NHS Devon

NICE Update Bulletin: December 2024

This bulletin includes details of the following new and updated NICE guidance – click on the titles below for further details:

1. **Tirzepatide for managing overweight and obesity TA1026**
2. **Ublituximab for treating relapsing multiple sclerosis TA1025**
3. **Toripalimab with chemotherapy for untreated advanced oesophageal squamous cell cancer *(terminated appraisal*) TA1024**
4. **Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments TA1023**
5. **Bevacizumab gamma for treating wet age-related macular degeneration TA1022**
6. **Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) TA1021**
7. **Urinary tract infection (recurrent): antimicrobial prescribing (UPDATE) NG112**
8. **MRI-guided focused ultrasound subthalamotomy for treating Parkinson's IPG797**
9. **MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's IPG796**
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Technology Appraisals (TAs)

Tirzepatide for managing overweight and obesity TA1026

Recommendations

Tirzepatide is **recommended** as an option for managing overweight and obesity, alongside a reduced-calorie diet and increased physical activity in adults, only if they have:

- an initial body mass index (BMI) of at least 35 kg/m^2 and
- at least 1 weight-related comorbidity.

Use a lower BMI threshold (usually reduced by 2.5 kg/m^2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds.

If less than 5% of the initial weight has been lost after 6 months on the highest tolerated dose, decide whether to continue treatment, taking into account the benefits and risks of treatment for the person.

These recommendations are not intended to affect treatment with tirzepatide that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

The Technology

Overweight and obesity is a chronic complex disease characterised by increased body fat. People living with overweight or obesity are at an increased risk of developing cardiovascular disease, type 2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension and dyslipidaemia (abnormal levels of fats in the blood). Other conditions associated with obesity include but are not limited to non-alcoholic fatty liver disease, non-diabetic hyperglycaemia, subfertility, osteoarthritis, dyslipidaemia, obstructive sleep apnoea and idiopathic intracranial hypertension. The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. Overweight is typically defined by a BMI of 25 kg/m^2 to <30 kg/m^2 and obesity by a BMI of 30 kg/m^2 or more. Some ethnic groups, as noted in **CG189**, maybe at increased risk of some ill health conditions at lower BMI than people of European family background. For people in these groups overweight is defined by a BMI of 23 kg/m^2 to 27.4kg/m^2 and obesity by a BMI of 27.5kg/m^2 or above.

CG189 'Obesity: identification, assessment and management' states that multicomponent interventions are the treatment of choice. Weight management programmes include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. Pharmacological treatments are usually considered only after dietary, exercise and behavioural approaches have been started and evaluated. **CG189** recommends orlistat for managing obesity in adults with a

BMI of 30 kg/m^2 or more, and in people with a BMI of 28 kg/m^2 or more with associated risk factors. If dietary and lifestyle advice, behaviour modification and drug treatments are unsuccessful, **CG189** recommends bariatric surgery for people with: a BMI of ≥40 kg/m^2; a BMI of between 35 kg/m^2 and 40 kg/m^2 and other significant disease, a BMI between 30 kg/m^2 and <35 kg/m^2 and with recent-onset of type 2 diabetes (surgery can be considered for people of Asian family background who have recent-onset type 2 diabetes at a lower BMI than other populations).

TA664 recommends liraglutide as an option for managing overweight and obesity alongside a reduced-calorie diet and increased activity in adults with a BMI of at least 35 kg/m^2 (or at least 32.5 kg/m^2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population), non-diabetic hyperglycaemia and a high risk of cardiovascular disease. **TA875** recommends semaglutide as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased activity in adults with one weight-related comorbidity and a BMI of at least 35 kg/m^2 or, a BMI of 30 kg/m^2 to 34 kg/m^2 and meet the criteria or referral to specialist weight management services outlined in **CG189**. In **TA875**, BMI thresholds are reduced by 2.5 kg/m^2 for people from some ethnic minority backgrounds.

Financial Factors

This technology is commissioned by ICBs.

Clinical trial evidence suggests that tirzepatide with diet and exercise support is more effective compared with diet and exercise support alone. Indirect comparisons suggest it is more effective compared with semaglutide alongside diet and exercise support.

The company proposed that tirzepatide could be used for adults with a BMI of at least 30 kg/m^2 and at least 1 weight-related comorbidity. But the most likely cost-effectiveness estimates for this group are above the range that NICE considers an acceptable use of NHS resources. Therefore, tirzepatide cannot be recommended for this group. The most likely cost-effectiveness estimates for adults with an initial BMI of at least 35 kg/m^2 and at least 1 weight-related comorbidity are within the range that NICE considers an acceptable use of NHS resources. Therefore, tirzepatide is recommended for this group.

NHS England submitted a funding variation request, on behalf of NHS providers and ICBs, to extend the time needed to comply with the recommendations. NHS England may request a longer time to implement technologies when the potential net budget impact is expected to exceed £20 million per year in any of the first 3 financial years of its use in the NHS.

NHS England proposed a total guidance implementation period of 12 years, in 3 parts:

- **A**: an additional 90 days before any requirement on ICBs to fund tirzepatide, providing a 180-day implementation period
- **B**: after the 180 days, a period of 3 years in which eligibility will increase in stages, selected based on health need and clinical benefit, and

- **C**: after this, up to a maximum of a further 9 years, dependent upon maturation of the obesity treatment pathway in primary care.

NICE will evaluate relevant evidence generated during the initial guidance implementation period of up to 3 years and review the effectiveness of the service delivery pilots. NICE may then set a revised timeline for the second phase of the guidance implementation period. A review conducted within the first 3 years will provide evidence on the most clinically and cost-effective service delivery models which could be used to shorten the total guidance implementation timeframe.

NICE estimate that at year 3 in Devon, 76,887 people will be eligible for treatment.

Ublituximab for treating relapsing multiple sclerosis TA1025

Recommendations

Ublituximab is **recommended** as an option for treating relapsing forms of multiple sclerosis, defined as active by clinical or imaging features in adults, only if:

- the multiple sclerosis is relapsing–remitting, and
- the company provides it according to the commercial arrangement.

Use the least expensive option of the available treatments (including ublituximab, ocrelizumab and ofatumumab). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments.

This recommendation is not intended to affect treatment with ublituximab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

The Technology

Multiple sclerosis is a chronic, neurological condition which affects the brain, optic nerves and spinal cord. It often results in progressive neurological impairment and severe disability. Multiple sclerosis has an unpredictable course which varies in severity and rate of progression. Symptoms can include pain, disturbance to muscle tone including weakness or spasticity, chronic fatigue, unsteady gait, speech problems, incontinence, visual disturbance and cognitive impairment. Relapsing–remitting multiple sclerosis is the most common clinical form of multiple sclerosis. It is characterised by periods of remission (where people may have no symptoms, or they may be relatively stable) followed by relapses (which may or may not result in residual disability). Relapsing–remitting multiple sclerosis can progress to secondary progressive multiple sclerosis. This is characterised by more persistent or gradually increasing disability; some people with secondary progressive disease continue to have relapses.

Current pharmacological management of multiple sclerosis includes disease modifying agents to reduce the frequency and severity of relapses and the rate of disease progression.

NICE recommends the following treatment options for relapsing multiple sclerosis:

- **TA794** diroximel fumarate for treating active relapsing-remitting multiple sclerosis that is not highly active or rapidly evolving severe multiple sclerosis
- **TA767** ponesimod for treating active relapsing-remitting multiple sclerosis
- **TA699** ofatumumab for treating relapsing multiple sclerosis in adults with active disease defined by clinical or imaging features
- **TA624** peginterferon beta-1a for treating relapsing-remitting multiple sclerosis
- **TA616** cladribine tablets for treating highly active multiple sclerosis only for rapidly evolving severe relapsing–remitting disease or disease that has responded inadequately to treatment with disease-modifying therapy
- **TA533** ocrelizumab for active relapsing–remitting multiple sclerosis only if alemtuzumab is contraindicated or otherwise unsuitable
- **TA527** interferon beta-1a and glatiramer acetate for relapsing–remitting multiple sclerosis and interferon beta-1b for relapsing–remitting multiple sclerosis with 2 or more relapses within the last 2 years and secondary progressive multiple sclerosis
- **TA303** and **TA320** teriflunomide and dimethyl fumarate for active relapsing–remitting multiple sclerosis, only if people do not have highly active or rapidly evolving severe relapsing–remitting multiple sclerosis
- **TA312** alemtuzumab for highly active and rapidly evolving severe relapsing–remitting multiple sclerosis
- **TA254** fingolimod for highly active relapsing–remitting multiple sclerosis in adults who have an unchanged or increased relapse rate or ongoing severe relapses compared with the previous year despite treatment with beta interferon
- **TA127** natalizumab for rapidly evolving severe relapsing–remitting multiple sclerosis
- **TA656** siponimod for active secondary progressive multiple sclerosis

Financial Factors

This technology is commissioned by NHS England.

Treatment options for active relapsing–remitting multiple sclerosis include immunomodulatory treatments such as teriflunomide and anti-CD20 monoclonal antibodies such as ocrelizumab and ofatumumab. Ublituximab is another treatment option that works in a similar way to ocrelizumab and ofatumumab and would be offered to the same population.

Clinical trial evidence shows that ublituximab is more effective at reducing the number of relapses than teriflunomide. Ublituximab has not been directly compared in a clinical trial with ocrelizumab and ofatumumab, but the results of an indirect comparison suggest that it is likely to work as well as these.

A comparison of ublituximab with ocrelizumab and ofatumumab using NICE's cost comparison methods suggests ublituximab has similar benefits to and lower costs than ocrelizumab and ofatumumab, therefore, ublituximab is recommended.

The company has a commercial arrangement. This makes ublituximab available to the NHS with a discount.

NICE estimate that in Devon, the eligible population will be 1,026 people.

Toripalimab with chemotherapy for untreated advanced oesophageal squamous cell cancer *(terminated appraisal)* TA1024

NICE is **unable to make a recommendation** about the use of toripalimab with chemotherapy for untreated advanced oesophageal squamous cell cancer in adults in the NHS. This is because the company has requested a delay to the evidence summary.

Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments TA1023

Recommendations

Elranatamab is **recommended** with **managed access** as an option for treating relapsed and refractory multiple myeloma in adults, only after 3 or more lines of treatment (including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody) when the multiple myeloma has progressed on the last treatment. It is only recommended if the conditions in the managed access agreement for elranatamab are followed.

This recommendation is not intended to affect treatment with elranatamab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

The Technology

Multiple myeloma is a form of cancer that arises from plasma cells (a type of white blood cell) in the bone marrow. Myeloma cells produce large quantities of an abnormal protein, known as paraprotein. Unlike normal antibodies, paraprotein has no useful function and lacks the capacity to fight infection. Myeloma cells supress the development of normal blood cells that are responsible for fighting infection, carrying oxygen around the body and blood clotting. The term multiple myeloma refers to the presence of more than one site of affected bone at the time of diagnosis. People with multiple myeloma can experience bone pain, bone fractures, tiredness (due to anaemia), infections, hypercalcaemia and kidney problems.

Multiple myeloma is most frequently diagnosed in older people and is more common in men than in women.

The main aims of therapy are to prolong survival and maintain a good quality of life by controlling the disease and relieving symptoms. If the disease progresses after initial treatment, the choice of subsequent therapy is influenced by previous treatment and response to it, duration of remission, comorbidities and patient preference.

NICE has published the following related guidance:

- **TA171** Lenalidomide for the treatment of multiple myeloma in people who have received at least 2 prior therapies
- **TA380** Panobinostat for treating multiple myeloma after at least 2 previous treatments
- **TA870** Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma
- **TA427** Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib
- **TA783** Daratumumab monotherapy for treating relapsed and refractory multiple myeloma
- **TA658** Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma

Financial Factors

This technology is commissioned by NHS England.

Even when considering the condition's severity and its effect on quality and length of life, the most likely cost-effectiveness estimates are above what NICE considers an acceptable use of NHS resources, therefore, elranatamab cannot be recommended for routine use in the NHS.

Elranatamab could be cost effective if further evidence shows that people live longer with this treatment. Longer-term evidence from a trial and NHS clinical practice could help address the remaining uncertainties. Therefore, elranatamab is recommended for use with managed access only after 3 or more lines of treatment (including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody) when the multiple myeloma has progressed on the last treatment.

NICE estimate that in Devon, the eligible population will be 18 people.

Bevacizumab gamma for treating wet age-related macular degeneration TA1022

Recommendations

Bevacizumab gamma is **recommended** as an option for treating wet age-related macular degeneration in adults, only if:

- The eye has a best-corrected visual acuity between 6/12 and 6/96
- There is no permanent structural damage to the central fovea
- The lesion size is 12-disc areas or less in greatest linear dimension
- There are signs of recent disease progression (for example, blood vessel growth as shown by fluorescein angiography, or recent visual acuity changes)
- The company provides it according to the commercial arrangement

Use the least expensive option of the available treatments (including bevacizumab gamma, aflibercept, faricimab and ranibizumab). Take account of administration costs, dosage, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments.

Only continue bevacizumab gamma treatment if an adequate response is maintained. Criteria for stopping should include persistent deterioration in visual acuity and anatomical changes in the retina.

These recommendations are not intended to affect treatment with bevacizumab gamma that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

The Technology

The macular is the central part of the retina responsible for colour vision and perception of fine detail. Age-related macular degeneration (AMD) is when aging causes damage to the macular, which can lead to severe visual impairment in the affected eye.

AMD is a common cause of vision loss in people aged over 50 and is associated with the loss of central vision and visual distortion. There are 2 main types of AMD:

- wet (neovascular)
- dry (non-neovascular)

Wet AMD usually develops much more quickly than dry AMD and is characterised by the growth of abnormal blood vessels beneath the retina. These new blood vessels are fragile and more likely to haemorrhage, which causes scarring of the macular leading to vision impairment.

The NICE guideline on AMD (**NG82**) recommends offering intravitreal anti-vascular endothelial growth factor (VEGF) treatment. Anti-VEGF medications that are licenced options for the treatment of wet AMD are ranibizumab (**TA155**), aflibercept solution for injection (**TA294**), brolucizumab (**TA672**) and faricimab (**TA800**).

NG82 also recommends considering anti-VEGF treatment for wet AMD with best-corrected visual acuity of 6/96 or worse if it will benefit the person's overall visual function (for example, if the affected eye is the person's better seeing eye).

Bevacizumab gamma is an ophthalmic formulation of bevacizumab.

Financial Factors

This technology is commissioned by ICBs.

NICE already recommends aflibercept, faricimab and ranibizumab as treatment options for wet age-related macular degeneration. Bevacizumab gamma works in a similar way to these treatments and would be offered to the same population.

Evidence from clinical trials shows that more people having bevacizumab gamma gain at least 15 letters in best corrected visual acuity than those having ranibizumab. And an indirect comparison of bevacizumab gamma with ranibizumab, aflibercept and faricimab suggests similar clinical effectiveness.

The total cost of bevacizumab gamma is similar to the cost of aflibercept, therefore bevacizumab gamma is recommended.

The company has a commercial arrangement. This makes bevacizumab gamma available to the NHS with a discount.

NICE estimate that in Devon, the eligible population will be 1,201 people.

Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) TA1021

Recommendations

Crizotinib is **recommended** as an option for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) in adults, only if:

- they have not had ROS1 inhibitors
- the company provides it according to the commercial arrangement.

Use the least expensive option of the available treatments (including crizotinib and entrectinib). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments.

This recommendation is not intended to affect treatment with crizotinib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS Healthcare professional consider it appropriate to stop.

The Technology

Lung cancer falls into 2 main histological categories: around 80-90% are classified as non-small cell lung cancer (NSCLC), with most remaining patients classified as small cell lung cancer.

NSCLC may be further classified by tumour histology into:

1. squamous cell carcinoma,	
2. adenocarcinoma	Non-squamous lung cancer
3. Large-cell carcinoma	

Most lung cancers are diagnosed at an advanced stage, when the cancer has spread locally in the chest, more widely in the chest, or to other parts of the body.

ROS1 is a rare type of gene alteration in which chromosomal rearrangement leads to fusion of a portion of ROS1, where resulting fusion kinases are constitutively activated and drive cellular transformation. These rearrangements are more commonly found in patients who have never smoked and who have histologic features of adenocarcinoma, having a similar patient profile to those who have anaplastic lymphoma kinase (ALK)-positive NSCLC. ROS1 tends to be mutually exclusive to ALK and other known oncogenic drivers such as EGFR, KRAS, HER-2, RET and MET aberrations.

NICE's guideline on lung cancer: diagnosis and management guideline (**NG122**) recommends entrectinib (**TA643**) as treatment for ROS1-positive advanced NSCLC. Upon disease progression, the guideline recommends treatment with platinum doublet chemotherapy, or pemetrexed and cisplatin (**TA181**) or carboplatin, or a combination of atezolizumab, bevacizumab, carboplatin, and paclitaxel (**TA584**).

Financial Factors

This technology is commissioned by NHS England.

Usual treatment for ROS1-positive advanced non-small-cell lung cancer is entrectinib, which works in a similar way to crizotinib. Crizotinib and entrectinib will likely be offered to the same population.

There is limited clinical evidence for crizotinib and it has not been directly compared in a trial with entrectinib. But indirect comparisons suggest that crizotinib may work as well as entrectinib.

A cost comparison suggests crizotinib has lower costs than or similar costs to entrectinib, therefore, crizotinib is recommended.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

None published this month

NICE Rapid COVID-19 Guidelines

None published this month

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

Urinary tract infection (recurrent): antimicrobial prescribing (UPDATE) NG112

This guideline sets out an antimicrobial prescribing strategy for preventing recurrent urinary tract infections in children, young people and adults who do not have a catheter. It aims to optimise antibiotic use and reduce antibiotic resistance.

December 2024: NICE have reviewed the evidence and made new recommendations on methenamine Hippurate for people with recurrent UTI. NICE have also amended recommendations on referral and seeking specialist advice, choice of antibiotic or antiseptic prophylaxis, and oestrogens without an evidence review.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

MRI-guided focused ultrasound subthalamotomy for treating Parkinson's IPG797

Recommendations

More research is needed on MRI-guided focused ultrasound subthalamotomy for treating Parkinson's before it can be used in the NHS.

This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

More research in the form of suitably-powered randomised controlled trials or prospective cohort studies, and safety data from a registry, is needed on:

- patient selection, including severity of condition and symptoms
- the site of the lesion for this procedure
- the technique used
- long-term outcomes
- safety outcomes.

The Condition

Parkinson's is a progressive neurodegenerative condition that damages the brain over many years. It is caused by a loss of the cells in the brain that produce dopamine, which helps to control and coordinate body movements. People with Parkinson's classically present with the symptoms and signs described as 'parkinsonism': these include bradykinesia (slow movements), rigidity, rest tremor (shaking) and postural instability (loss of balance). In later stages of Parkinson's, other symptoms sometimes described as the 'non-motor' manifestations of Parkinson's such as depression, cognitive impairment, dementia and autonomic disturbances may be prominent. The condition may progress to cause significant impairments, adversely affecting quality of life and, indirectly, the quality of life of family and carers.

For people with early Parkinson's, drug treatments such as levodopa, other dopamine agonists and monoamine oxidase B inhibitors may be considered. In the later stages, other drugs may be used with levodopa (as adjuvants) to reduce the motor complications associated with prolonged levodopa use. Non-pharmacological management such as physiotherapy, occupational therapy and speech and language therapy may be considered. Invasive surgical procedures may be considered for people with Parkinson's that is refractory to medical and supportive therapies. These include deep brain stimulation and, less commonly, radiofrequency thalamotomy. Treatments for non-motor symptoms such as sleep disturbance and depression may also be considered.

The Procedure

MRI-guided focused ultrasound subthalamotomy is an incisionless procedure that aims to treat tremor, slowness and stiffness associated with Parkinson's.

This outpatient procedure is done with the patient lying supine inside an MRI scanner for several hours. The patient's head is shaved, and a stereotactic head frame is attached. The person is usually kept awake during the procedure so they can be regularly assessed by the treating physician to evaluate the clinical response. Some people may be offered light sedation.

Real-time MRI guidance and thermal mapping are used to identify and adjust the target area of the brain (the subthalamic nucleus) precisely and continuously monitor treatment. Low-power ultrasound is delivered to confirm the location. Then, several high-power focused ultrasound pulses are delivered to ablate tissue in the subthalamic nucleus (in the dorsolateral motor region and above, and mediodorsally to affect the pallidothalamic tract). The energy released and the location of the ultrasound focus are monitored in real time during the procedure by MRI thermometry and adjusted to reach above the definitive ablation temperature (of 55°C) according to clinical response. Chilled water is circulated around the head during the treatment to prevent thermal damage to the scalp caused by the increase in bone temperature. The procedure is considered finished when there is sufficient clinical improvement, considering the total amount of energy delivered and the number of sonications. The procedure takes about 2 hours and symptom relief should be immediate.

MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's IPG796

This guidance replaces IPG606 (published February 2018)

Recommendations

More research is needed on MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's before it can be used in the NHS.

This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

More research is needed on:

- patient selection (including the severity of Parkinson's and impact of tremor)
- the technique used
- safety outcomes
- longer-term efficacy outcomes.

Patient selection should be done by a movement disorders multidisciplinary team experienced in managing the condition. The procedure should only be done by a multidisciplinary team including a neurosurgeon with specialist expertise in the procedure.

The Condition

See 'The Condition' for IPG797 above.

The Procedure

MRI-guided focused ultrasound thalamotomy is a minimally invasive procedure that may benefit a subgroup of people who do not want the risks of more invasive brain surgery (that is, deep brain stimulation or radiofrequency thalamotomy), or when brain surgery is not an option, especially in older and more frail people.

This outpatient procedure is done with the patient lying supine inside an MRI scanner for several hours. The person's head is shaved and a stereotactic head frame is attached. The person is usually kept awake during the procedure so they can be regularly assessed by the treating physician to evaluate the clinical response. Some people may be offered light sedation.

Real-time MRI guidance and thermal mapping are used to identify the target area of the brain (the thalamic nucleus) precisely and monitor treatment. Low-power ultrasound is delivered to confirm the chosen location. Then, several high-power focused ultrasound pulses are delivered to ablate target tissue in the thalamus. The energy released and the location of the ultrasound focus are monitored in real time during the procedure by MRI thermometry and adjusted to reach above the definitive ablation temperature (of 55°C) according to clinical response. Chilled water is circulated around the head during the treatment to prevent thermal damage to the scalp caused by the increase in bone temperature. The procedure is considered finished when there is sufficient clinical improvement, considering the total amount of energy delivered and the number of sonications. The procedure takes about 2 hours and symptom relief should be immediate.

Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant IPG795

This guidance replaces IPG270 (published July 2008)

Recommendations

Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant can be used in the NHS while more evidence is generated. It can only be used with **special arrangements** for clinical governance, consent, and audit or research.

Healthcare professionals wanting to do direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant should:

- Inform the clinical governance leads in their healthcare organisation.

- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- ensure systems are in place that support healthcare professionals to collect and report data on outcomes and safety for everyone having this procedure
- regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team with specific training and experience in the procedure and should include:

- an orthopaedic surgeon experienced in amputation and device implantation
- a plastic surgeon with experience in the necessary bone and soft tissue reconstruction
- an anaesthetist, and
- rehabilitation specialists including:
    - experts in prosthetics
    - occupational therapists, and
    - clinical psychologists.

The procedure should only be done in specialised centres by a multidisciplinary team with specific training and experience in the procedural techniques, and management and rehabilitation after the procedure.

The Condition

Limb amputation is traumatic and affects quality of life. Lower-limb amputation (above or below the knee) is the most common reason for a person to use a prosthetic limb (customised prosthesis). The most common reason for lower-limb amputation is peripheral vascular disease. Other causes include trauma, infection, diabetes and cancer. Upper-limb amputations are less common and are mainly a result of trauma. A small proportion of people need prosthetic limbs because of congenital limb loss or deformities.

The customised prosthesis is fitted to replace the function of the missing limb and provide cosmesis for major amputations. The type of prosthesis depends on what part of the limb is missing. Conventionally, the prosthesis is attached to the residual stump by belts and cuffs, suction, or by a suspension system. The conventional prosthesis usually has a socket, which is custom made from a plaster cast of the stump. Every effort is made to ensure people have sockets that fit well and are comfortable. One of the main problems with this type of prosthesis is rubbing between the stump and the socket. This can cause pain, ulceration and improper distribution of body weight that can affect balance and lead to falls. This may mean the user has limited use of the prosthesis or may have to abandon it for a period because of poor fit. For most people a conventional prosthesis is appropriate and well tolerated. But, when a conventional socket prosthesis is unsuitable or causes problems, direct skeletal fixation of limb prostheses using an osseointegrated implant may be an option for some people.

The Procedure

The procedure aims to surgically insert an osseointegrated implant, producing a secure connection between the remaining bone and the implant for prosthetic attachment. The implant may be in 1 piece or modular with a separate small, metal extension (abutment).

The advantages of direct skeletal fixation of an osseointegrated implant are:

- proper transfer of load from the prosthesis to the person's body
- better function and mobility (such as walking)
- improved comfort while sitting
- better balance
- fewer stump problems
- increased prosthesis use, and
- improved quality of life.

The potential problems are:

- soft-tissue infection where the skin and the prosthesis meet
- deep infection
- fracture or loosening around the implant, and
- implant failure.

Direct skeletal fixation of limb prostheses using an osseointegrated implant is done under general or regional anaesthesia (depending on the level of amputation). The procedure can be done all in 1 stage or in 2 stages separated by a period of time. In the first stage, a metallic implant (with either an outer surface threaded like a screw or a press-fit design) is inserted into the medullary

cavity of the residual bone. Then healing components are attached to the implant to secure the bone graft during healing. The second stage of the procedure is usually done about 2 to 6 months later, after the implant has integrated into the bone (osseointegration) and the stump wound is completely closed and healed. It involves surgically removing the healing components and re-exposing the distal end of the implant. It is then attached to an abutment with an abutment screw or bridge component. The wound is closed with the abutment penetrating the skin. The external limb prosthesis can then be attached to the osseointegrated implant using various components, depending on the level of amputation.

A period of extensive physiotherapy and rehabilitation follows the procedures, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.

Medical Technologies Guidance (MTGs)

None published this month

Diagnostics Guidance (DGs)

Home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome DG62

Recommendations

PEOPLE 16 YEARS AND OVER

Use as an option

Use the following home-testing devices as options to diagnose and assess the severity of obstructive sleep apnoea hypopnoea syndrome (OSAHS) in people 16 years and over:

- AcuPebble SA100
- Sunrise
- WatchPAT 300
- WatchPAT ONE.

When considering whether to use these devices in place of home respiratory polygraphy or home oximetry, take into account:

- whether the device can provide the outputs that are needed for decisions about care, including whether a third-party oximeter can be used, particularly for identifying OSAHS in people with comorbidities
- whether the person has hair in the area that the device attaches to that would need to be removed, and if this is acceptable for the person

- whether the person has physical features such as skin conditions or scars that may affect how well the device attaches
- the internet and smartphone access that would be needed to use the device
- if attaching or using the device would be difficult for the person, and if they will have support with using the device.

These devices can only be used once they have appropriate regulatory approval including CE or UKCA marking, and NHS England's Digital Technology Assessment Criteria (DTAC) approval.

Can only be used in research

More research is needed on using the Brizzy home-testing device to diagnose and assess the severity of OSAHS in people 16 years and over before it can be used in the NHS.

PEOPLE UNDER 16 YEARS

Can only be used in research

More research is needed on the following home-testing devices to diagnose and assess the severity of OSAHS in people under 16 years, before they can be used in the NHS:

- Brizzy
- Sunrise
- WatchPAT 300
- WatchPAT ONE.

WHAT RESEARCH IS NEEDED

More research is needed on:

- how accurately the Brizzy device diagnoses and assesses the severity of OSAHS in people 16 years and over
- how accurately Brizzy, Sunrise, WatchPAT 300 and WatchPAT ONE devices diagnose and assess the severity of OSAHS in people under 16 years
- how accurately the home-testing devices diagnose and assess the severity of OSAHS in people with black or brown skin.

Access to the technologies for the populations and indications in sections 1.4 and 1.5 should be through company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

The Technology

Obstructive sleep apnoea hypopnoea syndrome (OSAHS) is a condition in which the upper airway becomes blocked repeatedly during sleep. This can intermittently reduce airflow (hypopnoea) or stop airflow completely (apnoea). Both apnoea and hypopnoea can occur in the same night. Symptoms of sleep apnoea can include loud snoring, breathing pauses, gasping, choking, sleep disruption and unrefreshing sleep. Because of the sleep disturbance, symptoms may also occur during waking hours, including excessive sleepiness. Sleep disruption and excessive sleepiness can reduce quality of life, cognitive function and affect mental health. COPD–OSAHS overlap syndrome occurs in people who have both chronic obstructive pulmonary disease (COPD) and OSAHS.

In adults, OSAHS is associated with various conditions, such as overweight or obesity, hypertension, type 2 diabetes and cardiovascular disease. In children, the most common cause of OSAHS is adenotonsillar hypertrophy (enlarged tonsils or adenoids), which can partially obstruct the airway during sleep.

Recommendations on detecting OSAHS and the care pathway can be found in **NG202** and the British Thoracic Society's guideline for diagnosing and monitoring paediatric sleep-disordered breathing. NICE recommends home respiratory polygraphy as the initial test for OSAHS in people over 16. If home respiratory polygraphy is unavailable, home oximetry can be used. But oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung conditions. Hospital respiratory polygraphy or polysomnography can also be used if additional monitoring is needed.

Home respiratory polygraphy systems include wired components that need instructions for people to operate them and they can be uncomfortable to wear. Oximetry is a widely used alternative.

Expert clinical advice suggests that hospital sleep-testing capacity has reduced since the COVID-19 pandemic, creating more reliance on home testing for sleep diagnostics. Some home-testing devices can be sent directly to the person by the manufacturer or NHS provider, which may increase access to home testing and reduce waiting times. This can potentially reduce time to diagnosis, leading to more timely treatment and symptom improvement. Newer home-testing devices may be easier to put on and operate than the devices currently used in the NHS and may also be more comfortable to wear.

Home-testing devices can be used for diagnosing OSAHS. The devices vary in terms of their indications, contraindications for use, physiological parameters measured, lifespan and their need for an internet connection or a smartphone.

Financial Factors

These technologies are commissioned by ICBs.

The economic model suggests that the AcuPebble SA100, Sunrise, WatchPAT 300 and WatchPAT ONE devices are cost effective compared with home oximetry and home respiratory polygraphy in people 16 years and over. So, these devices can be used in this group. The estimates of diagnostic accuracy for the Brizzy device are uncertain, so the cost-effectiveness estimates are also uncertain. So, more research is needed.

There is very limited evidence for all the home-testing devices in people under 16 years and the evidence from adults is not generalisable to people under 16. So, more research is needed in this group.

NICE estimate that in Devon the prevalence of OSAHS is 191,134 people and the number of people undiagnosed and eligible for treatment is 172,020.

Health Technology Evaluations (HTE)

Digital technologies to support self-management of COPD: early value assessment HTE19

This guidance and HTE18 update and replace MTG68 (published March 2022)

Recommendations

Can be used in the NHS while more evidence is generated

Seven digital technologies to support self-management of chronic obstructive pulmonary disease (COPD) in adults can be used in the NHS during the evidence generation period. The technologies are:

- Active+me REMOTE
- Clinitouch
- COPDhub
- COPDPredict
- Lenus COPD Support Service
- Luscii
- myCOPD.

  These technologies can only be used once they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

The companies or developers of these technologies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan). They should contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

At the end of the evidence generation period (3 years, during which 1 year of follow-up data will be collected), the companies should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

Can only be used in research

More research is needed on the standalone Doccla WellGuide patient app to support self-management of COPD before it can be used in the NHS.

Access to the standalone Doccla WellGuide patient app should be through the company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

What evidence generation and research is needed

Evidence generation is needed on:

- how well the digital technologies work compared with standard management of COPD without digital technologies, which may include face-to-face appointments and monitoring, measuring the following outcomes:
    - health-related quality of life using the EQ-5D-3L
    - respiratory function using the COPD Assessment Test score
    - resource use, including:
        - technology costs, including licence fees
        - COPD exacerbation-related costs
        - number of primary care visits
        - number of hospital visits and admissions, and associated costs related to COPD
        - staff time needed to support the service
        - training costs
        - implementation costs
    - uptake rates
    - intervention adherence rates

- preferences and experiences of people with COPD
- adverse events
- COPD exacerbation rate

- where the technologies are used in the care pathway
- outcomes in the following subgroups:
  - people living in urban areas compared with people living in rural areas
  - people with a new COPD diagnosis compared with people who have established COPD
  - people recently discharged from hospital after a COPD exacerbation, within 4 weeks of the exacerbation
  - people with different COPD severity (using the Global Initiative for Chronic Obstructive Lung Disease [GOLD] classification).

The Technology

Chronic obstructive pulmonary disease (COPD) exacerbations are the second most common cause of emergency hospital admissions, accounting for 1 in 8 of all UK hospital admissions. Exacerbations requiring hospital treatment are associated with poorer prognosis and an increased risk of death.

NG115 recommends that people who have had an exacerbation of COPD are provided with an individualised exacerbation action plan, for early recognition of future exacerbations, management strategies (including appropriate provision of antibiotics and corticosteroids for self-treatment at home) and a named contact.

For people with COPD, the following should be offered before commencing pharmacological treatment: smoking cessation, once-only pneumococcal vaccination and an annual flu vaccination, pulmonary rehabilitation, co-developing a personalised self-management care plan and optimising treatment for co-morbidities. These should be reviewed at each patient contact.

For people who are more symptomatic and taking pharmacological treatment, their inhaler technique, compliance with administration instructions and tolerance of the current device should be checked before stepping up treatment to the next stage in therapeutic management of COPD.

The NHS Long-Term Plan includes commitments related to respiratory disease, including the need to detect respiratory diseases earlier, ensuring pharmacological treatment is appropriate. It also highlights the use of digital tools that should be offered to provide support to a wider group of people with COPD with self-management support and pulmonary rehabilitation and to ensure breathlessness is managed effectively. The Long-Term Plan also recognises the role for COPD

management in the community is large and support is required to help people with COPD manage their condition at home.

Digital technologies to support self-management of COPD provide various aspects of self-management. These technologies are multicomponent and include at least 3 components of self-management:

- education about the condition
- an individualised self-management plan within the technology
- symptom tracking by the user
- remote monitoring functionality
- exercise
- communication features with healthcare providers.

  While some of these technologies also feature pulmonary rehabilitation and virtual ward components, these are not included within the scope of this health technology evaluation.

Financial Factors

These technologies are commissioned by ICBs.

NICE anticipate that there will be additional costs incurred to implement the guidance. There may be costs associated with implementation, staff training, integration with NHS patient medication record systems and providing smart devices with an internet connection. Costs will depend on the type of technology procured and the pricing arrangements in place. The technology prices are commercial in confidence and likely to vary across companies.

There may be a reduction in exacerbations and potential slowing of progression of COPD and this may provide some savings to offset the potential costs of implementing the technologies. However, this is uncertain because of the limited evidence base, as there is uncertainty about how effective these technologies may be at reducing these symptoms in practice.

NICE Quality Standards

Meningitis (bacterial) and meningococcal disease QS19 (UPDATE)

This quality standard covers recognising, diagnosing and managing bacterial meningitis and meningococcal disease in babies, children, young people and adults. It describes high-quality care in priority areas for improvement.

December 2024: This quality standard was updated and statements prioritised in 2012 were replaced. The review identified changes in the priority areas for improvement, updated guidance on meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management.

Current NICE Consultations

Title/link	End date of consultation
Robot-assisted surgery for orthopaedic procedures: early value assessment	07/01/2025
Cladribine for treating relapsing multiple sclerosis	09/01/2025
Ruxolitinib for treating acute graft versus host disease refractory to corticosteroids in people aged 12 and over	10/01/2025
Highly specialised technologies: NICE prioritisation board routing criteria	30/01/2025
Health inequalities modular update to NICE health technology evaluations: the manual	31/01/2025