NHS Devon

NICE Update Bulletin: August 2024

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

1. **Risankizumab for treating moderately to severely active ulcerative colitis TA998**
2. **Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced HER2-negative gastric or gastro-oesophageal junction adenocarcinoma TA997**
3. **Linzagolix for treating moderate to severe symptoms of uterine fibroidsTA996**
4. **Relugolix for treating hormone-sensitive prostate cancer TA995**
5. **Enzalutamide for treating non-metastatic prostate cancer after radical prostatectomy or radiotherapy (*terminated appraisal*) TA994**
6. **Burosumab for treating X-linked hypophosphataemia in adults TA993**
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Technology Appraisals (TAs)

Risankizumab for treating moderately to severely active ulcerative colitis TA998

Recommendations

Risankizumab is **recommended** as an option for treating moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or has lost response to treatment, only if:

- a tumour necrosis factor (TNF)-alpha inhibitor:
    - has not worked (that is the condition has not responded well enough or has lost response to treatment), or
    - cannot be tolerated or is not suitable, and
- the company provides it according to the commercial arrangement.

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

These recommendations are not intended to affect treatment with risankizumab 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

Ulcerative colitis is the most common inflammatory bowel disease. The cause of ulcerative colitis is unknown. Hereditary, infectious and immunological factors have been proposed as possible causes. It can develop at any age, but peak incidence is between the ages of 15 and 25 years, with a second, smaller peak between 55 and 65 years.

Ulcerative colitis can cause inflammation in the inner lining of the large intestine. This is usually restricted to the mucosal surface. The symptoms of ulcerative colitis include bloody diarrhoea, pain, urgency, ulceration, tenesmus, fatigue, and anaemia.

Ulcerative colitis is associated with significant morbidity; symptoms can have a debilitating impact on quality of life and daily life, including physical, social, and mental well-being. It is a lifelong disease, and symptoms can recur, or the disease can go into remission for months or even years. Ulcerative colitis can be defined as mild or moderate to severe.

Complications of ulcerative colitis may include haemorrhage, bowel perforation, stricture formation, abscess formation and anorectal disease. Some people may also develop primary sclerosing cholangitis, osteoporosis, and toxic megacolon. People with long-standing disease have an increased risk of bowel cancer.

The aim of treatment in active disease is to address symptoms of bloody diarrhoea, urgent need to defecate and abdominal pain, and to promote mucosal healing and maintain remission. Initial management depends on clinical severity, extent of disease and the person's preference, and may include aminosalicylates, corticosteroids and immunomodulators. Options for people whose disease has responded inadequately to conventional therapy or who cannot tolerate or have medical contraindications for such therapies include:

- **TA329** infliximab, adalimumab and golimumab
- **TA342** vedolizumab
- **TA547** tofacitinib
- **TA633** ustekinumab (only if a tumour necrosis factor-alpha inhibitor has failed, cannot be tolerated or is not suitable)
- **TA792** filgotinib
- **TA828** ozanimod (only if infliximab is not suitable, or biological treatment is not tolerated or not working well enough)
- **TA865** upadacitinib

Surgery may be considered as emergency treatment for severe ulcerative colitis that does not respond to drug treatment. People may also choose to have elective surgery for unresponsive or frequently relapsing disease that is affecting their quality of life. The scope of this appraisal does not include severe ulcerative colitis that is a medical emergency requiring intensive inpatient treatment.

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 and the overall cost of treatment for this patient group will be similar.

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

NICE estimate that at year 5 in Devon, 544 people will be eligible for treatment.

Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced HER2-negative gastric or gastro-oesophageal junction adenocarcinoma TA997

This guidance partially updates TA737 (published October 2021)

Recommendations

Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy is **recommended**, within its marketing authorisation, as an option for untreated locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) of 1 or more. Pembrolizumab is only recommended if the company provides it according to the commercial arrangement.

The Technology

Gastric cancer is a malignant tumour arising from cells in the stomach. The most common type of stomach cancer is gastric or gastro-oesophageal junction. Gastroesophageal junction cancer describes cancers where the centre of the tumour is less than 5cm above or below where the oesophagus meets the stomach.

Oesophageal cancer is a malignant tumour arising from cells lining the oesophagus. The most common histological subtype of gastric, gastro-oesophageal junction and oesophageal cancer is adenocarcinoma, with 95% of gastric cancers being adenocarcinomas.

Initial symptoms of gastric or oesophageal cancer are vague and are similar to other stomach conditions, but symptoms of advanced stages may include a lack of appetite and subsequent weight loss; fluid in the abdomen, vomiting blood, blood in the stool or black stool. Because of the nature of symptoms, gastric and oesophageal cancer are often diagnosed at an advanced stage.

The aim of treatment in advanced or metastatic gastric, gastro-oesophageal junction cancer or oesophageal adenocarcinoma is primarily palliative; to prevent progression, extend survival and relieve symptoms with minimal adverse effects.

Related NICE guidance:

- **NG83** Oesophago-gastric cancer: assessment and management in adults
- **TA191** Capecitabine for the treatment of advanced gastric cancer
- **TA737** Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer
- **TA857** Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma

Financial Factors

This technology is commissioned by NHS England.

When considering the condition's severity and its effect on quality and length of life, the most likely cost-effectiveness estimates for pembrolizumab plus doublet chemotherapy compared with doublet chemotherapy alone are within the range that NICE considers an acceptable use of NHS resources. Pembrolizumab plus doublet chemotherapy has similar costs to nivolumab plus doublet chemotherapy. Therefore, pembrolizumab plus doublet chemotherapy is recommended.

Linzagolix for treating moderate to severe symptoms of uterine fibroids TA996

Recommendations

Linzagolix is **recommended** as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age only if:

- It is intended to be used for longer-term treatment (normally for more than 6 months and not for people who need short-term treatment, for example, before planned surgery).
- The following dosage is used:
    - with hormonal add-back therapy (ABT): 200 mg once daily
    - without hormonal ABT: 200 mg once daily for 6 months, then 100 mg once daily.

This recommendation is not intended to affect treatment with linzagolix 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

Uterine fibroids are noncancerous growths of the uterus. The exact cause of fibroids is not known, but they have been linked to the hormones oestrogen and progesterone. Most are asymptomatic, but they can cause significant morbidity. The most common symptom of uterine fibroids is heavier than normal or prolonged menstrual bleeding, with approximately one third of people with uterine fibroids experiencing heavy menstrual blood loss. Other symptoms include pelvic pressure or pain, frequent urination, constipation and pain or discomfort during sex. In rare cases, complications with fibroids can interfere with pregnancy or cause infertility.

Fibroids are generally classified by their location:

- Intramural fibroids grow within the muscular uterine wall
- Submucosal fibroids grow in the muscle layer beneath the uterus' inner lining and grow into the uterine cavity.
- Subserosal fibroids develop outside of the uterus and grow into the pelvis.

Fibroids usually develop during the reproductive years (from around 16 to 50 years) when oestrogen levels are at their highest. Risk factors for uterine fibroids include family history of fibroids, age and obesity.

Oestrogen and progesterone control the proliferation and maintenance of uterine fibroids. Most medical treatments act by interfering with their production or function.

For people with uterine fibroids less than 3 cm in diameter and not causing distortion of the uterine cavity, **NG88** recommends considering a levonorgestrel-releasing intrauterine system (LNG-IUS) for the treatment of heavy menstrual bleeding. If heavy menstrual bleeding worsens or an LNG-IUS is not suitable, pharmacological treatments (such as tranexamic acid and non-steroidal anti-inflammatory drugs) and hormonal treatments (such as combined hormonal contraception, cyclical oral progestogens and gonadotrophin-releasing hormone analogues) are recommended. Surgery is recommended as an option if treatment is unsuccessful or declined, or symptoms are severe.

TA832 recommends relugolix-estradiol-norethisterone acetate as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age.

Financial Factors

This technology is commissioned by ICBs.

Clinical trial evidence shows that linzagolix works better than placebo at treating moderate to severe symptoms of uterine fibroids. It has not been compared with relugolix combination therapy (CT) in a clinical trial. Indirect treatment comparisons of linzagolix compared with relugolix CT are highly uncertain.

Even when taking this uncertainty into account, linzagolix with or without hormonal ABT is cost effective, but only when it is intended to be used for longer-term treatment (normally for more than 6 months). It is not recommended for people who need short-term treatment, for example, before planned surgery. The economic analysis for short term use did not compare linzagolix against all relevant comparators, so the NICE committee was unable to determine whether linzagolix was cost effective in this population, therefore, it is only recommended for longer-term use.

NICE estimate that in Devon at year 5, the prevalence of uterine fibroids will be 48,612 people. 30,869 people will have moderate to severe uterine fibroids and 2,669 people will be eligible for treatment with linzagolix.

Relugolix for treating hormone-sensitive prostate cancer TA995

Recommendations

Relugolix is **recommended**, within its marketing authorisation, as an option for treating prostate cancer in adults:

- with advanced hormone-sensitive prostate cancer
- alongside radiotherapy for high-risk localised advanced hormone-sensitive prostate cancer
- as neoadjuvant treatment before radiotherapy for high risk localised or locally advanced hormone-sensitive prostate cancer.

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 cancer can be classified into localised, locally-advanced and metastatic, depending on whether and how far the cancer has spread. Localised and locally-advanced prostate cancer can be further classified as being at low, intermediate of high risk of progression based on prostatic-specific antigen concentration, Gleason score and clinical stage.

The description ‘hormone-sensitive prostate cancer’ refers to a population that includes people with prostate cancer who have not had androgen deprivation therapy, or whose disease is continuing to respond to androgen deprivation therapy.

Related NICE guidance:

- **TA404** degarelix for treating advanced hormone-dependent prostate cancer
- **TA712** enzalutamide for treating hormone-sensitive metastatic prostate cancer
- **TA741** apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer
- **TA903** darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer.

Financial Factors

This technology is commissioned by ICBs.

Clinical trial evidence suggests that relugolix is better at reducing testosterone to levels that stop cancer growth in the long term, and reduces the risk of serious cardiovascular events, compared with leuprolide. An indirect treatment comparison suggests that relugolix works as well as other ADTs, but this is uncertain.

The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. Therefore, relugolix is recommended.

NICE estimate that at year 5, the eligible population for treatment in Devon will be 889 people.

Enzalutamide for treating non-metastatic prostate cancer after radical prostatectomy or radiotherapy (*terminated appraisal*) TA994

NICE is **unable to make a recommendation** about the use in the NHS of enzalutamide for treating non-metastatic prostate cancer after radical prostatectomy or radiotherapy. This is because the company did not provide and evidence submission.

Burosumab for treating X-linked hypophosphataemia in adults TA993

Recommendations

Burosumab is **recommended**, within its marketing authorisation, as an option for treating X-linked hypophosphataemia (XLH) in adults. Burosumab is only recommended if the company provides it according to the commercial arrangement.

The Technology

X-linked hypophosphataemia (XLH) is a genetic disorder characterised by low levels of phosphate in the blood. Excess activity of a type of signalling peptide FGF23 results in phosphate being abnormally processed in the kidneys, which causes a loss of phosphate in the urine and leads to soft, weak bones.

It is the most common form of hereditary hypophosphatemia and is equally common in both sexes. Clinical manifestations of XLH vary in severity, but patients most commonly present in childhood with bowed or bent legs, disproportionate short stature, bone pain, delayed walking and dental anomalies.

Symptoms generally present at 12-15 months of age, however symptoms can be misdiagnosed as vitamin D deficient rickets, especially if there is no family history of XLH. In adults, the main manifestations of XLH include bone pain, fractures and pseudofractures, joint stiffness and restricted movement, neurological complications, including hearing problems and in severe cases, spinal cord compression.

There are currently no treatments that target the underlying cause of XLH in adults. There is no consensus on the management of XHL in adults however options include +phosphate supplementation, vitamin D analogues such as alfacalcidol or calcitriol, or supportive care. Conventional therapy is taken 4-6 times a day which interferes with usual activities including work and can disturb sleep. Management of XLH differs across treatment centres, for example phosphate is not always offered to adults without fractures because of the risks of treatment-related complications such as hyperparathyroidism, but most people with XLH receive treatment. Corrective surgery of skeletal deformities and joint replacements may be required.

Burosumab is an anti-FGF23 human monoclonal antibody which improves phosphate homeostasis by targeting excess FG23. Burosumab binds to FGF23 rendering it inactive and thereby restores renal tubular reabsorption of phosphate a d increases the production of 1,25-dihydroxyvitamin D which enhances intestinal absorption of calcium and phosphate. Burosumab is administered by subcutaneous injection.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence shows that burosumab increases the level of phosphate in the blood more effectively than placebo. The evidence also suggests that people having burosumab may have less pain and fatigue and improved physical functioning compared with placebo in the short term, but this is uncertain.

Although there are some uncertainites in the economic model, the cost-effectiveness estimates are within the range considered an acceptable use of NHS resources. Therefore, burosumab is recommended.

NICE estimate that at year five in Devon, 9 people will be eligible for treatment.

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

Abaloparatide for treating osteoporosis after menopause TA991

Recommendations

Abaloparatide is **recommended** as an option for treating osteoporosis after menopause in women, trans men and non-binary people, only if they have a very high risk of fracture. It is only recommended if the company provides it according to the commercial arrangement.

If people with the condition and their healthcare professional consider abaloparatide, romosozumab and teriparatide to be suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive suitable treatment should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

This recommendation is not intended to affect treatment with abaloparatide 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

Osteoporosis is a progressive skeletal disorder which is characterised by low bone mass and deterioration of the structure of the bone, leading to an increase in bone fragility and risk of fracture.

Osteoporosis is asymptomatic and often remains undiagnosed in the absence of fracture. Osteoporosis is defined as having a bone mineral density (BMD) that is 2.5 standard deviations or more below the average value for young healthy adults. The prevalence of osteoporosis increases markedly with age. In women, decreased oestrogen levels after the menopause accelerate bone loss, increasing the risk of osteoporosis. Osteoporosis can also be caused by the long-term systemic use of corticosteroids.

Osteoporotic fragility fractures occur most commonly in the hip, vertebrae and wrist. After a hip fracture, a high proportion of people are permanently unable to walk independently or to perform other activities of daily living and consequently, many are unable to live independently. Vertebral fractures can be associated with curvature of the spine and height loss and can result in chronic pain, breathing difficulties, gastrointestinal problems and difficulties in performing activities of daily living. Both hip and vertebral fractures are associated with increased mortality.

Related NICE guidance:

- **CG146** makes recommendations on the assessment of fracture risk.
- **TA464** recommends bisphosphonates, alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid for treating osteoporosis
- **TA791** recommends romosozumab for severe osteoporosis in people after the menopause who are at high risk of fracture.
- **TA204** recommends denosumab for preventing osteoporotic fragility fractures in postmenopausal women.
- **TA161** recommends raloxifene and teriparatide for preventing osteoporotic fragility fractures in postmenopausal women who have osteoporosis.

Financial Factors

This technology is commissioned by ICBs.

Usual treatments for osteoporosis after menopause include romosozumab or teriparatide and bisphosphonates such as alendronic acid. Abaloparatide would be used as an alternative treatment to romosozumab or teriparatide.

Clinical trial evidence shows that abaloparatide followed by alendronic acid is more effective at reducing the risk of some types of fracture than placebo followed by alendronic acid. Indirect comparisons suggest that abaloparatide is likely to work at least as well as romosozumab and teriparatide.

The most likely cost-effectiveness estimates for abaloparatide are within the range that NICE considers an acceptable use of NHS resources. Therefore, abaloparatide is recommended.

NICE estimate that at year five in Devon, 332 people will be eligible for treatment and that abaloparatide will represent 11% of the market share (37 people choosing abaloparatide).

The company has a commercial arrangement. This makes abaloparatide available to the NHS with a discount. The size of the discount is commercial in confidence.

Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer TA737 (UPDATE)

August 2024: Recommendation 1.1 was updated and partially replaced by NICE technology appraisal guidance TA997. This is because the marketing authorisation for pembrolizumab has been updated since this guidance was published and it now has a marketing authorisation for locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) of 1 or more. Because HER2-negative locally advanced unresectable or metastatic gastro-oesophageal junction adenocarcinoma is now covered by the new recommendation in TA997, this indication has been removed from the recommendation in this guidance.

Highly Specialised Technology Guidance (HSTs)

None published this month

NICE Guidelines (NGs)

Adrenal insufficiency: identification and management NG243

This guideline covers identifying and managing adrenal insufficiency (hypoadrenalism) in babies, children, young people and adults. It aims to improve the treatment of primary, secondary and tertiary adrenal insufficiency, and the prevention and management of adrenal crisis.

Diabetic retinopathy: management and monitoring NG242

This guideline covers managing and monitoring diabetic retinopathy in people under the care of hospital eye services. This includes non-proliferative and proliferative diabetic retinopathy and diabetic macular oedema.

NICE Rapid COVID-19 Guidelines

None published this month

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)

Phrenic nerve pacing for ventilator-dependent high cervical spinal cord injury IPG792

Recommendations

Use phrenic nerve pacing as an option to treat ventilator-dependent high cervical spinal cord injury 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).

Patient selection should be done by a multidisciplinary team experienced in managing the condition in specialist centres.

This procedure should only be done in specialist centres by clinicians with specific training and experience in the procedure.

The Condition

A high cervical spinal cord injury (SCI) is an injury in the upper neck between the first and fourth cervical vertebrae (C1 to C4). SCIs can damage the phrenic nerve that controls the diaphragm (the main muscle used in breathing) and cause chronic respiratory insufficiency. Some people with high cervical SCIs cannot breathe on their own, so they need a mechanical ventilator to help them breathe.

Standard care for managing respiratory insufficiency caused by SCIs includes non-invasive ventilation and invasive mechanical ventilation. An alternative to ventilatory support is intramuscular diaphragm stimulation for people with intact phrenic nerve function.

The Procedure

This procedure involves directly stimulating the phrenic nerve so that it sends a signal to the diaphragm to contract, which produces the inhalation phase of breathing. It aims to provide ventilatory support for people with intact phrenic nerves and functioning diaphragm muscles.

The procedure is usually done using a thoracic approach and under general anaesthesia. Once the phrenic nerve is identified and tested, an electrode is placed around the nerve in the chest, and then stabilised. The electrode is connected to a subcutaneous receiver, usually placed in the chest wall. An external transmitter (powered by batteries) then sends radiofrequency signals to the device through an antenna which is worn over the receiver. The receiver translates radio waves into stimulating electrical pulses that are delivered to the phrenic nerve by the electrode, to achieve diaphragm contraction and support breathing. The device is tested during and after the surgery to ensure that it is working. This procedure is usually done bilaterally but can also be done unilaterally. A cervical approach can also be used and is done under general or local anaesthesia.

After the procedure, the person follows a diaphragm conditioning programme, which involves progressive use of the system for increasing periods of time with gradual weaning from the ventilator.

Caval valve implantation for tricuspid regurgitation IPG791

Recommendations

More research is needed on caval valve implantation for tricuspid regurgitation in adults.

This procedure should only be done as part of a formal research study, with NHS research ethics committee approval.

More research:

More research, in the form of suitably powered randomised controlled trials and supported by safety data from a registry, is needed on:

- patient selection
- type of procedure
- changes in cardiac function
- quality of life
- short- and long-term outcomes
- safety outcomes.

The Condition

The tricuspid valve sits between the right atrium and right ventricle of the heart. Tricuspid regurgitation occurs because the tricuspid valve does not close properly during systole. It can result in blood refluxing back into the right atrium and the 2 main caval veins. This makes the heart work harder and, if severe, can lead to heart failure. Tricuspid regurgitation can mainly be because of a problem with the valve anatomy itself. But it is more commonly secondary to an underlying cardiac problem that causes tricuspid annular dilatation or leaflet tethering. The valve leaflets and chords may be normal but, because of annulus dilatation, the valve leaflets fail to close properly and regurgitation of blood occurs.

People with mild tricuspid regurgitation do not usually have symptoms. If the regurgitation is severe, there may be fatigue and weakness, active pulsing in the neck veins, an enlarged liver, ascites, peripheral oedema and renal impairment. Pulmonary hypertension may develop.

Treatment may not be needed if there are no or mild symptoms. There are no specific medicines for treating tricuspid regurgitation itself, but symptoms of heart failure are managed with medicines such as diuretics and angiotensin-converting enzyme inhibitors. Medicines to reduce pulmonary artery pressure, pulmonary vascular resistance or both, may be used when there is severe functional tricuspid regurgitation and severe pulmonary hypertension.

People with severe symptoms may have surgery to repair or replace the tricuspid valve. Isolated tricuspid valve surgery is rarely done because it is associated with high morbidity and mortality. More commonly, it is done at the same time as surgery to the valves on the left side of the heart (mitral and aortic). Transcatheter tricuspid valve interventions (tricuspid valve repair and replacement) are an alternative for managing tricuspid regurgitation.

The Procedure

Caval valve implantation is indicated for haemodynamically significant tricuspid regurgitation and caval reflux in people who have advanced disease (with severe leaflet tethering and a large coaptation gap) and are at extreme risk from surgery. The aim is to reduce caval reflux and stop venous congestion, so improving symptoms of heart failure and quality of life for people who cannot have open heart surgery.

The procedure is done under local or general anaesthesia and with fluoroscopy guidance. Transoesophageal echocardiography may be used to monitor the position and function of the deployed bioprostheses. Depending on the anatomical suitability, caval valve implantation can be single or bicaval. The bioprostheses can be dedicated self-expandable valves or balloon expandable prostheses used for transcatheter aortic valve replacement. They are implanted percutaneously through a delivery system using transfemoral access. The valves are implanted in the inferior vena cava, superior vena cava or both, at the level of the atriocaval junction. This is done without disturbing the native tricuspid valve in a cranial-caudal direction.

Phrenic nerve pacing for congenital central hypoventilation syndrome IPG790

Recommendations

Use phrenic nerve pacing as an option to treat congenital central hypoventilation syndrome (CCHS) 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).

Patient selection should be done by a multidisciplinary team experienced in managing the condition in specialist centres.

This procedure should only be done in specialist centres by clinicians with specific training and experience in the procedure. Patients should be followed up by clinicians experienced in managing the condition.

The Condition

Congenital central hypoventilation syndrome (CCHS) is a rare genetic condition, with around 1,000 cases identified worldwide. CCHS affects how the autonomic nervous system manages or controls breathing. Normally, when breathing is shallow while asleep, the levels of carbon dioxide in the blood increase, which stimulates breathing. In CCHS, this stimulus does not happen, and breathing can stop. Common symptoms include difficulty breathing (especially during sleep), hypercapnia and hypoxemia. So, life-long ventilatory support is needed during sleep or all the time.

There is no cure for CCHS, but the symptoms can be managed. As CCHS can affect several systems in the body, it needs to be managed by several medical teams. For respiratory insufficiency, the most common treatment includes positive pressure ventilation by tracheostomy or a mask, to assist with breathing.

The Procedure

Phrenic nerve pacing involves the direct stimulation of the phrenic nerve, which sends a signal to the diaphragm to contract, producing the inhalation phase of breathing. It aims to provide ventilatory support for people with intact phrenic nerves and functioning diaphragm muscles.

The procedure is usually done using a thoracic approach (often using a thoracoscopic technique; thoracotomy is rarely used) and under general anaesthesia. Once the phrenic nerve is identified and tested, an electrode is placed around the nerve in the chest, and then stabilised. The electrode is connected to a subcutaneous receiver usually placed in the chest wall. An external transmitter, which is powered by batteries, then sends radiofrequency signals to the device through an antenna that is worn over the receiver. The receiver translates radio waves into stimulating electrical pulses that are delivered to the phrenic nerve by the electrode, to achieve

diaphragm contraction and support breathing. The device is tested during and after the surgery to ensure that it works. This procedure is usually done bilaterally and can also be done unilaterally. A cervical approach can also be used and is done under general or local anaesthesia, but this is less common.

Medical Technologies Guidance (MTGs)

None published this month

Diagnostics Guidance (DGs)

None published this month.

Health Technology Evaluations (HTE)

None published this month.

NICE Quality Standards

None published this month.

Current NICE Consultations

Title/link	End date of consultation
MRI-guided focused ultrasound subthalamotomy for treating Parkinson's	04/09/2024
Maternal and child nutrition	11/09/2024
Urinary Tract Infection (recurrent): antimicrobial prescribing	12/09/2024
12 SQ-HDM SLIT for treating allergic rhinitis and allergic asthma caused by house dust mites (review of TA834) [ID6280]	16/09/2024
MRI-guided focused ultrasound thalamotomy for treating moderate to severe tremor in Parkinson's	16/09/2024
Ovarian cancer QS update	18/09/2024
Pembrolizumab for adjuvant treatment of resected non-small-cell lung cancer [ID3907]	19/09/2024
Lecanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease [ID4043]	20/09/2024
Artificial intelligence (AI) technologies for assessing and triaging skin lesions within the urgent suspected skin cancer pathway	25/09/2024
Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis	26/09/2024
Electrically stimulated intravesical therapy for interstitial cystitis or overactive bladder	26/09/2024
Alcohol-mediated perivascular renal sympathetic denervation for resistant hypertension	26/09/2024