, young people and adults with suspected or diagnosed ME/CFS
- 16 • Specific consideration will be given to children, young people and adults
 17 with severe symptoms.

18 **Groups that will not be covered**

- 19 • People for whom a diagnosis of ME/CFS has been excluded

20 ***3.2 Settings***

21 **Settings that will be covered**

22 All settings where NHS or social care is provided or commissioned

3.3 *Activities, services or aspects of care*

Key areas that will be covered

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

- 1 Identification and assessment before diagnosis
- 2 Diagnosis of ME/CFS
- 3 Management of ME/CFS
- 4 Monitoring and review
- 5 Information, education and support for people with suspected and diagnosed ME/CFS, their families and carers

Note that 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.

Areas that will not be covered

- 1 The management of comorbid conditions
- 2 The specific management of symptoms where NICE guidance already exists (see below related NICE guidelines)

Related NICE guidance

Published

- Lyme disease (2018). NICE guideline NG95
- Neuropathic pain in adults: pharmacological management in non-specialist settings (2013). NICE guideline CG173
- Headaches in over 12s: diagnosis and management (2012). NICE guideline CG150
- Common mental health problems: identification and pathways to care (2011). NICE guideline CG123

- Irritable bowel syndrome in adults: diagnosis and management (2008).
NICE guideline CG61

In development

- Thyroid disease: assessment and management NICE guideline. Publication expected November 2019
- Chronic pain: assessment and management. NICE guideline. Publication expected January 2020

NICE guidance that will be updated by this guideline

- Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (2007) NICE guideline CG53

NICE guidance about the experience of people using NHS services

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

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

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and Personal Social Services perspective.

3.5 Key issues and draft questions

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

- 1 1 Identification and assessment before diagnosis
- 2 1.1 In whom should ME/CFS be suspected?
- 3 1.2 What is the most clinically and cost effective method of assessing
- 4 people with suspected ME/CFS?
- 5 1.3 Can disability or assessment scales aid the identification of people
- 6 with ME/CFS?
- 7 1.4 What are the barriers and facilitators to the identification of ME/CFS?
- 8
- 9 2 Diagnosis of ME/CFS
- 10 2.1 What tests are clinically and cost effective in supporting or excluding
- 11 a diagnosis of ME/CFS?
- 12 2.2 In people with suspected ME/CFS how accurate are the criteria used
- 13 to establish the diagnosis?
- 14
- 15 3 Management of ME/CFS
- 16 3.1 What is the clinical and cost effectiveness of pharmacological
- 17 interventions for people with ME/CFS?
- 18 3.2 What is the clinical and cost effectiveness of non-pharmacological
- 19 interventions for people with ME/CFS (including dietary supplementation,
- 20 graded exercise therapy, pacing, the Lightning Process and
- 21 psychological interventions such as CBT)?
- 22 3.3 What is the clinical and cost effectiveness of self-management
- 23 strategies such as heart rate monitors for people with ME/CFS?
- 24
- 25 4 Monitoring and review
- 26 4.1 What is the most clinically and cost effective method of monitoring
- 27 people with ME/CFS?
- 28 4.2 What is the most clinically and cost effective method of reviewing
- 29 people with ME/CFS?
- 30
- 31 5 Information and support for people with suspected and diagnosed
- 32 ME/CFS?
- 33 5.1 What information and support do people with ME/CFS and their
- 34 families / carers require?

3.6 Main outcomes

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

- 1 Quality of life (for example EQ-5D, SF-36)
- 2 Pain
- 3 Fatigue
- 4 Physical functioning (a person's ability to do everyday tasks and activities)
- 5 Psychological well-being
- 6 Care needs

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

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

- [Title of quality standard] ([year]) NICE quality standard [number]
- [Use 'Bullet left 1 last' style for final point.]

NICE quality standards that will use this guideline as an evidence source when they are being developed

- [Title of quality standard] NICE quality standard. Publication expected [Month Year] **or** Publication date to be confirmed
- [Use 'Bullet left 1 last' style for final point.]

4.2 NICE Pathways

[Type here; use 'NICE normal' style]

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 2010.

You can follow progress of the guideline.

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

[After consultation, delete the first paragraph above and replace it with 'This is the final scope, which takes into account comments from registered stakeholders during consultation'.]

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

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