

**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 will replace the NICE guideline on chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy; CG53).

**1 Why the guideline is needed**

This guideline scope uses 'ME/CFS' but this is not intended to endorse a particular definition of this illness, which has been described using many different names. The description and diagnostic criteria used in clinical practice and research have been contested, and many people do not meet the existing criteria but still need care. Diagnostic criteria will be considered as part of the guideline development.

ME/CFS is a chronic and disabling illness that has considerable personal, social and economic consequences. The severity of the condition varies widely, with symptoms ranging from mild to very severe, and its fluctuating course means that everyday life for people with ME/CFS and their family members and carers is disrupted and unpredictable. People with very severe ME/CFS can be bedbound with little functional capacity and need 24-hour care.

People with ME/CFS experience a wide range of symptoms and comorbidities. 'Profound malaise' has been proposed instead of fatigue to describe a characteristic symptom on the basis that fatigue does not adequately describe the severity of symptoms. Post-exertional malaise and deterioration of symptoms are considered typical of ME/CFS. Other common symptoms include chronic pain, disordered sleep, cognitive difficulties, digestive, autonomic, sensory and motor dysfunction.

It is not clear what causes ME/CFS. Ongoing research into underlying causes and pathological processes have examined immune function, autonomic function, neuroendocrine disorders, neuroimaging, gut microbiome, metabolomics and gene expression. One commonly reported factor is the onset of a viral illness followed by post-viral malaise although the mechanisms for this being a factor for ME/CFS are not currently understood.

In 2011, the estimated minimum prevalence rate of ME/CFS in the UK was 0.2% for people meeting either the Centers for Disease Control and Prevention (CDC) or Canadian case definitions in a UK primary care cross-sectional study.

People with ME/CFS report delays in diagnosis, and research has highlighted that many GPs lack the confidence and knowledge to recognise, diagnose and manage ME/CFS. One review of diagnoses at a referral centre found that 40% of people referred did not have CFS but had fatigue associated with another chronic disease, including sleep disorders, psychological or psychiatric illnesses, or cardiovascular disorders. In the same review, 5.2% of the people referred did not have a clear cause identified to explain their fatigue.

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

The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). Concerns have since been raised about these interventions, including challenges to the evidence supporting them and reports that people with ME/CFS have been pressured to participate in exercise programmes, leading to a worsening of symptoms. There is a need to review the evidence for these and other interventions.

## 2 Who the guideline is for

This guideline is for:

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

It may also be relevant for:

- Schools and other education providers
- Occupational health services
- Voluntary sector organisations.

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

### ***Equality considerations***

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

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

The guideline will look at inequalities relating to disability, sex, sexual orientation and gender identity.

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

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

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

- People with suspected or diagnosed ME/CFS
- Specific consideration will be given to:
  - children and young people
  - people with severe ME/CFS.

### **3.2 *Settings***

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

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

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

#### **Key areas that will be covered**

We will look at evidence in the below areas when developing the guideline, but it may not be possible to make recommendations in all of the areas. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

- 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 or diagnosed ME/CFS and their families and carers
- 6 Information, education and support for health and social care professionals.

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 specific management of conditions for which NICE guidance already exists or is in development (see below for related NICE guidelines) and management is not expected to be different in ME/CFS.

### **Related NICE guidance**

#### ***Published***

- [Lyme disease](#) (2018). NICE guideline NG95.
- [Transition from children's to adults' services for young people using health or social care services](#) (2016). NICE guideline NG43.
- [Coeliac disease recognition, assessment and management](#) (2015). NICE guideline NG20.
- [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.
- [Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition](#) (2006). NICE guideline CG32.
- [Referral guidelines for suspected cancer](#) (2005). NICE guideline CG27.

#### ***In development***

- [Thyroid disease: assessment and management](#). NICE guideline.  
Publication expected November 2019.

- [Chronic pain: assessment and management](#). NICE guideline. Publication expected January 2020
- [Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s](#). NICE guideline. Publication expected August 2020.
- [Infant, children and young people's experience of healthcare](#). NICE guideline. Publication expected April 2021.
- [Shared decision making](#). NICE guideline. Publication expected April 2021.
- [Suspected neurological conditions](#). NICE guideline. Publication TBC.

***NICE guidance that will be replaced 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.
- [People's experience in adult social care services](#) (2018). NICE guideline NG86.

### **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 Identification and assessment before diagnosis
  - 1.1 In whom should ME/CFS be suspected?
  - 1.2 What is the most clinically and cost-effective method of assessing people with suspected ME/CFS?
  - 1.3 Can disability or assessment scales aid the identification of people with ME/CFS?
  - 1.4 What are the barriers and facilitators to the identification of ME/CFS?
  - 1.5 What are the precautionary management strategies that should be adopted before diagnosis?
- 2 Diagnosis of ME/CFS
  - 2.1 What tests are clinically and cost effective in diagnosing ME/CFS?
  - 2.2 In people with suspected ME/CFS, what are the criteria used to establish a diagnosis?
  - 2.3 What are the barriers and facilitators to the diagnosis of ME/CFS?
- 3 Management of ME/CFS
  - 3.1 What is the clinical and cost effectiveness of pharmacological interventions for people with ME/CFS?
  - 3.2 What is the clinical and cost effectiveness of non-pharmacological interventions (such as diet and pacing) for people with ME/CFS?
  - 3.3 What is the clinical and cost effectiveness of self-management strategies for people with ME/CFS?
  - 3.4 In people with ME/CFS, what is the clinical and cost effectiveness of different models of multidisciplinary care, including team composition?
- 4 Monitoring and review
  - 4.1 What is the most clinically and cost-effective method of monitoring people with ME/CFS?
  - 4.2 What is the most clinically and cost-effective method of reviewing people with ME/CFS?
  - 4.3 What are the barriers and facilitators to the care of people with ME/CFS?

- 5 Information, education, and support for people with suspected or diagnosed ME/CFS and their families and carers
  - 5.1 What information, education and support do people with ME/CFS and their families and carers need?
- 6 Information, education and support for health and social care professionals
  - 6.1 What information, education and support do health and social care professionals who provide care for people with ME/CFS need?
  - 6.2 What are the barriers and facilitators to providing information, education and support for health and social care professionals?

### **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 and cognitive functioning (a person's ability to do everyday tasks and activities)
- 5 Care needs
- 6 Sleep
- 7 Impact on the carer
- 8 Adverse effects

## **4 NICE Pathways**

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

## **5 Further information**

This is the final scope, which takes into account comments from registered stakeholders during consultation.



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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