NHS Devon

# NICE Update Bulletin: November 2023

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

1. **Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments *(terminated appraisal)* TA936**
2. **Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms TA934**
3. **Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies *(terminated appraisal)* TA933**
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11. **Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer CG164 (UPDATE)**
12. **Transient loss of consciousness ('blackouts') in over 16s CG109 (UPDATE)**
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# Technology Appraisals (TAs)

## Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments *(terminated appraisal)* TA936

NICE is **unable to make a recommendation** on idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments in adults. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

## Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms TA934

### Recommendations

Foslevodopa–foscarbidopa is **recommended** as an option for treating advanced levodopa-responsive Parkinson's in adults whose symptoms include severe motor fluctuations and hyperkinesia or dyskinesia, when available medicines are not working well enough, only if:

- they cannot have apomorphine or deep brain stimulation, or these treatments no longer control symptoms, and
- the company provides foslevodopa–foscarbidopa according to the commercial arrangement.

This recommendation is not intended to affect treatment with foslevodopa–foscarbidopa 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 clinician consider it appropriate to stop.

### The Technology

Parkinson's disease is a progressive chronic disorder of the central nervous system. It is caused by a loss of cells in the brain that are responsible for producing dopamine, which helps to control and coordinate body movements. In the early stages of Parkinson's disease, the 3 main symptoms are shaking, slowness of movement and muscle stiffness. These develop gradually, in no particular order. Other physical symptoms that can occur early on include balance problems, nerve pain and sleep disturbances. People with advanced Parkinson's disease have more complex symptoms that significantly impact daily living, including anxiety, depression and dementia. Pharmacological treatment may also be less effective in later stages. Advanced Parkinson's disease has a severe negative impact on the quality of life of patients, their families and carers.

Men are more likely to develop Parkinson's disease than women and the risk of developing the disease increases sharply with age. It is estimated that around 34% of people in the UK have complex disease.

NICE guideline NG71 recommends levodopa as the first-line treatment for people in the early stages of Parkinson's disease whose motor symptoms impact their quality of life. However, people having long-term levodopa treatment develop motor complications. These include motor fluctuations, where the patient switches between being able to move ('on' phase) and being immobile ('off' phase), and involuntary movements (dyskinesias). Dopamine agonists, monoamine oxidase Type B (MAO-B) inhibitors or catechol-O-methyl transferase (COMT) inhibitors are offered as an add on to levodopa for people who have developed dyskinesia or motor fluctuations despite optimal therapy. If the dyskinesia remains uncontrolled, amantadine can be considered.

Best medical therapy for people with advanced Parkinson's disease may include intermittent apomorphine injection and/or continuous apomorphine infusion. Surgery (for example, deep brain stimulation) can be considered in people whose disease has not responded adequately to best medical therapy. An NHS England Clinical Commissioning Policy recommends that levodopa-carbidopa intestinal gel can be considered in certain people with advanced levodopa-responsive Parkinson's disease, with severe motor fluctuations that have not responded to available medications.

Foslevodopa-foscarbidopa is a prodrug combination of levodopa and carbidopa. Levodopa is metabolised to dopamine once it has reached the brain, improving nerve conduction and reducing the physical symptoms associated with Parkinson's disease. Carbidopa prevents metabolism of levodopa until it has crossed the blood-brain barrier. This means that a lower dose of levodopa is needed, reducing the risk of side effects. Foslevodopa-foscarbidopa is administered via subcutaneous infusion over 24 hours.

## Financial Factors

This technology is commissioned by ICBs.

Foslevodopa–foscarbidopa was only considered as an alternative to standard care and levodopa–carbidopa intestinal gel. This does not include everyone who foslevodopa–foscarbidopa is licensed for.

Evidence from a clinical trial suggests that foslevodopa–foscarbidopa improves motor symptoms compared with standard care. But some people in the trial had previously had apomorphine, so it is uncertain how well foslevodopa–foscarbidopa works for people who cannot have apomorphine. An indirect comparison suggests that foslevodopa–foscarbidopa works as well as levodopa–carbidopa intestinal gel, but the results are uncertain.

Even when considering this uncertainty, the most likely cost-effectiveness estimates are within the range that NICE usually considers an acceptable use of NHS resources. Therefore, foslevodopa–foscarbidopa is recommended.

The company has a commercial arrangement. This makes foslevodopa–foscarbidopa available to the NHS with a discount.

## Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies *(terminated appraisal)* TA933

NICE is **unable to make a recommendation** on tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma in adults after 2 or more systemic therapies. This is because the company did not provide a complete evidence submission.

## Decitabine–cedazuridine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable *(terminated appraisal)* TA932

NICE is **unable to make a recommendation** on decitabine–cedazuridine for untreated acute myeloid leukaemia in adults when intensive chemotherapy is unsuitable. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

## Zanubrutinib for treating chronic lymphocytic leukaemia TA931

### Recommendations

Zanubrutinib is **recommended** as an option for treating chronic lymphocytic leukaemia (CLL) in adults. It is only recommended if the CLL is:

- untreated and
    - there is a 17p deletion or tumour protein 53 (TP53) mutation or
    - there is no 17p deletion or TP53 mutation, and fludarabine plus cyclophosphamide and rituximab (FCR), or bendamustine plus rituximab (BR) is unsuitable, or
- relapsed or refractory.

  Zanubrutinib is recommended only if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with zanubrutinib 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 clinician consider it appropriate to stop.

## The Technology

Chronic lymphocytic leukaemia (CLL) is the most common form of chronic leukaemia and is a type of cancer that affects the white blood cells. It tends to progress slowly over many years. The risk of developing CLL increases with age and is more common in men. CLL mostly affects people 60 years of age and over and is rare in people 40 years of age and younger.

In CLL, the material found inside some bones produces too many white blood cells, called lymphocytes, that are not fully developed and do not work properly. CLL usually progresses slowly, but over time people can develop anaemia, swollen lymph nodes, spleen enlargement and unexplained weight loss. People with CLL may live with a considerable burden of symptoms and an increased susceptibility to infection impacting on their quality of life, whether or not they have had treatment.

The British Society of Haematology defines people with 'high risk' CLL as those with previously untreated CLL associated with a 17p deletion or TP53 mutation. The presence of 17p deletion or TP53 mutation influences the rate of cell growth and is associated with resistance of the disease to conventional chemotherapy treatments.

The presence of 17p deletion or TP53 mutation can be used as markers to predict the prognosis of people with CLL. The presence of an immunoglobulin heavy chain gene (IgHV) mutation may also affect clinical outcomes. Treatment of CLL is complex and depends on several factors such as stage of disease, previous treatment, patient's age, symptoms, and general state of health. Many people with CLL will not have symptoms when they are first diagnosed and will have a period of active surveillance. The disease is monitored for progression and treatment is initiated upon progression. Chemotherapy can achieve complete remission, but the disease may eventually relapse. Immunotherapies, such as rituximab, have been shown to improve survival and remission rates, particularly when combined with chemotherapy. Targeted therapies, such as acalabrutinib, ibrutinib, idelalisib and venetoclax are particularly useful in people with a poor prognosis, such as those with relapsed or refractory disease and those with 17p deletion or TP53 mutation.

## Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence suggests that zanubrutinib extends the length of time people have before their condition gets worse compared with BR and ibrutinib in untreated CLL and relapsed or refractory CLL respectively. But there are no clinical trials comparing it with other CLL treatments and the results of indirect comparisons are uncertain.

For untreated CLL, despite the uncertainty, zanubrutinib is only cost effective or cost saving compared with usual treatments in high-risk CLL, or for non-high-risk CLL when FCR or BR is unsuitable. So, it is only recommended in these populations.

For people with relapsed or refractory CLL, despite the uncertainty, zanubrutinib is cost effective or cost saving compared with the usual treatments. So, it is recommended in this population.

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

NICE estimate that the incidence of chronic lymphocytic leukaemia is 64 people in Devon, of these, 54 are eligible for treatment.

## Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments TA930

### Recommendations

Lutetium-177 vipivotide tetraxetan is **not recommended**, within its marketing authorisation, for treating prostate-specific membrane antigen (PSMA)-positive hormone-relapsed metastatic prostate cancer in adults:

- after taxane-based chemotherapy and an anti-androgen or
- when taxanes are 'medically unsuitable'.

This recommendation is not intended to affect treatment with lutetium-177 vipivotide tetraxetan 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 clinician consider it appropriate to stop.

### The Technology

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer. Prostate cancers can highly express a transmembrane protein called prostate specific membrane antigen (PSMA). PSMA expression is further increased in poorly differentiated, metastatic, and hormone-refractory prostate cancers.

NG131 recommends androgen deprivation therapy (luteinising hormone-releasing hormone agonist therapy, bicalutamide or bilateral orchidectomy) for people whose prostate cancer is sensitive to such hormonal therapy. Docetaxel can be added to luteinising hormone-releasing hormone agonist therapy. Hormone-relapsed prostate cancer refers to prostate cancer which has progressed on androgen deprivation therapy.

Other NICE recommended treatment options:

- TA712 enzalutamide for treating hormone-sensitive metastatic prostate cancer
- TA741 apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer
- TA660 darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer
- TA740 apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer
- TA580 enzalutamide for hormone-relapsed non-metastatic prostate cancer
- TA387 abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated
- TA377 enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated
- TA259 abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen
- TA316 enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen
- TA412 radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases
- TA391 cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel

$^{177}$Lu vipivotide tetraxetan is a human PSMA targeted ligand that is conjugated to the beta-emitting radioisotope lutetium ($^{177}$Lu). It is delivered by intravenous infusion. It works by releasing an energetic beta particle to precisely deliver radiation to kill prostate cancer cells. $^{177}$Lu vipivotide tetraxetan can be administered by intravenous infusion or injection.

## Financial Factors

This technology is commissioned by NHS England.

When compared with best supportive care, lutetium-177 vipivotide tetraxetan meets NICE's criteria for a life-extending treatment at the end of life. It is unclear whether this is the case when it is compared with cabazitaxel because of the uncertainty in the clinical evidence. The most likely cost-effectiveness estimates for lutetium-177 vipivotide tetraxetan compared with best supportive care and cabazitaxel are higher than what NICE normally considers an acceptable use of NHS resources, even when taking the end-of-life criteria into consideration. Therefore, it is not recommended for routine use.

Because of the high cost-effectiveness estimates and a lack of new data comparing lutetium-177 vipivotide tetraxetan with relevant medicines, it cannot be recommended for use in the Cancer Drugs Fund.

## Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction TA929

### Recommendations

Empagliflozin is **recommended**, within its marketing authorisation, as an option for treating symptomatic chronic heart failure with preserved or mildly reduced ejection fraction in adults.

If people with the condition and their clinicians consider empagliflozin to be 1 of a range of suitable treatments (including dapagliflozin), after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

### The Technology

Heart failure is a complex clinical syndrome of signs and symptoms, generally defined as the inability of the heart to supply sufficient blood flow to meet the body's needs. It is caused by structural or functional abnormalities of the heart, commonly resulting from coronary artery disease. Other conditions that can increase the risk of heart failure include; ischaemic heart disease, atrial fibrillation, valve disease, hypertension, diabetes, chronic obstructive pulmonary disease, and asthma.

The European Society of Cardiology (ESC) defines 3 types of chronic heart failure based on left ventricular ejection fraction (LVEF), a measurement of how much blood the left ventricle pumps out with each contraction. The ESC defines heart failure with reduced ejection fraction as a LVEF of 40% or less; mildly reduced ejection fraction as a LVEF between 41% and 49%; and preserved ejection fraction as a LVEF of 50% or more.

NG106 states that heart failure with preserved ejection fraction is usually associated with impaired left ventricular relaxation, rather than left ventricular contraction and is characterised by normal or preserved LVEF with evidence of diastolic dysfunction.

Symptoms of heart failure commonly include breathlessness, fatigue and ankle swelling. Quality of life is affected by the physical limitations imposed by the symptoms. Both the prevalence and incidence of heart failure increase with age. Around 24% of people diagnosed with heart failure die within the first year, with a 5-year mortality rate of about 55%.

NG106 recommends low to medium dose loop diuretics for people with chronic heart failure with preserved ejection fraction. Specialist advice is needed if the disease does not respond. Most people with chronic heart failure with preserved ejection fraction also have symptomatic treatments for comorbidities, including angiotensin converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs), betablockers or mineralocorticoid receptor antagonists (MRAs).

## Financial Factors

This technology is commissioned by ICBs.

NICE do not expect this guidance to have a significant impact on resources. This is because the technology is a further treatment option, is available at the same price as dapagliflozin and clinical outcomes are expected to be similar.

NICE estimate that in Devon, 4,451 people are eligible for treatment with empagliflozin. Of these, 3,116 (70%) people will receive standard care. There will be an equal market share (15% each) for people receiving treatment with either empagliflozin or dapagliflozin (668 people).

**Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine TA928**

## Recommendations

Cabozantinib is **not recommended**, within its marketing authorisation, for treating locally advanced or metastatic differentiated thyroid cancer (DTC) that is unsuitable for or refractory to radioactive iodine, and that has progressed after systemic treatment, in adults.

This recommendation is not intended to affect treatment with cabozantinib 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 clinician consider it appropriate to stop.

## The Technology

Thyroid cancer is a rare type of cancer that affects the thyroid gland, a gland at the base of the neck that produces hormones. Thyroid cancers can be differentiated or undifferentiated. Differentiated thyroid cancer cells retain the appearance of normal thyroid cells and do not spread as quickly as undifferentiated cancer cells.

There are 4 main types of thyroid cancer: papillary, follicular, medullary and anaplastic. Papillary and follicular carcinomas are differentiated thyroid cancers and the most common types of thyroid cancer, with similar management and prognosis. There are also several less common variants of differentiated thyroid cancer, including but not limited to Hürthle cell, tall cell, insular and columnar.

Thyroid cancer is usually treated by partial or total thyroidectomy. The choice of surgery depends on the type and size of cancer amongst other factors. Surgery may be followed by adjuvant treatments. Primarily, this is radioactive iodine which is used to destroy any residual thyroid tissue and any remaining cancer cells. External beam radiotherapy or palliative chemotherapy can also be used. The British Thyroid Association's 'Guidelines for the management of thyroid cancer' notes that the use of external beam radiotherapy and chemotherapy in palliative care has begun to be superseded by targeted therapy.

In clinical practice, best supportive care or monitoring is offered until the disease starts to progress and symptoms occur, or there is rapid progression that is likely to become symptomatic. For residual or recurrent disease targeted therapy (tyrosine kinase inhibitors) may be used.

TA535 recommends lenvatinib and sorafenib. TA742 recommends selpercatinib for use within the Cancer Drugs Fund as an option for treating advanced RET fusion-positive thyroid cancer. TA630 recommends larotrectinib for use within the Cancer Drugs Fund as an option for treating for treating NTRK fusion-positive solid tumours.

### Financial Factors

This technology is commissioned by NHS England.

Because it is not clear if cabozantinib increases how long people live, the cost-effectiveness estimates would need to be within the lower half of the range that NICE considers an acceptable use of NHS resources. But the most likely cost-effectiveness estimates are towards the higher end of the range that NICE considers an acceptable use of NHS resources. This is true when considering the condition's severity, its effect on quality and length of life and the unmet need.

More evidence could help address the uncertainty about the benefits of cabozantinib, but the company has said that there would be no more evidence from the trial. Therefore, cabozantinib is not recommended.

## Highly Specialised Technology Guidance (HSTs)

None published this month.

## NICE Guidelines (NGs)

**Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management NG237 (UPDATE)**

This guideline covers assessment of people aged 16 and over with symptoms and signs of an acute respiratory infection (both bacterial and viral) at first remote or in-person contact with NHS services. It also covers the initial management of any infections. It aims to support healthcare practitioners in making sure that people's treatment follows the best care pathway. It forms part of a suite of work on virtual wards being undertaken by NICE.

**November 2023: NICE amended their guidance to clarify that the threshold for treatment or referral for further assessment may be lower for people with an acute respiratory infection who are more likely to have a poor outcome.**

## Hypertension in adults: diagnosis and management NG136 (UPDATE)

This guideline covers identifying and treating primary hypertension (high blood pressure) in people aged 18 and over, including people with type 2 diabetes. It aims to reduce the risk of cardiovascular problems such as heart attacks and strokes by helping healthcare professionals to diagnose hypertension accurately and treat it effectively.

**November 2023: NICE updated their guidance on measuring and managing postural hypotension. NICE also added tables to the section on monitoring treatment and blood pressure targets to summarise blood pressure targets in this guideline and their guidelines on type 1 diabetes and chronic kidney disease.**

## Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer CG164 (UPDATE)

This guideline covers care for people with a family history of breast, ovarian or another related (prostate or pancreatic) cancer. It aims to improve the long-term health of these families by describing strategies to reduce the risk of and promote early detection of breast cancer (including genetic testing and mammography). It also includes advice on treatments (tamoxifen, raloxifene) and surgery (mastectomy).

**November 2023: NICE removed the off-label warning for anastrozole in recommendations 1.7.22 and 1.7.26 on chemoprevention for women at moderate or high risk of breast cancer, in line with the MHRA licence variation.**

## Transient loss of consciousness ('blackouts') in over 16s CG109 (UPDATE)

This guideline covers assessment, diagnosis and referral for people over 16 who have had a transient loss of consciousness (TLoC; also called a blackout). It aims to improve care for people with TLoC by specifying the most effective assessments and recommending when to refer to a specialist.

**November 2023: In the section on assessment and referral for suspected postural hypotension NICE amended recommendation 1.2.1.1 and made a new recommendation (1.2.1.2).**

## NICE Rapid COVID-19 Guidelines

**COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)**

This guideline covers the management of COVID-19 for babies, children, young people and adults in all care settings.

**November 2023: NICE replaced two recommendations on managing acute cough with a link to the NICE guideline on cough (acute): antimicrobial prescribing (NG120).**

**NICE removed the recommendation to consider benzodiazepine for managing anxiety or agitation because health system support for people with COVID-19 has changed significantly since the guideline was developed.**

**NICE removed the recommendations on medicines for end of life care because these are covered by the NICE guidelines on care of dying adults in the last days of life (NG31), end of life care for adults: service delivery (NG142) and care and support of people growing older with learning disabilities (NG96), which are already linked from this guideline.**

## Public Health Guidelines

None published this month.

## Antimicrobial Prescribing Guidelines

None published this month.

## Social Care Guidelines

None published this month.

## Interventional Procedures Guidance (IPGs)

**Percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism IPG778**

### Recommendations

**High-risk pulmonary embolism (PE) when alternative treatments are not suitable:**

For high-risk PE in people who cannot have thrombolysis, or when there are no other suitable treatment options or alternative treatments have failed, percutaneous thrombectomy should only be used with **special arrangements** for clinical governance, informed consent and audit.

Clinicians wanting to do percutaneous thrombectomy for high-risk PE when alternative treatments are not suitable 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 clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

**Intermediate-risk PE or high-risk PE when alternative treatments are suitable:**

For intermediate-risk PE or high-risk PE when alternative treatments are suitable, pulmonary thrombectomy **should only be used in research**.

Further research should be in the form of randomised controlled trials or registries. It should report:

- patient selection
- size and position of the clot
- degree of right ventricular dysfunction
- details of the procedure, including the device used
- short- and long-term outcomes, including patient-reported outcomes.

## The Condition

A pulmonary embolism (PE) is when a pulmonary artery is obstructed by an embolus (usually a blood clot) that travels to the lungs from deep veins in the leg or pelvis. PE often causes shortness of breath, chest pain and cough. The symptoms and severity vary from no symptoms to cardiovascular collapse and death.

A high-risk PE (also known as massive PE) is defined by sustained systemic hypotension or shock. An intermediate-risk PE (also known as sub massive PE) involves right ventricular dysfunction or myocardial injury without major haemodynamic compromise. High-risk PE accounts for less than 10% of acute PE cases and is a medical emergency with a high mortality rate.

The first-line treatment for PE is systemic or oral anticoagulants. For high- or intermediate-risk PE with haemodynamic compromise, systemic thrombolysis may be used or, rarely, open surgical embolectomy. Catheter-directed therapies may also be used, including catheter-directed thrombolysis and percutaneous thrombectomy. Catheter-directed therapies are usually used if someone has a high-risk PE and they cannot have surgery, or when systemic thrombolysis is contraindicated or has failed.

### The Procedure

In this endovascular procedure, a catheter is inserted percutaneously into the peripheral vasculature and advanced through the right side of the heart into the pulmonary arteries under image guidance. This procedure is usually done by interventional radiologists and interventional cardiologists. It is usually done using local anaesthesia with or without sedation.

There are several thrombectomy devices available with some variation in their mechanism of action. The thrombus may be fragmented before removal or not. There are several methods by which the thrombus can be removed: vacuum suction, aspiration with a syringe, mechanical removal with a clot removal device, or a combination of methods. It is a minimally invasive procedure that may be used alone or in combination with other treatment options for PE.

The aim of the procedure is to rapidly remove the obstruction and restore pulmonary circulation, reducing right ventricular strain, while avoiding the bleeding risks associated with thrombolysis.

## Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis IPG777

**This guidance updates and replaces IPG388 (published April 2011).**

### Recommendations

Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis should:

- Tell the clinical governance leads in their healthcare organisation.

- Make sure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Consider 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:

- Make sure systems are in place that support clinicians 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 that should include an interventional radiologist or a neuroradiologist, a vascular surgeon, and a stroke physician or neurologist.

The procedure should only be done by clinicians with specific training and expertise in this technique.
NICE encourages clinicians to submit data to the National Vascular Registry.

Further research should include details of patient selection and report longer-term outcomes.

## The Condition

The main arteries in the neck can become narrowed by fatty deposits. Blood clots can form on these fatty deposits. Fragments can then detach and lodge in thinner arteries that supply blood to parts of the brain. This can cause a stroke or a transient ischaemic attack (sometimes called a 'mini stroke'). In some people, the carotid stenosis is asymptomatic. It may be identified incidentally during imaging and investigations for other conditions, or during health screening.

For people with asymptomatic extracranial carotid stenosis, management includes lifestyle modification (diet, exercise and smoking cessation) and pharmacological therapy (antithrombotics, lipid-lowering agents, blood pressure reduction and glycaemic control). Some people with severe stenosis may be offered revascularisation and the conventional surgical approach used is carotid endarterectomy (CEA). This involves making an incision in the side of the neck to access the narrowed section of artery to remove the fatty deposits. A newer alternative approach is transcervical carotid artery revascularisation, which uses a transcarotid neuroprotection system. The common carotid artery is accessed directly, through a smaller incision than in CEA. This procedure is not being considered in this guidance. NICE's

interventional procedures guidance on transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting (IPG561) was published in 2016.

### The Procedure

Carotid artery stent placement is usually done under local anaesthetic, after imaging. It involves passing a guidewire into the carotid artery. The usual access point is the common femoral artery, but radial access has also been used. The carotid stenosis is then usually predilated using a balloon catheter. A metal mesh (stent) is inserted, which keeps the artery open to maintain blood flow and prevent restenosis and embolism.

Embolic protection devices are often used during the procedure to reduce the risk of procedural cerebral emboli.

Carotid stenting is a less invasive percutaneous alternative to CEA. Potential advantages include the avoidance of general anaesthesia and the need for a neck incision that may result in cranial and cutaneous nerve damage. The rate of general surgical complications such as myocardial infarction may also be reduced.

## Extracorporeal carbon dioxide removal for acute respiratory failure IPG776

**This guidance updates and replaces IPG564 (published June 2012).**

### Recommendations

**People with acute hypoxic respiratory failure**

For people with acute hypoxic respiratory failure, extracorporeal carbon dioxide removal (ECCO2R) **should not be used**.

**People with acute hypercapnic respiratory failure**

For people with acute hypercapnic respiratory failure, ECCO2R should be used **only in research**.

Patient selection should be done by a multidisciplinary team including healthcare professionals with specialist expertise in managing acute hypercapnic respiratory failure.

The procedure should only be done by healthcare professionals with specialist expertise in the procedure in specialist intensive care centres with appropriate levels of support.

Research should report:

- short-term and long-term:
    - patient-reported outcomes
    - improvements in respiratory function

- adverse events including:
    - bleeding
    - symptomatic and asymptomatic intracranial bleeding
    - infection
    - cannulation complications
    - pain.

## The Condition

Acute respiratory failure is a life-threatening condition. It can be categorised as **acute hypoxic respiratory failure** (abnormally low levels of oxygen in the blood) or **acute hypercapnic respiratory failure** (abnormally low levels of oxygen and abnormally high levels of carbon dioxide in the blood). Acute respiratory distress syndrome is a severe type of acute respiratory failure. It can be caused by conditions such as:

- sepsis
- pneumonia
- respiratory viruses
- chest trauma
- inhalational injury
- aspiration and
- pancreatitis.

    The most common cause of hypercapnic respiratory failure is an acute exacerbation of chronic obstructive pulmonary disease.

The management of acute respiratory failure involves treating the underlying cause and providing increased oxygen by non-invasive or invasive ventilation.

## The Procedure

The 2 main types of extracorporeal carbon dioxide removal (ECCO2R) are venovenous (vvECCO2R) and arteriovenous (avECCO2R). In both types, cannulae are connected to a low-resistance synthetic membrane device where exchange of carbon dioxide takes place. In vvECCO2R, either a single-access double-lumen catheter or a dual-access system using 2 venous catheters is inserted into a large vein or veins (usually the femoral or internal jugular veins). It is then connected to a venovenous circuit. Flow across the membrane is maintained using a pump. In avECCO2R, cannulae are inserted into an artery and a vein (usually the femoral

artery and femoral vein). Arterial blood pressure drives blood continuously through the device and it is returned through the vein.

ECCO2R can be done using either a true ECCO2R system or a modified extracorporeal membrane oxygenation system. People having ECCO2R are given blood-thinning drugs such as heparin to prevent blood clots forming in the circuit.

For people with **acute hypoxic respiratory failure**, ECCO2R aims to lower carbon dioxide levels in the blood, independently of the lungs. Lung-protective ventilation settings such as lower airway pressures and lower tidal volumes can be used to reduce the risk of ventilator-induced lung injury. But, using lung-protective settings can cause carbon dioxide levels to rise, leading to negative effects. ECCO2R is used to reduce blood carbon dioxide levels so that lung-protective ventilation settings can be maintained. This may improve the likelihood and speed of lung recovery.

For people with **acute hypercapnic respiratory failure**, ECCO2R aims to reduce the need for intubation and mechanical ventilation. It may also reduce the length of time that a person has non-invasive ventilation.

## Biodegradable subacromial spacer insertion for rotator cuff tears IPG775

**This guidance updates and replaces IPG558 (published May 2016)**

### Recommendations

**When debridement is a suitable option:**

When debridement is a suitable option, biodegradable subacromial spacer insertion for rotator cuff tears **should not be used**.

**When debridement is not a suitable option:**

When debridement is not a suitable option, biodegradable subacromial spacer insertion for rotator cuff tears should be used **only in research**.

Further research should ideally be randomised controlled trials. It should report details of patient selection (including demographics and the tear size), measures of shoulder function, pain relief and quality of life. Follow up should ideally be for at least 2 years.

Patient selection should be done by a multidisciplinary team experienced in managing the condition, including clinicians with specific training in the procedure.

The procedure should only be done by surgeons with specific training in inserting the device.

### The Condition

People who have rotator cuff tears may have shoulder pain and weakness, with reduced shoulder function, leading to a reduced quality of life. Rotator cuff tears can be caused by an injury or can develop gradually. They can be minor or severe depending on the degree of damage to the tendons. Minor tears to the rotator cuff are very common and may not cause any symptoms at all. Diagnosis is usually by ultrasound or MRI.

Conservative treatment may include physical therapy, pharmacological treatments and corticosteroid injections. If the tear is severe or has not responded to other treatments, surgical interventions such as debridement, rotator cuff repair, subacromial smoothing, tendon transfer or shoulder arthroplasty may be needed.

### The Procedure

Inserting a biodegradable subacromial spacer aims to improve pain and restore shoulder function in people who have irreparable rotator cuff tears. The aim is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It is a less invasive and potentially safer alternative to reverse shoulder arthroplasty or tendon transfer and has shorter procedure and rehabilitation times.

The procedure is done under general or regional anaesthesia. The subacromial space is visualised using either arthroscopy or mini-open surgery. The damaged area is surgically cleared. Measurements are taken to determine the size of biodegradable spacer needed. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once a sufficient volume is reached, the balloon is sealed and left in place. The balloon spacer is made from a biodegradable polymer and resorbs over about 1 year.

## Medical Technologies Guidance (MTGs)

None published this month.

## Diagnostics Guidance (DGs)

None published this month.

# Health Technology Evaluations (HTE)

## Virtual reality technologies for treating agoraphobia or agoraphobic avoidance: early value assessment HTE15

### Recommendations

**Can be used in the NHS with evidence generation:**

gameChangeVR (a virtual reality [VR] technology) can be used in the NHS while more evidence is generated, to treat severe agoraphobic avoidance in people with psychosis aged 16 and over. It should be used with the support of a mental health professional.

The company must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and 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, or sooner if enough evidence is available), the company 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 following VR technologies:

- Amelia Virtual Care to treat agoraphobia
- gameChangeVR to treat mild to moderate agoraphobic avoidance in people with psychosis
- XR Therapeutics to treat agoraphobia.

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

The technologies can only be used once they have appropriate regulatory approval.

**Evidence generation and research:**

More evidence generation and research are needed on:

- clinical effectiveness, including long-term benefits and who may benefit most from using VR technologies
- rates of relapse or worsening of symptoms, including use and effectiveness of extra VR therapy sessions

- adverse effects
- resource use, including maintenance and lifespan of the hardware, and mental health professional grade and time needed to deliver treatment or support.

## The Technology

Agoraphobia is an anxiety disorder characterised by marked and excessive fear of being in situations where escape may be difficult or help may not be available. Some people may describe this experience as feeling threatened or worried about going out. It involves fear and avoidance of places or situations that might cause panic and feelings of being trapped, helpless or embarrassed. This anxious avoidance of everyday situations may occur with other mental health disorders including panic disorder, depression, social anxiety and psychosis.

Agoraphobia may further impact a person's ability to access mental health services and support. Clinical experts advised that agoraphobia is often untreated or undertreated when it occurs with other mental health conditions because treatment tends to focus on the more severe or prominent disorder. Some people with agoraphobia or agoraphobic avoidance may also discontinue treatment because of difficulty tolerating techniques such as exposure therapy, which gradually increases a person's exposure to situations they fear and avoid.

VR may increase access to care by offering another treatment option for people with agoraphobia or agoraphobic avoidance. VR is a simulated 3-dimensional environment with scenes and objects that people can explore and interact with, most typically using a VR headset. This creates an immersive experience that can trigger emotional responses similar to those in real-world situations. VR may be used as a tool in therapy sessions or as a digital intervention with the support of a mental health worker. It allows people to immerse themselves in real-world situations while being in the safety of their home or clinic. Virtual environments can be adjusted based on a person's needs and individual treatment plan. This could allow more gradual exposure to stressful situations and increased comfort and confidence in completing interventions.

VR would support remote delivery of treatment which would allow some people to receive treatment in their own home. This could increase access to care for those who are unable or prefer not to attend face-to-face treatment. Clinical experts suggested that this may help with quicker management of symptoms and could help people work towards accessing face-to-face treatment in the future if needed. VR interventions are scalable and may allow mental health professionals to treat more people in less time. This could save time and resources compared with standard care interventions for agoraphobia and agoraphobic avoidance.

## Financial Factors

This technology is commissioned by NHS England and ICBs.

Based on the economic evidence supporting gameChangeVR, the resources needed for implementation include the licence fee per person, per course of treatment, the virtual reality (VR) headset, clinical psychologist time, mental health worker time, and training. The mental health

professional salary band and the time needed to deliver or support therapy sessions varies across the country. Therapy is delivered in around 6 weekly 30-minute sessions. The cost per session, and for a course of treatment, would depend on local service configuration and should be assessed at that level. The annual licence fee is commercial in confidence.

Access to therapy may be limited by NHS workforce pressures, including not having enough trained staff to deliver CBT in community mental health teams. Because gameChangeVR can be delivered and supported by a wider range of mental health professionals than standard care, more people could have access to treatment.

## NICE Quality Standards

None published this month.

## Current NICE Consultations

| Title/link | End date of consultation |
|---|---|
| Early and locally advanced breast cancer: diagnosis and management - further surgery (update) | 01/12/2023 |
| Motor Neurone Disease | 04/12/2023 |
| Caesarean birth - placenta accreta spectrum | 11/12/2023 |
| Rheumatoid arthritis (update) | 11/12/2023 |
| Ritlecitinib for treating severe alopecia areata in people 12 years and over [ID4007] | 15/12/2023 |
| Cabozantinib with nivolumab for untreated advanced renal cell carcinoma [ID6184] | 21/12/2023 |