NHS Devon

NICE Update Bulletin: January 2024

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

1. **Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments TA948**
2. **Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments TA947**
3. **Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer TA946**
4. **Treosulfan with fludarabine before allogeneic stem cell transplant for people aged 1 month to 17 years with non-malignant diseases (*terminated appraisal*) TA945**
5. **Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer TA944**
6. **Sebelipase alfa for treating Wolman disease HST30**
7. **Caesarean birth NG192 (UPDATE)**
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10. **COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)**
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12. **Temperature control to improve neurological outcomes after cardiac arrest IPG782**
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Technology Appraisals (TAs)

Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments TA948

Recommendations

Ivosidenib is **recommended**, within its marketing authorisation, as an option for treating locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation in adults after 1 or more systemic treatments. It is only recommended if the company provides it according to the commercial arrangement.

The Technology

Cholangiocarcinoma is cancer of the bile duct. It mainly affects people aged over 65. Most people already have advanced cholangiocarcinoma when they are diagnosed because early disease is often asymptomatic. When symptoms occur, they include jaundice, weight loss, pain, sickness and fever.

Cholangiocarcinoma can be classified into 3 subtypes, depending on which part of the bile duct the cancer starts in:

- Intrahepatic cholangiocarcinoma starts in the bile ducts inside the liver
- Peri-hilar cholangiocarcinoma starts just outside the liver (where the left and right hepatic ducts meet)
- Distal cholangiocarcinoma starts in the bile ducts near the bowel.

Surgery is currently the only curative treatment for cholangiocarcinoma. When surgery is not an option people can be offered gemcitabine and cisplatin. After systemic chemotherapy, people may be offered modified folinic acid, fluorouracil and oxaliplatin (mFOLFOX). TA722 recommends pemigatinib for treating advanced cholangiocarcinoma with FGFR2 fusion or rearrangement after systemic therapy in adults

Ivosidenib is a small molecule inhibitor of IDH1. Blocking IDH1 activity is expected to reduce the growth and spread of the cancer. It is administered orally.

Financial Factors

This technology is commissioned by NHS England.

NICE do not expect a significant impact of implementing the recommendation in England. This is because the population is small and any increase in drug cost will be partly offset by ivosidenib being an oral treatment and requiring fewer administrations than its comparator, mFOLFOX, which is administered by intravenous (IV) infusion. As a consequence, treatment with ivosidenib incurs lower administration costs.

In addition to capacity benefits, there are also wider benefits to people and environmental benefits associated with reduced need to travel to chemotherapy day centres.

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

NICE estimate that in Devon, 4 people are eligible for treatment, rising to 5 people at year five.

Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments TA947

Recommendations

Loncastuximab tesirine is **recommended** as an option for treating relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) after 2 or more systemic treatments in adults, only if:

- they have previously had polatuzumab vedotin, or if polatuzumab vedotin is contraindicated or not tolerated, and
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with loncastuximab tesirine 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

Lymphomas are cancers of the lymphatic system, which is a part of the immune system. Lymphomas are divided into Hodgkin lymphoma and non-Hodgkin lymphoma.

Non-Hodgkin lymphomas (NHL) are a diverse group of conditions which are categorised according to the cell type affected (B-cell or T-cell), as well as the clinical features and rate of progression of the disease. High-grade NHL is an aggressive, fast-growing form of the disease.

The most common B-cell lymphomas are:

- Follicular lymphoma (FL), a slow growing, low grade form of NHL
- Diffuse large B-cell lymphomas (DLBCL), a fast-growing, high-grade NHL.

Some FLs transform into high grade DLBCL (transformed high grade FL). There are also other forms of high-grade B-cell lymphomas.

It is estimated that around 40% of NHL cases are DLBCL. DLBCL is more common in men than women and most cases are diagnosed in people aged 65 years or older. Around 60% of people will survive 5 years or more following a diagnosis of DLBCL.

Although most patients are cured with first-line chemotherapy, about 10-15% have primary refractory disease and a further 20-30% relapse. NG52 recommends multi-agent chemotherapy in combination with rituximab for relapsed or refractory disease, potentially followed by stem cell transplantation for people fit enough to have it.

Chemotherapy regimens commonly used in clinical practice include DHAP, GDP, ICE and IVE. If stem cell transplantation is not suitable, further chemotherapy or immunotherapy may be used alone.

For people with relapsed or refractory DLBCL, NICE recommends: TA306, TA649, TA874, TA933.

Financial Factors

This technology is commissioned by NHS England.

Standard treatment for relapsed or refractory DLBCL after 2 or more systemic treatments includes polatuzumab vedotin with rituximab and bendamustine (polatuzumab plus BR), and chemotherapy. There is no standard treatment for HGBL, but people are usually offered the same treatments as for DLBCL. Because a polatuzumab-containing therapy has recently been made available earlier in the treatment pathway, in the future, people are more likely to have chemotherapy if they have already had treatment with polatuzumab vedotin.

Evidence from 1 clinical trial shows that some people with DLBCL and HGBL having loncastuximab tesirine have all signs and symptoms of their cancer disappear. But it was not compared with any other treatments in the trial, so it is not known how it directly compares with standard treatment. The results from indirect comparisons of loncastuximab tesirine with other treatments are very uncertain, but suggest it is as effective as polatuzumab plus BR and more effective than chemotherapy.

Because of their similar clinical effectiveness, only the difference in cost between loncastuximab tesirine and polatuzumab plus BR was considered, and loncastuximab tesirine is more expensive. For loncastuximab tesirine compared with chemotherapy, when considering the condition's severity, and its effect on quality and length of life, the most likely cost-effectiveness estimates are below what NICE normally considers an acceptable use of NHS resources. Therefore, loncastuximab tesirine is recommended, but only for people who have previously had polatuzumab vedotin, or if polatuzumab vedotin is contraindicated or not tolerated.

Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer TA946

This guidance updates and replaces TA693 (published April 2021)

Recommendations

Olaparib with bevacizumab is **recommended**, within its marketing authorisation, for maintenance treatment of high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults whose cancer:

- has completely or partially responded after first-line platinum-based chemotherapy with bevacizumab
- is advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages 3 and 4) and
- is homologous recombination deficiency (HRD) positive (defined as having either a BRCA1 or BRCA2 mutation, or genomic instability).

The Technology

Ovarian cancer is a cancerous growth that occurs in different parts of the ovary or fallopian tubes. The most common type of ovarian cancer, high-grade serous carcinoma, is thought to arise from the fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage I to stage IV. Advanced ovarian cancer falls within stages II and IV; in stage II the disease has grown outside the ovaries but is still within the pelvic area, stage III denotes disease that is locally advanced and has spread outside the pelvis into the abdominal cavity and stage IV denotes that distant metastasis to other body organs such as the liver and the pleura (two thin layers of tissue that protect and cushion the lungs) has occurred. Most people are diagnosed with advanced stage disease. Some people have gene mutations that may increase the risk of ovarian cancer. Mutated inherited genes that increase the risk of ovarian cancer include BRCA 1 or 2. Around half of high-grade serous ovarian cancers are positive for homologous recombination deficiency (HRD), a deficiency in DNA double-strand break repair.

Financial Factors

This technology is commissioned by NHS England.

This evaluation reviews the evidence for **TA693**. It also reviews new evidence collected as part of the managed access agreement. New clinical trial evidence shows that people taking olaparib with bevacizumab have more time before their cancer comes back than people having bevacizumab alone and that they also live longer.

The most likely cost-effectiveness estimates for olaparib with bevacizumab are within what NICE considers an acceptable use of NHS resources Therefore, it is recommended for routine use in the NHS.

NICE estimate that in Devon 12 people will be eligible for treatment.

Treosulfan with fludarabine before allogeneic stem cell transplant for people aged 1 month to 17 years with non-malignant diseases (*terminated appraisal*) TA945

NICE is **unable to make a recommendation** on treosulfan with fludarabine before allogeneic stem cell transplant for babies, children and young people aged 1 month to 17 years with non-malignant diseases. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer TA944

Recommendations

Durvalumab plus gemcitabine and cisplatin is **recommended**, within its marketing authorisation, as an option for treating locally advanced, unresectable, or metastatic biliary tract cancer in adults. It is only recommended if the company provides durvalumab according to the commercial arrangement.

The Technology

The biliary tract includes the organs and ducts that make and store bile. The liver and gallbladder are connected to the small bowel by a network of small tubes called ducts which carry bile. Biliary tract cancer (BTC) includes bile duct cancer, gallbladder cancer and ampullary cancer. Cancer of the bile ducts is called cholangiocarcinoma and is classified depending on which part of the bile duct the cancer originates. The main types of cholangiocarcinoma include intrahepatic (affects bile ducts inside the liver) and extrahepatic (affects the bile ducts outside the liver and includes perihilar and distal cholangiocarcinoma).

Surgery remains the curative intent treatment option leading to long-term survival for people diagnosed with resectable BTC. Most people with BTCs are diagnosed with unresectable locally advanced or metastatic disease. People with unresectable tumours are offered palliative treatment. The treatments vary depending on Eastern Cooperative Oncology Group (ECOG) performance status (PS), molecular profiling and disease distribution.

Chemotherapy is typically used in the first-line treatment of BTC that cannot be surgically removed. People with unresectable BTC are typically offered chemotherapy with a combination of cisplatin and gemcitabine. For some BTCs, oxaliplatin might be offered instead of cisplatin, especially if there are any concerns over kidney function. Frailer people might be offered single-agent chemotherapy with gemcitabine, fluorouracil (5-FU) or capecitabine alone. For disease that has progressed following first-line treatment, further chemotherapy is recommended. Radiotherapy in addition to chemotherapy may also be offered to some people to relieve symptoms.

Financial Factors

This technology is commissioned by NHS England.

Limited treatments options are available for unresectable or advanced biliary tract cancer, including cancer which reoccurs after surgery. Standard treatment includes chemotherapy with gemcitabine and cisplatin.

Clinical trial evidence shows that, compared with standard treatment, durvalumab plus gemcitabine and cisplatin increases how long people have before their condition gets worse and how long they live.

The cost-effectiveness estimates are uncertain. When considering the condition's severity, and its effect on quality and length of life, the most likely estimates are within the range that NICE considers an acceptable use of NHS resources. Therefore, durvalumab plus gemcitabine and cisplatin is recommended.

NICE estimate that in Devon, 17 people will be eligible for treatment.

Highly Specialised Technology Guidance (HSTs)

Sebelipase alfa for treating Wolman disease HST30

Recommendations

Sebelipase alfa is **recommended** as an option for long-term enzyme replacement therapy in Wolman disease (rapidly progressive lysosomal acid lipase deficiency [LAL-D]), only if people are 2 years or under when treatment starts. It is recommended only if the company provides sebelipase alfa according to the commercial arrangement.

This recommendation is not intended to affect treatment with sebelipase alfa 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. This decision should be made jointly by the clinician, the child, and their parents or carers.

The Technology

Lysosomal acid lipase (LAL) deficiency is an inherited autosomal recessive lysosomal storage disorder. It is caused by a deficiency of the LAL enzyme resulting in abnormal accumulation of lipids in cells primarily in the gastrointestinal, hepatic and cardiovascular systems. LAL deficiency is caused by a marked decrease or loss in LAL enzyme activity and affects people of all ages from infancy through adulthood.

Wolman disease is a type of LAL deficiency that presents in babies and children under 2 years as rapidly progressing multisystem disease. Wolman disease is characterised by intestinal failure and severe malabsorption, growth failure, hepatosplenomegaly and progressive liver fibrosis and cirrhosis. The condition normally results in death in the first 6 months of life, usually due to multiple organ failure. For the smaller group of children diagnosed slightly later (under 2 years), there is still usually evidence of growth failure in the first 6 months of life.

It is estimated that on average 1 or 2 babies with Wolman disease are born every 1 or 2 years in England. The estimated incidence rate for Wolman disease is approximately 1 in 350,000 births.

Enzyme replacement therapy with sebelipase alfa is the only licensed treatment option for LAL deficiency, including the subgroup with Wolman disease. Treatment for Wolman disease without sebelipase alfa is usually palliative and supportive, because of the severe multiorgan and rapidly progressive nature of the condition. A minimal or fat free diet may be used to reduce accumulation of LAL substrates in the body. Intravenous nutritional support is also provided. Medication may be needed to supplement adrenal hormones as adrenal gland dysfunction is common. Hematopoietic stem cell transplant may be used in some people.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence suggests that sebelipase alfa increases how long people live. But it is not clear how much longer people will live or how their long-term quality of life compares with people without the condition.

Because of the clinical uncertainties, including those related to how sebelipase alfa is used in the treatment pathway for people with Wolman disease, the cost-effectiveness estimates are also uncertain. When considering the condition's severity, and the effect of sebelipase alfa on quality and length of life, the most likely cost-effectiveness estimates are within the range NICE considers an acceptable use of NHS resources. Therefore, sebelipase alfa is recommended.

NICE Guidelines (NGs)

Caesarean birth NG192 (UPDATE)

This guideline covers when to offer and discuss caesarean birth, procedural aspects of the operation, and care after caesarean birth. It aims to improve the consistency and quality of care for women and pregnant people who are thinking about having a caesarean birth or have had a caesarean birth in the past and are now pregnant again.

January 2024: NICE have reviewed the evidence and updated the recommendations on placenta accreta spectrum.

Early and locally advanced breast cancer: diagnosis and management NG101 (UPDATE)

This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences.

January 2024: NICE have reviewed the evidence and have updated and made new recommendations on further surgery after breast-conserving surgery.

Suspected sepsis: recognition, diagnosis and early management NG51 (UPDATE)

This guideline covers the recognition, diagnosis and early management of suspected sepsis. It includes recommendations on recognition and early assessment, initial treatment, escalating care, finding the source of infection, early monitoring, information and support, and training and education.

January 2024: NICE reviewed the evidence and made new recommendations on risk evaluation and management of suspected sepsis for people aged 16 or over who are not and have not recently been pregnant, in mental health, ambulance and acute hospital settings. This covers the population and settings in which the national early warning score (NEWS2) applies.

NICE Rapid COVID-19 Guidelines

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

This guideline covers managing COVID-19 in babies, children, young people and adults in community and hospital settings. It includes recommendations on communication, assessment, therapeutics for COVID-19, non-invasive respiratory support, preventing and managing acute complications, and identifying and managing co-infections.

January 2024: NICE made editorial changes to ensure recommendations reflect the current context for COVID-19, including updating a recommendation to reflect that isolation is no longer mandatory. NICE transferred the guideline recommendations, evidence reviews and supporting information from the MAGICapp platform to the NICE website, changing the presentation.

COVID-19 rapid guideline: managing the long-term effects of COVID-19 NG188 (UPDATE)

This guideline covers identifying, assessing and managing the long-term effects of COVID-19, often described as 'long COVID'. It makes recommendations on care in all healthcare settings for adults, children and young people who have new or ongoing symptoms 4 weeks or more after the start of acute COVID-19. It also includes advice on organising services for long COVID.

January 2024: NICE transferred the guideline recommendations, evidence reviews and supporting documentation from the MAGICapp platform to the NICE website, changing the presentation. The recommendations are unchanged.

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)

Temperature control to improve neurological outcomes after cardiac arrest IPG782

Recommendations

To prevent fever:

Use temperature control as an option to prevent fever and improve neurological outcomes after cardiac arrest with **standard arrangements** in place for clinical governance, consent and audit.

For auditing the outcomes of this 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).

To induce therapeutic hypothermia:

More research is needed on temperature control to induce therapeutic hypothermia (a temperature of less than 36°C) to improve neurological outcomes after cardiac arrest.

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

More research, in the form of randomised controlled trials, is needed on:

- patient selection
- timing of the intervention
- degree and duration of temperature control
- neurological outcomes
- survival.

The Condition

Cardiac arrest is when normal blood circulation suddenly stops because the heart fails to contract effectively. The underlying abnormal cardiac rhythms most commonly associated with cardiac arrest are:

- ventricular fibrillation (VF)
- asystole
- pulseless electrical activity
- pulseless ventricular tachycardia (VT).

Cardiac arrest leads to loss of consciousness, respiratory failure and ultimately, death.

Treatment for cardiac arrest includes immediate cardiopulmonary resuscitation to restore the circulation and prevent subsequent brain injury. Defibrillation may be used to treat VF and pulseless VT rhythms. Standard care may also include mechanical ventilation and drugs such as adrenaline and amiodarone.

The Procedure

After cardiac arrest, people in a coma who have a return of spontaneous circulation (ROSC) can have their core body temperature actively controlled. This is done to:

- prevent fever or
- induce therapeutic hypothermia (by cooling to a core temperature)

The aim is to reduce brain injury and improve neurological outcomes. The exact mechanism by which cooling may protect against brain injury is unclear. Possible mechanisms include reductions in metabolic demand, release of excitatory neurotransmitters and inflammation after ischaemia.

Temperature control is done using either:

- surface techniques (for example, heat exchange cooling pads, cooling blankets and ice packs), or

- internal techniques (for example, an endovascular cooling device).

  Core body temperature is monitored using a temperature probe and is controlled to a preset point determined by the clinician.

If therapeutic hypothermia is induced, controlled rewarming is usually done over several hours. In addition, people who have had cardiac arrest generally have standard critical care measures and may need intravenous sedation and muscle relaxants, to prevent shivering.

Pharyngeal electrical stimulation for neurogenic dysphagia IPG781

Recommendations

People with neurogenic dysphagia who have a tracheostomy after stroke:

For people with neurogenic dysphagia who have a tracheostomy after stroke, pharyngeal electrical stimulation 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.

Clinicians wanting to do pharyngeal electrical stimulation for people with neurogenic dysphagia who have a tracheostomy after stroke 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.

Patient selection should be done by healthcare professionals experienced in managing neurogenic dysphagia and with specific training in the procedure. An endoscopic or videofluoroscopic assessment may be used.

The procedure should only be done by healthcare professionals with specific training in the procedure.

People with neurogenic dysphagia after stroke who do not have a tracheostomy and people with other causes of neurogenic dysphagia:

For people with neurogenic dysphagia after stroke who do not have a tracheostomy and people with other causes of neurogenic dysphagia, more research is needed on pharyngeal electrical stimulation.

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

More research is needed on:

- details of patient selection (including the cause of dysphagia and the timing of the intervention)
- effects on length of hospital stay compared with usual care.

The Condition

Difficulty in swallowing (dysphagia) is caused by neurological impairment. It can happen because of several conditions, including stroke, traumatic brain injury, disorders of cerebral development, neurodegenerative diseases, major head and neck surgery (for example, to remove cancer), trauma and intensive care treatment (intubation and tracheostomy). Dysphagia may lead to malnutrition, dehydration, aspiration pneumonia and death.

Treatment options depend on the cause and severity of the dysphagia. Compensatory strategies include modifying diet and in moderate or severe dysphagia, nasogastric tubes, percutaneous endoscopic gastrostomy tubes or jejunostomy tubes may be used to provide nutritional support. Rehabilitation strategies include swallowing therapy (to help relearn swallowing and strengthen muscles) and for some people, transcutaneous neuromuscular stimulation.

The Procedure

A catheter with 2 electrodes on the outside is passed through the nose into the pharynx. Guide marks on the catheter are used to ensure it is correctly positioned to deliver low-level pharyngeal electrical stimulation. The catheter is connected to a portable base station, which stores the person's information and adjusts the stimulation variables. The exact stimulation level is calculated for each person at the start of each treatment session. Treatment is given by a healthcare professional with appropriate training and typically a treatment cycle consists of 10 minutes of stimulation each day for 3 consecutive days, for up to 2 cycles. People may experience a fizzing or tingling sensation in the throat during the procedure. The focused stimulation aims to increase brain activity in the swallowing control centre and restore neurological control of the swallowing function. The dual function catheter can also be used to administer enteral nutrition and fluids, if needed, as well as delivering electrical stimulation.

Intravascular lithotripsy for calcified arteries in peripheral arterial disease IPG780

Recommendations

Intravascular lithotripsy for calcified arteries in peripheral arterial disease should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do intravascular lithotripsy for calcified arteries in peripheral arterial disease 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.

Patient selection should be done by a vascular multidisciplinary team including interventional radiologists and vascular surgeons.

NICE encourages further research into intravascular lithotripsy for calcified arteries in peripheral arterial disease. Research should include:

- details of patient selection, including the location and degree of stenosis
- details of additional interventions
- longer-term outcomes, including mortality and amputation
- patient-reported outcomes including quality of life
- the need for revascularisation and amputation.

The Condition

Peripheral arterial disease (PAD) is caused when a build-up of fatty substances in the arteries restricts blood supply to the limbs, usually the legs. The plaque can calcify and become like bone.

This is known as intravascular calcification and it is particularly common in people with diabetes mellitus or chronic kidney disease. The most common initial symptom of PAD is leg pain while walking, known as intermittent claudication. If blood flow is severely restricted, chronic limb-threatening ischaemia (CLTI, also known as critical limb ischaemia) can develop. Symptoms include severe pain at rest, ulceration or gangrene. CLTI is associated with a high risk of amputation and death and the presence of arterial calcification increases these risks.

Management of PAD is described in CG147. For CTLI, revascularisation using percutaneous transluminal angioplasty (with or without stent placement) or a bypass graft is recommended. Atherectomy devices that vaporise, cut or grind away plaque within the artery are sometimes used alongside balloon angioplasty. If revascularisation is not an option, major amputation may be offered.

The Procedure

Arterial access is established as for a standard angioplasty, usually through the femoral artery in the groin. An angioplasty balloon with a source of acoustic pressure waves (lithotripsy emitters) is introduced and inflated next to the heavily calcified arterial plaques. The pressure exerted by the balloon is too low to expand the vessel but high enough to ensure good contact between the surface of the balloon and the arterial walls. Acoustic pressure waves are then transmitted from the balloon, fracturing superficial and deep calcium within the arterial wall. As with standard angioplasty, a stent is sometimes inserted after the lithotripsy to keep the artery patent. The procedure is used as a preparatory treatment for balloon angioplasty or as an alternative to standard angioplasty.

The aim of intravascular lithotripsy is to improve the blood flow in the affected limb and prevent the need for amputation.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

Artificial intelligence (AI)-derived software to help clinical decision making in stroke DG57

Recommendations

Can be used in the NHS with evidence generation:

The following artificial intelligence (AI)-derived software **can be used** in the NHS while more evidence is generated, to support review and reporting of CT brain scans for people who have had a suspected stroke:

- e-Stroke
- RapidAI.

  These technologies can only be used once they have appropriate Digital Technology Assessment Criteria (DTAC) approval.

The software should only be used with healthcare professional review and centres should maintain existing scan reporting protocols to reduce the risk of incorrect results. Centres should ensure that images shared between different stroke centres can be remotely reviewed to help with decision making by healthcare professionals at a different site.

Can only be used in research:

More research is needed on the following AI-derived software to support review and reporting of CT brain scans for people who have had a suspected stroke:

- Accipio
- Aidoc
- BioMind
- BrainScan CT
- Cercare Perfusion
- CINA Head
- CT Perfusion 4D
- icobrain ct
- Neuro Solution
- qER.

Access to the technologies above should be through company or research funding (non-core NHS funding).

Evidence generation and more research:

Evidence generation and more research is needed on:

- the impact of the addition of AI-derived software on a healthcare professional's ability to identify people for whom thrombolysis and thrombectomy is suitable
- how often the software is unable to analyse CT brain scans, with reasons for this
- the impact of using the software on time to thrombolysis or thrombectomy
- the impact of using the software on how many people have thrombolysis or thrombectomy

The Tests

Stroke is a serious life-threatening medical condition that happens when blood supply to a part of the brain is severely compromised. Stroke is a leading cause of disability and one of the most common causes of early death in the UK.

Treatment of stroke depends on the cause, the length of time the blood supply to brain has been compromised and the severity of the damage caused by the stroke. In ischaemic stroke (the most common type), when blood supply to the brain gets blocked by a clot, treatments aim to restore blood flow by dispersing the clot with an intravenous injection of a clot-busting drug (thrombolysis) and mechanically removing the clot (thrombectomy). Thrombolysis needs to be started within 4.5 hours of onset of stroke symptoms. Thrombectomy should be offered as soon as possible to people who were last known to be well within the last 6 hours, or considered as soon as possible for people who were last known to be well between the last 6 and 24 hours. In the less common type of stroke, intracerebral haemorrhage, when a weakened blood vessel in the brain bursts and blood leaks into soft brain tissues, these treatments would be harmful and should not be offered.

CT brain scans are used to help guide treatment choice. In people with a suspected acute stroke, a non-enhanced CT scan is used first to determine if the stroke is ischaemic so that thrombolysis can start. In people with confirmed ischaemic stroke, CT angiography is then used to confirm the presence of a clot and to assess if it is a large vessel occlusion. When the impact of stroke is likely to be more severe because the blood supply to the brain has been reduced for a longer time (between 6 and 24 hours), CT perfusion is used to assess if there is the potential to salvage brain tissue by doing a thrombectomy.

Software with artificial intelligence (AI)-derived algorithms can be used to analyse CT brain scan images from people with suspected acute stroke to detect and report imaging abnormalities or findings. The result of this analysis is intended to support the scan review and reporting by a trained healthcare professional. By identifying, quantifying and highlighting stroke-related changes in the brain, the AI-derived algorithms may support clinical decisions about suitability of an appropriate time-sensitive treatment. Using the software in the radiology pathway may lead to quicker review of scans by a multi-site clinical team, improved decisions about treatment, expedited patient transfer, faster access to the correct treatment and improved patient outcomes. Some software has features that can prioritise the review of stroke CT scans.

Financial Factors

These technologies are commissioned by ICBs.

Some AI technologies are already widely in use in the NHS. Access to the technologies has been available through a £21 million funding scheme set up by the government.

Implementing AI software may provide the following benefits:

- Ability for units to share diagnostic images between hospitals and clinicians, to support image interpretation
- Faster interpretation of imaging therefore quicker clinical decisions about treatment, patient transfer and access to the correct treatment
- Improved access to both thrombolytic therapy and mechanical thrombectomy therefore reducing the risk of severe disability, limb loss or death and any associated healthcare costs
- Improving services and outcomes for stroke patients, a key objective outlined in the NHS Long Term Plan to drive expansions in life saving treatments.

e-Stroke and RapidAI can be used in the NHS while further evidence is generated to help better determine their cost effectiveness. Other technologies that have no evidence on how they impact time or access to treatment should only be used in research.

Devices for remote monitoring of Parkinson's disease DG51 (UPDATE)

Recommendations

Kinesia 360, KinesiaU, PDMonitor, Personal KinetiGraph (PKG) and STAT-ON are **conditionally recommended** as options for remote monitoring of Parkinson's disease to inform treatment if:

- further evidence is generated, including:
    - the impact on resources associated with using the technologies
    - the size of impact of using the technologies on symptoms or health-related quality of life (for people with Parkinson's disease and their carers) and how long this lasts for
    - how frequently the devices are used, and under what circumstances, in the NHS and
- cost impact is managed

Commissioners should consider the available payment options for the technologies when deciding which to use (for example, pay per use, a subscription model or outright purchase). They should take into account the fact that the technologies may not be needed any more if further data shows they are not cost effective.

Clinicians should consider features of the devices and how they are used when identifying which may be most suitable for a person, particularly for people with restricted movement, missing limbs, or people who are frail or have cognitive impairment. Clinicians should also support people to set up and operate the remote monitoring devices if needed.

January 2024: NICE have developed tools and resources, in association with relevant stakeholders, to help organisations put this guidance into practice, including an evidence generation plan. The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

Health Technology Evaluations (HTE)

None published this month.

NICE Quality Standards

Skin cancer QS130 (UPDATE)

This quality standard covers preventing, assessing, diagnosing and managing skin cancer (melanoma and non-melanoma skin cancer). It describes high-quality care in priority areas for improvement.

January 2024: this quality standard was updated and replaced the previous version published in 2016. The topic was identified for update following the annual review of quality standards. The review identified, changes in the priority areas for improvement and updated guidance on melanoma.

Neonatal infection QS75 (UPDATE)

This quality standard covers preventing bacterial infection in newborn babies, treating pregnant women and pregnant people whose babies are at risk of infection, and treating newborn babies with suspected or confirmed bacterial infection. It includes when to give antibiotics to prevent and treat neonatal bacterial infection and describes high-quality care in priority areas for improvement. This includes early-onset (within 72 hours of birth) and late-onset (between 72 hours and 28 days following birth) neonatal infection.

January 2024: This quality standard was updated and replaced the previous quality standard published in December 2014. The topic was identified for update following a review of quality standards. The review identified new and updated guidance on neonatal infection (see NG195).

Current NICE Consultations

Title/link	End date of consultation
Digital health technologies to help manage symptoms of psychosis and prevent relapse: early value assessment	01/02/2024
Remdesivir and tixagevimab plus cilgavimab for treating COVID-19 [ID6261]	08/02/2024
Twin and triplet pregnancy - progesterone for preventing preterm birth	13/02/2024
Fenfluramine for treating Lennox-Gastaut seizures in people aged 2 and over [ID1651]	21/02/2024
Ruxolitinib for treating non-segmental vitiligo in people 12 years and over [ID3998]	21/02/2024
Efgartigimod for treating generalised myasthenia gravis [ID4003]	29/02/2024