Policy for the treatment of Chronic Fatigue Syndrome (CFS) and Myalgic Encephalomyelitis (ME)
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision is considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

Chronic Fatigue Syndrome (CFS) / Myalgic Encephalomyelitis (ME)

Chronic Fatigue Syndrome (CFS) is also referred to as Myalgic Encephalomyelitis (ME) or Post Viral Fatigue Syndrome, it is characterised by long term tiredness that affects everyday life and does not go away with sleep or rest. It can encompass both physical (eg. fatigue) and psychological difficulties (eg. muddled thinking).

Although Chronic Fatigue Syndrome can sometimes follow a viral infection, quite often the trigger is unclear.

Symptoms may include:

- Fatigue for four months or more
- Feeling unusual tiredness, made worse by activity
- Impaired concentration or memory
- Unrested/disturbed sleep
- Aching joints/muscles
- Sore throat
- Headaches
- Tender/sore lymph nodes
- Hypersensitivity reactions (light, smells, noise)
- Post-exertional malaise
- Symptoms similar to IBS
- Autonomic symptoms

CFS/ME is a clinically defined syndrome with a characteristic pattern of symptoms but no consistent abnormalities on physical examination or on imaging/laboratory evaluation. It is often called a “diagnosis of exclusion” but in practice the symptomatology is frequently consistent enough to allow a fairly confident positive clinical diagnosis to be made.

NICE (2007) recommends that a small number of investigations are carried out to exclude conditions that potentially could be confused with CFS/ME. The following tests should usually be done:

- Urinalysis for protein, blood and glucose
- Full blood count
- Urea and electrolytes
- Liver function
- Thyroid function
- Erythrocyte sedimentation rate or plasma viscosity
- C-reactive protein
• HbA1c
• serum creatinine
• screening blood tests for gluten sensitivity
• serum calcium
• creatine kinase
• assessment of serum ferritin levels (children and young people only). Clinical judgement should be used when deciding on additional investigations to exclude other diagnoses.

Tests for serum ferritin in adults should not be carried out unless a full blood count and other haematological indices suggest iron deficiency.

Tests for vitamin B₁₂ deficiency and folate levels should not be carried out unless a full blood count and mean cell volume show a macrocytosis.

The following tests should NOT be done routinely to aid diagnosis:
• the head-up tilt test
• auditory brainstem responses
• electrodermal conductivity.

Serological testing should NOT be carried out unless the history is indicative of an infection.

Depending on the history, tests for the following infections may be appropriate:
• chronic bacterial infections, such as borreliosis
• chronic viral infections, such as HIV or hepatitis B or C
• acute viral infections, such as infectious mononucleosis (use heterophile antibody tests)
• latent infections, such as toxoplasmosis, Epstein–Barr virus or cytomegalovirus.

As indicated above, CFS/ME is a characteristic set of symptoms with no consistently identifiable pathology. Asymptomatic CFS/ME by definition cannot exist. Therefore in addition to referral for definitive therapy patients with CFS/ME may need symptomatic remedies to help with specific symptoms whilst waiting for definitive therapy to become available and/or to become effective.
Prevalence

Adults
- In 2011 the London School of Hygiene and Tropical Medicine conducted a cross-sectional study in three English regions on the primary care clinical presentation, prevalence and incidence of CFS/ME. The estimated minimum prevalence was found to be 0.2% in adults aged 18-64 (40 per 10,000 patients). Estimated minimal yearly incidence for this age group was 0.015% and the regions were found to have consistently higher prevalence in women than men. A Norwegian study also identified an incidence rate ratio of 3.1 for women compared to men.vi

Children
- Less information is available on paediatric prevalence of CFS/ME. A review paper from 2013 reported variable North American prevalence estimates for 12-17 years olds ranging from 0.002%-0.116%.vii Studies have also consistently shown a female-to-male ratio of 3:1.

Evidence of clinical effectiveness of interventions for CFS/ME.

Based upon the evidence identified there is some evidence to show that cognitive behavioural therapy has a positive impact on patients with CFS/ME through reducing symptoms of fatigue. There was also moderate quality evidence that Exercise therapy was more effective at reducing fatigue compared to ‘passive’ treatment or no treatment and had a positive effect on people’s daily physical functioning, sleep and self-ratings of overall health.

There was no evidence identified on the clinical effectiveness of inpatient therapy or residential settings.

Current NICE guidelines highlight the importance of shared decision making and any decision to refer a person to specialist CFS/ME care should be based on their needs, the type, duration, complexity and severity of their symptoms, and the presence of comorbidities.
Eligibility Criteria:

In patient care or therapy in a residential setting are NOT routinely commissioned for the treatment of CFS / ME due to the lack of clinical evidence to support this intervention.

CBT in the form of a PACE Programme or an individualised care package which combines CBT and exercise therapy as required to support the individual patient will be funded in an out-patient / community setting through the currently commissioned provider in the following circumstances:

1. The patient has a confirmed diagnosis of mild or moderate CFS / ME

   AND

2. The patient has undergone a holistic assessment with a CFS / ME treatment specialist team and either a group or individualised programme has been deemed by the specialist clinical team the most appropriate intervention for the patient in their individual circumstances.

All referrals for assessment of CFS/ME or treatment plans should be undertaken in a process of shared decision making and any decision to refer a person to specialist CFS/ME care should be based on their needs, the type, duration, complexity and severity of their symptoms, and the presence of comorbidities.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Definitions of ME


VERY SEVERE

100% DISABLED: Severe symptoms – often on a continual basis. Cognitive function (i.e. short-term memory, concentration, attention span) is likely to be very poor. Bedridden and incapable of living independently. Requires a great deal of supervision and practical support – including disability aids such as a hoist or a stair lift – with all aspects of personal care (i.e. feeding, dressing, washing) on a 24-hour basis.

90% DISABLED: Severe symptoms, often including marked cognitive dysfunction, for much or all of the time. Bedridden and housebound for much or all of the time. Has considerable difficulties with all aspects of personal care. Unable to plan or prepare meals. Requires practical support and supervision on a 24-hour basis.

SEvere

80% DISABLED: Moderate to severe symptoms for most or all of the time. Only able to carry out a very limited range of physical activities relating to personal care without help. Requires help with meal planning and preparation. Frequently unable to leave the house and may be confined to a wheelchair when up, or spends much of the day in bed. Unable to concentrate for more than short periods of time. Usually requires daytime and night-time supervision.

70% DISABLED: Moderate to severe symptoms for most or all of the time. Confined to the house for much or all of the time. Normally requires help with various aspects of personal care and meal planning and preparation, possibly on a 24-hour basis. Very limited mobility. May require wheelchair assistance.

MODERATE

60% DISABLED: Moderate symptoms for much or all of the time. Significant symptom exacerbation follows mental or physical exertion. Not usually confined to the house but has significant restrictions on mobility when outside and may require wheelchair assistance. Likely to require help with aspects of personal care and meal preparation – but not necessarily on a full-time basis. Requires regular rest periods during the day. Unable to resume any meaningful regular employment or education.
50% DISABLED: Moderate symptoms for much or all of the time. Symptom exacerbation follows mental or physical exertion. Not usually confined to the house, but mobility restricted to walking up to a few hundred yards at best. May require help with some aspects of personal care. May require help with meal planning and preparation. Requires regular rest periods during the day. Able to carry out light activities (i.e. housework, desk work) linked to normal daily living for short periods but not able to resume regular employment or education.

40% DISABLED: Moderate symptoms for some or much of the time. Normally able to carry out most activities linked to personal care and normal daily living, but may require assistance with meal preparation. May be able to cope with some work-related tasks for short periods – provided they are not mentally or physically strenuous – but not able to resume regular work or education.

MODERATE TO MILD

30% DISABLED: Fluctuating level of mild to moderate symptoms. Normally able to carry out all aspects of personal care and to plan and prepare meals. Able to walk short distances on a regular basis. May be able to return to work on a flexible or part-time basis – provided adjustments are made to cope with physical activity or cognitive problems. May have to stop leisure or social pursuits to resume work or education.

20% DISABLED: Normally only mild symptoms at rest but exacerbation will follow activity. Able to carry out all aspects of personal care and to plan and prepare meals. Able to walk short to medium distances (i.e. up to half a mile) on a regular basis. Normally able to return to flexible or part-time work or education.

10% DISABLED: Generally well with only occasional mild symptoms. No problems with personal care or daily living. Mobility and cognitive functions may still be restricted but almost back to previous levels. May be able to return to full-time work or education.

0% DISABLED: Fit and well for at least the past three months. No symptoms at rest or after exertion. Capable of full-time work or education.
Guidance

https://www.nice.org.uk/guidance/cg53

Colin, S.m; Nuevo, R.; Van de Putte, E.M.; Nijhof, S.L.; Crawley, E. (2015) Chronic fatigue syndrome (CFS) or myalgic encephalomyelitis (ME) is different in children compared to in adults: a study of UK and Dutch clinical cohort. BMJ Online. 5(10)  
http://bmjopen.bmj.com/content/5/10/e008830

NICE (expected publication 2020) Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management  
https://www.nice.org.uk/guidance/inddevelopment/gid-ng10091

http://europepmc.org/articles/PMC3170215

https://link.springer.com/content/pdf/10.1186/s12916-014-0167-5.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3856907/

Birmingham and Solihull Mental Health NHS Foundation Trust. The Chronic fatigue Syndrome Service.  
http://www.bsmhft.nhs.uk/our-services/specialist-services/neuropsychiatry/the-chronic-fatigue-syndrome-service/


