NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin074
Sleep Apnoea or Narcolepsy referral and management

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

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 Adults with suspected narcolepsy, with or without cataplexy should be referred for designated specialist[1] assessment.

1.2 Sleep studies or polysomnography will only be commissioned for patients with suspected sleep apnoea according to the following criteria:

- They have engaged with lifestyle advice such as weight reduction, alcohol consumption, sleep hygiene and smoking cessation and despite a concerted effort for at least 6 months (unless there is an urgent clinical need), their symptoms have not improved.

AND

- Their Epworth Sleepiness Symptom score is ≥ 11 or their STOP-Bang score is >4. The Epworth score should be used initially but STOP-Bang may be used in addition or on its own as not all patients will exhibit daytime sleepiness which the Epworth score is designed to measure.

1.3 Uvulopalatopharyngoplasty for obstructive sleep apnoea/hypopnoea is not routinely commissioned.

2. Exclusions

2.1 Patients with severe obstructive sleep apnoea who have been unable to tolerate Continuous Positive Airway Pressure (CPAP) and a customised mandibular advancement splint, despite medically supervised attempts, may be eligible for surgery and are excluded from this policy.

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.

[1] In Cheshire and Merseyside, there is currently a specialist centre at the Aintree Tertiary Sleep Centre

- 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/

4. Rationale behind the policy statement

4.1 The policy statement on suspected narcolepsy is in line with NICE guidance.

4.2 The policy statement on sleep apnoea and its relationship with lifestyle measures and use of the Epworth sleepiness symptom and STOP- Bang scores is also in line with NICE guidance.

4.3 A Cochrane review found no convincing evidence to support the widespread use of surgery (uvulopalatopharyngoplasty) for obstructive sleep apnoea.

5. Summary of evidence review and references

5.1 Obstructive sleep apnoea/hypopnoea syndrome (OSA) is the periodic and repeated reduction or cessation of airflow during sleep.[1] It is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). The patient will briefly wake up from sleep in order to restore normal breathing. [2]

5.2 Symptoms include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. In some, excessive daytime sleepiness can adversely affect cognitive function, mood, and overall quality-of-life. OSA is associated with high blood pressure which in turn increases the risk of cardiovascular disease and stroke. There is also an association of OSA with an increased risk of road traffic collisions.

5.3 Major risk factors are increasing age, obesity, and male gender. Other factors include specific craniofacial characteristics, enlarged tonsils or tongue. Alcohol or other sedatives can also increase the risk or severity. The prevalence of OSA has been reported to occur in up to 4% of middle-aged men and 2% of middle-aged women in the UK. Around 1% of men in the UK may have severe OSA.[2]

5.4 Various treatment options are available, and these include behavioural and lifestyle modifications, oral appliance devices, surgery and continuous positive airway pressure (CPAP) therapy. CPAP is considered to be the current gold standard of treatment [3] and is a required treatment for adults with moderate or severe OSA in a NICE technology appraisal. [2] Adherence may be suboptimal because some people find wearing the device to be uncomfortable. An alternative is positional therapy (i.e. a system to keep people sleeping on their side) and this is less invasive and is expected to have better adherence. However, a Cochrane review found that CPAP had a greater effect on improving respiratory parameters compared to positional therapy which in turn was superior to inactive controls.

5.5 A 2nd Cochrane review examined the data on drug therapy for OSA in adults. Drug therapy included acetazolamide, eszopiclone, naltrexone, nasal lubricants, physostigmine, donepezil, fluticasone, ondansetron, fluoxetine and paroxetine.[4] The review concluded there was insufficient evidence to recommend the use of drug therapy, the small studies had reported positive effects of certain agents on short-term outcomes but longer term trials are required. However, a recent Cochrane review concluded that modafinil is effective for the treatment of several aspects of idiopathic hypersomnia symptomatology (excessive daytime sleepiness). [5]

5.6 Finally, a 2005 Cochrane review (updated in 2013) examined the effects of various surgical procedures on OSA, which included *inter alia* uvulopalatopharyngoplasty. The review concluded that the identified studies had failed to demonstrate consistent effects in favour of surgery and didn't provide convincing evidence to support the widespread use of surgery in people with mild to moderate daytime sleepiness associated with sleep apnoea. [1]

5.7 How then, should patients be selected for specialist referral? Daytime sleepiness is one of the cardinal symptoms of OSA and the Epworth Sleepiness Scale (ESS) is a widely used, "validated" questionnaire for effectively examining patients' sleepiness in a range of different situations.[6]

5.8 First developed in 1990, the ESS is a self-administered questionnaire with 8 questions.[2] Respondents are required to rate on a 4-point scale (0 = would never doze to 3 = high chance of dozing) their chances of dozing off or falling asleep while engaged in 8 different activities. These are: sitting and reading, watching TV, sitting- inactive in a public place, as a passenger in a car, lying down to rest in the afternoon, sitting and talking to someone, sitting quietly after lunch or in a car while stopped for a few minutes in the traffic. A score of 24 indicates severe excessive daytime sleepiness whereas a score of 11 or higher indicates mild – moderate excessive daytime sleepiness. Despite its widespread use, there are limited studies on the reliability of the ESS in clinical practice. [7]

5.9 A Hungarian sleep centre examined the test – retest reliability of the ESS questionnaire in 100 consecutive patients by measuring the ESS initially and one hour later. There was wide variation between the 1st and 2nd scores with a mean difference of 7.62 points. The authors commented on the poor test – retest reliability.[6] A similar study of 133 patients compared initial ESS scores at referral and found poor test – retest reliability between values in primary versus secondary care. The authors suggested against using ESS for clinical decision-making or prioritisation of services [7] , a suggestion repeated by other researchers. [8] Walker classified 85 patients into "normal" (ESS <11) or "sleepy" (ESS >11) yet 20% of normal patients still had a score which was greater than 11 and 11% of sleepy patients had a score which was <11. [9]

5.10 In other studies, on the validity of ESS, Lok examined the association of ESS scores with 55 sleep and medical variables in the sleep heart health study. Analysis of the main dataset resulted in low explained variance. The authors concluded that ESS scores are not well explained by habitual or polysomnography sleep values or other biomedical characteristics and that interpretation of the clinical meaning of these scores should be done with caution. [10]

5.11 Thorarinsdottir had previously investigated the relationship between perceived daytime sleepiness and the ESS score (which effectively is a measure of the tendency to "doze off"). [11] A total of 1,338 subjects were administered both the Epworth test and also a Nordic questionnaire which measures daytime sleepiness. A cohort of 175 patients obtained an ESS score of >10. Of these, 89 (50%) were not sleepy as measured by the Nordic questionnaire. Interestingly, these patients had a similar symptom profile as the non-sleepy, control subjects. The authors concluded that reporting only risk of dozing off without feeling sleepy may not reflect problematic sleepiness and more instruments in addition to ESS are needed when evaluating daytime sleepiness. Similarly, in a separate study, Baiardi found a lack of concordance in estimating excessive daytime sleepiness among commercial drivers and previous studies using the same psychometric measure indicating that the ESS is not a reliable tool in this context. [12]

[2] https://epworthsleepinessscale.com/about-the-ess/

5.12 Perhaps the answer lies in adapting the existing ESS questionnaire. Guo examined the relationship between ESS and the apnoea–hypopnoea index (AHI) in 756 adults with suspected OSA and 810 individuals in a validation cohort. Weighting components within the ESS produced significant improvements in predicting the AHI and this could have implications for clinical triage decisions to prioritise patients for polysomnography.[13]

5.13 The validity of the ESS has been further questioned by Trimmel who investigated the interrelation with mean sleep latency which is a measure of how quickly a person falls asleep (under laboratory conditions) during the daytime. The results suggested that the predictive value of the ESS score in patients with subjective excessive daytime sleepiness is low and that the commonly used cut off value of 11 points may be insufficient for clinical practice.[14] Finally, Panchasara conducted a retrospective audit and concluded that ESS is not an appropriate screening tool for OSA but the "STOP-Bang" tool remains a useful screening device with the ability to detect patients with OSA in need of treatment.[15]

National guidance

5.14 In NICE's 2019 guidance on suspected neurological conditions (NG 127), adults with excessive sleepiness and a history of sleep-related obstructive symptoms should have their ESS score measured to assess the likelihood of sleep apnoea.[16] In addition, advice on weight reduction, alcohol consumption and smoking cessation should be offered where appropriate. Adults with narcolepsy, with or without cataplexy should be referred for neurological assessment. In the full guideline, NICE states that the Epworth score is an appropriate, simple, well-established measure for screening people with excessive sleepiness.

5.15 In its NG 202 guidance (20th August, 2021) on obstructive sleep apnoea in the over 16s, NICE recommends use of the ESS in the *preliminary* assessment of sleepiness. [17] However, ESS should not be used alone to determine if referral is needed because not all people with OSA have excessive sleepiness. Clinicians are advised to use the STOP-Bang questionnaire in conjunction with the ESS. The accompanying notes explain that ESS is used to assess sleepiness only whereas STOP–Bang is used to assess the risk of having OSA and includes parameters such as snoring, tiredness, history of high blood pressure, BMI, age, neck size and gender.

5.16 In conclusion, even before publication of NICE's draft guidance on OSA, the validity of the ESS score has been questioned and should no longer be used alone as a screening tool. In terms of referrals, NICE give a list of criteria for *prioritising* people for rapid assessment by a sleep service. These include: individual has a vocational driving job, job requires vigilance which is critical for safety, unstable cardiovascular disease e.g. poorly controlled arrhythmia, nocturnal angina or treatment resistant hypertension, pregnancy, preoperative assessment for major surgery or non-arteritic anterior ischaemic optic neuropathy.

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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/Optometrist/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/Optometrist/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)**

Investigation [15.2 or 15.3]
A84.7 Sleep studies NEC or U33.1 Polysomnography

Treatment [15.2]
F32.5 Uvulopalatopharyngoplasty

9.2 **International classification of diseases (ICD-10)**

With G47.3 Sleep apnoea (treatment or investigation) [15.2]

Or With (investigation) [15.3]
F51.1 Nonorganic hypersomnia
Or G47.1 Disorders of excessive somnolence [hypersomnias]
Or G47.4 Narcolepsy and cataplexy

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