

Clinical Commissioning Policy

CMICB_Clin066

Chronic fatigue syndrome/Myalgic Encephalomyelitis (CFS/ME): Inpatient Management

Category 1 Interventions – Not routinely commissioned

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Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

- 1.1 Inpatient management of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is not routinely commissioned.

2. Exclusions

- 2.1 None.

3. Core Eligibility Criteria

- 3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

- 3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the [NHS England gender services programme](https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/) - <https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/>

4. Rationale behind the policy statement

- 4.1 Based on NICE guideline NG 206 (myalgic encephalomyelitis /chronic fatigue syndrome: diagnosis and management) and other literature, current evidence doesn't support widespread hospital admissions for these patients.

5. Summary of evidence review and references

- 5.1 Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a disabling clinical condition characterised by unexplained and persistent post exertional fatigue accompanied by a variety of symptoms related to cognitive, immunological, endocrinological, and autonomic dysfunction. It results in a substantial reduction in previous levels of occupational, educational, social and personal activities in a patient's lifetime.¹ Unsurprisingly, the condition imposes an immense burden on patients, carers and families.² Diagnosis and treatment of ME/CFS presents a challenge to specialists because this syndrome is not a clearly identified, uniform disease but is a set of symptoms resembling those occurring in many other diseases in which chronic fatigue predominates. In order to illustrate this latter point, in a cross-sectional study, out of a cohort of 1400 people who self-presented with fatigue, only 69 (4.9%) were subsequently confirmed as having ME/CFS.³
- 5.2 A major problem in the context of this disease is that many UK doctors do not recognise the condition as a genuine clinical entity. Disbelief is widespread and many physicians lack the knowledge and understanding of the illness. The literature suggests that between a third and a half of GPs refuse to accept the reality of the condition.⁴ Controversy exists whether ME/CFS is an organic disease, a psychosomatic illness, or whether it even exists at all.⁵
- 5.3 Global prevalence of ME/CFS has been estimated to lie between 0.2% to 2.6%^{3,6}, the estimates vary depending on case definition and recruitment methodology. Prevalence has also been estimated at 0.1% – 0.5% in the USA¹ and 0.2% in the UK.³ The disease affects all ages, races and socio-economic groups and approximately 3 – 4 times as many women as men will present with symptoms. Unemployment in those affected is said to occur in 35% – 69% of cases.¹ There are approximately 250,000 sufferers in the UK⁴ and is most commonly observed in 20 – 40-year-olds and more frequently in professionally active women.³
- 5.4 Unfortunately, ME/CFS also occurs in children with a peak incidence occurring in ages 10 – 19 years. This peak occurs in addition to the one for adults in their 20s and 30s.⁷ An Australian study reviewed the medical records of all patients attending the paediatric chronic fatigue clinic over a 12-month period. Median age was 15.4 years with almost two thirds of patients being female. There was a high occurrence of fatigue, sleep disturbance, pain, postexertional malaise and autonomic and cognitive symptoms. Functional impact was classified as mild (20%), moderate (66%) and severe (14%).⁸ Prognosis is better in children with 54% – 94% of children improving or making a complete recovery from the illness compared to a maximum of 22% in adults.⁹
- 5.5 The two main treatment modalities for ME/CFS are cognitive behaviour therapy (CBT) and exercise therapy. In 2008 a Cochrane review concluded that CBT was effective in reducing the symptoms and may be more effective in reducing fatigue symptoms compared with other psychological therapies. However, the evidence base on follow-up is limited to a small group of studies with inconsistent findings and further studies are required to inform the development of effective treatment programmes.¹⁰ A more recent Cochrane review (2019) compared exercise therapy with a variety of other options such as CBT, adaptive pacing, antidepressants and controls. The authors concluded that exercise therapy *probably* has a positive effect on fatigue in adults compared to usual care or passive therapies. However, due to the limited evidence, it was difficult to draw conclusions about the comparative effectiveness of CBT, adaptive pacing or other interventions and the authors were uncertain if the improvement lasts in the long term.¹¹

Specialist management

- 5.6 The literature search for this rapid review combined the terms chronic fatigue syndrome and myalgic encephalomyelitis/encephalopathy with hospital, inpatient and secondary care limited to publications from 2013 – 2022. This was performed to identify any articles which discuss the need for hospitalisation and associated referral criteria.
- 5.7 Limited data were found but a couple of articles which covered specialist care for ME/CFS in the UK are worthy of note. There are approximately 50 specialist centres in the UK who collectively see around 8, 000 patients per annum. A study in 2013 compared the impact on patient outcomes of patients being treated by 6 (representative) specialist centres to clinical trial data for participants receiving CBT/exercise therapy.⁶ The authors concluded that patients who attend NHS specialist services can expect similar improvements in fatigue, anxiety and depression to those participants receiving CBT and graded exercise therapy in the trial. Specialist centre patients, however, were likely to experience less improvement in physical function and this required urgent investigation.
- 5.8 A second, more recent (2017) review, again looked at patient outcomes in 11 specialist services and tracked progress from 1 – 5 years.² After one year, 64% of patients had improved whereas 20% were worse or very worse. Interestingly, for those patients followed up 5 years later, reported improvement occurred in 57.9% and worse outcomes in 30.6% of participants. This could be interpreted that the long-term benefit associated with the specialist centres may deteriorate over time. Overall, however, the specialist centres achieve good outcomes in a substantial proportion of patients, but (as the authors themselves concluded), ME/CFS is a long-term condition which persists with the majority of adult patients even after receiving specialist treatment.
- 5.9 Most importantly, none of the identified studies describe any pathway which involves hospitalisation or inpatient referral for any degree of disease severity.

NICE guidance

- 5.10 NICE published its guideline (NG 206) on the diagnosis and management of ME/CFS in October 2021.¹² NICE acknowledge there is no diagnostic test or universally accepted definition for this condition. It notes that CBT and graded exercise therapy treatments are controversial and there are disagreements and uncertainty about the effectiveness among patients and health providers. Evidence of effectiveness for other prescribed therapies has also been questioned.
- 5.11 Irrespective of this, NG 206 further states that everyday life for people with ME/CFS, their family and carers is disrupted and unpredictable. Many patients are unemployed and less than a fifth work full-time. Approximately 25% have severe disease and are housebound or bedbound. The quality-of-life is lower than that of many people with other severe chronic conditions including multiple sclerosis and some forms of cancer.
- 5.12 Although there are no universally accepted definitions, NICE provide a guide to the level of impact of symptoms and describe severe/very severe disease as follows:
- 5.13 People with **severe** ME/CFS:
- are unable to do any activity for themselves or can carry out minimal daily tasks only (e.g. face washing or cleaning teeth).
 - have severe cognitive difficulties and may depend on a wheelchair for mobility.
 - are often unable to leave the house or have a severe and prolonged after-effect if they do so.
 - may spend most of their time in bed and are often extremely sensitive to light and sound.

5.14 People with **very severe** ME/CFS:

- are in bed all day and dependent on care.
- may need help with personal hygiene and eating.
- are very sensitive to sensory stimuli.
- may be unable to swallow and may need to tube feed.

5.15 Importantly, NICE specify that its recommendations apply to all patients, regardless of symptom severity. For people with severe or very severe ME/CFS, the specialist team should offer home visits to carry out their holistic assessment and develop their care and support plan. Service providers should also be flexible in delivering services to people with severe/very severe disease and this could include home visits, online or phone consultations etc. The only reference to hospital care for severe/very severe patients is concerned with preadmission planning. This relates to facilities/support steps which must be in place to maximise the patient's comfort during any potential admission which isn't necessarily related to their ME/CFS.

5.16 There are no referral criteria to hospital and it is not unreasonable to infer that NICE are expecting the bulk of management to be driven by the specialist team, who would perform home visits when necessary, irrespective of severity. There is no specific suggestion within the guidance that patients with severe disease should be admitted to hospital.

Controversy surrounding NICE guideline NG 206

5.17 NG 206, as discussed above, was first published on 10th November 2020. The guideline recommended against graded exercise therapy and cautioned that CBT was not a cure for ME/CFS. This stance caused significant controversy amongst interested professionals and patients to the extent that on 17th August 2021, NICE announced a "pause" in the publication. Part of the problem is the disease is still poorly understood and because of this there are strong views around its management.

5.18 Despite its rigorous methodology and process, in bringing together the available evidence and real, lived experience and testimony of patients, NICE had been unable to produce a guideline which was supported by all. NICE's concern was unless the recommendations were supported and implemented by professionals, people with ME/CFS may not get the care and help they needed.

5.19 In order to progress this matter, on 21st September 2021, NICE announced a forthcoming roundtable discussion for all parties to discuss the key issues. Professor Dame Carol Black had agreed to act as the independent chair of the roundtable discussion. The agenda focused on diagnosis, graded exercise therapy, children and young people and CBT. On the 29 October 2021, the updated guideline was republished. The new guideline emphasised the importance of a personalised management plan yet reiterated its stance on graded exercise therapy and CBT which should be offered to control symptoms and not regarded as a cure.

5.20 To support commissioners, NICE issued a statement (12th of May 2022) which acknowledged that many of its recommendations represented a change to current practice and will take some time for the various agencies (NHS included) to implement. The areas requiring most consideration were listed as:

- Ensuring the availability of experts in secondary care to provide guidance to primary care.
- Updating training for all staff to ensure that up-to-date recommendations are disseminated.
- Ensuring early access to paediatric review.

- Investment will be needed to increase the number of specialist clinics and specialists with expertise to diagnose and develop care plans.
- Developing capacity in primary care, specialist clinics and paediatric clinics to enable the recommended appointments.

Reviewing the Cheshire CCG policy

- 5.21 Based on NICE guidance and other literature, there is no published evidence which would support admission to hospital for management purely of ME/CFS. The controversy surrounding the newly introduced NG 206 is mainly concerned with graded exercise therapy and CBT. It is concluded, therefore, that the current Cheshire CCG policy for inpatient admission for ME/CFS of “not routinely commissioned” should be maintained.
- 5.22 *In summary*, myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a disabling condition characterised by unexplained and persistent postexertional fatigue accompanied by a variety of symptoms related to cognitive, immunological, endocrinological and autonomic dysfunction. It imposes an immense burden on patients, carers and their families.
- 5.23 The estimated prevalence in the UK is 0.2% and a major problem is distinguishing ME/CFS from many other illnesses which also present with fatigue. Controversy exists whether this is an organic disease, a psychosomatic illness or whether it even exists at all. In 2020, NICE first published its guideline (NG 206) which acknowledged the disruption to daily life which ME/CFS causes and also highlighted the lack of objective diagnostic criteria and the controversy surrounding the effectiveness of the 2 most common treatments i.e. CBT and graded exercise therapy. The main focus of NG 206 is having adequate specialist capacity to advise on diagnosis and treatment. The guidance applies to all ranges of severity but there are no referral criteria or recommendations for hospital admission.
- 5.24 There was initial controversy regarding the guideline as soon as it was published which was followed by a pause in implementation. This resulted in a few months delay which was eventually resolved by October 2021. The main areas of concern seem to be concerned with the recommendations on graded exercise therapy and CBT.
- 5.25 Based on the new NICE guideline and other literature, it was concluded that published literature doesn't provide evidence which supports hospital admission for these patients. With the exception of north Staffordshire and Mersey CCGs (who do not routinely commission inpatient management of ME/CFS patients), the other neighbouring CCGs together with the EBI programme and the Specialised Commissioning manual contain no policy for this intervention
- 5.26 It is therefore concluded that the current CCG policy to not routinely commission inpatient management for ME/CFS should be maintained.

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6. Advice and Guidance

6.1 Aim and Objectives

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.
- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.
- At the time of publication, the evidence presented per procedure/treatment was the most current available.
- The main objective for having healthcare commissioning policies is to ensure that:
 - Patients receive appropriate health treatments
 - Treatments with no or a very limited evidence base are not used; and
 - Treatments with minimal health gain are restricted.
- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:
 - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
 - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
 - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
 - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
 - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
 - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
 - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.
- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website:
<https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/>

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.
- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.
- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink:
<http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx> and
<http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx>

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrlist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrlist/Dentist, in order for them to make a decision on future treatment.

6.6 Clinical Trials

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

- 7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.
- 7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.
- 7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
 - Post activity monitoring through routine data
 - Post activity monitoring through case note audits
- 7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

- 8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 Office of Population Censuses and Surveys (OPCS)

Any in the primary position

- X66.1 Cognitive behavioural therapy by unidisciplinary team
- X66.2 Cognitive behavioural therapy by multidisciplinary team
- X66.8 Other specified
- X66.9 Unspecified

9.2 International Classification of Diseases (ICD-10)

Must be included with any of the following

- G93.3 Postviral fatigue syndrome OR
- R53 Malaise and fatigue OR
- F48.0 Neurasthenia

Document Control

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