NHS Devon

NICE Update Bulletin: April 2023

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

1. **Tezepelumab for treating severe asthma TA880**
2. **Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic gastric or gastro-oesophageal junction cancer after anti-HER2 treatment *(terminated appraisal)* TA879**
3. **Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 TA878 (UPDATE)**
4. **Eladocagene exuparvovec for treating aromatic L-amino acid decarboxylase deficiency HST26**
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6. **Onasemnogene abeparvovec for treating presymptomatic spinal muscular atrophy HST24**
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Technology Appraisals (TAs)

Tezepelumab for treating severe asthma TA880

Recommendations

Tezepelumab as an add-on maintenance treatment is **recommended** as an option for severe asthma in people 12 years and over, when treatment with high-dose inhaled corticosteroids plus another maintenance treatment has not worked well enough. It is recommended only if people:

- have had 3 or more exacerbations in the previous year, or
- are having maintenance oral corticosteroids.

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

Stop tezepelumab if the rate of severe asthma exacerbations, or the maintenance oral corticosteroid dose, have not been reduced by at least 50% at 12 months.

These recommendations are not intended to affect treatment with tezepelumab 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. For young people, this decision should be made jointly by them, their clinician, and their parents or carers.

The Technology

Asthma is a chronic inflammatory disease associated with variable airflow obstruction and airway hyperresponsiveness. It is characterised by exacerbations associated with symptoms such as breathlessness, chest tightness, wheezing, sputum production and cough. Asthma is classified as severe when it does not improve with standard therapy. Eosinophils are thought to play a major role in airway inflammation in asthma. Asthma can also have an allergic component, resulting in over-production of human immunoglobulin E (IgE). People with severe asthma often have a severely impaired quality of life which can lead to fatigue, absence from school or work and psychological problems including stress, anxiety and depression.

NICE guideline NG80 recommends a stepwise approach for treating asthma. Control is maintained by stepping up treatment as necessary using combinations of inhaled corticosteroids (ICS), leukotriene receptor antagonists (LTRAs) and long-acting beta-2 agonists (LABAs) and stepping down when control is good. People whose asthma is inadequately controlled by medium-dose ICS plus a LABA with or without an LTRA should be stepped up to have high-dose ICS or offered a trial of an additional drug.

Tezepelumab is a monoclonal antibody against thymic stromal lymphopoietin (TLSP). Blocking TLSP may prevent the release of proinflammatory cytokines by immune cells, preventing asthma exacerbations and improving disease control. Tezepelumab is administered subcutaneously in addition to best standard asthma care.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial results show that tezepelumab, when added to usual treatment, reduces exacerbations and the dose of oral corticosteroids needed, compared with placebo. An indirect comparison of tezepelumab with other biological treatments suggests similar clinical effectiveness, but this is uncertain.

The cost-effectiveness estimates show that tezepelumab as an add-on maintenance therapy is cost effective compared with standard care and other biological treatments. Therefore, tezepelumab is recommended when treatment with high-dose inhaled corticosteroids plus another maintenance treatment has not worked well enough, for people who have had 3 or more exacerbations in the previous year or who are having maintenance oral corticosteroids.

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

Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic gastric or gastro-oesophageal junction cancer after anti-HER2 treatment *(terminated appraisal)* TA879

NICE is **unable to make a recommendation** on trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic gastric or gastro-oesophageal junction cancer after a previous anti-HER2-based regimen 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.

Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 TA878 (UPDATE)

This guidance was published in March 2023. In April 2023, NICE updated the recommendations on nirmatrelvir plus ritonavir and sotrovimab to link to the updated independent advisory group report commissioned by the Department of Health and Social Care.

Highly Specialised Technology Guidance (HSTs)

Eladocagene exuparvovec for treating aromatic L-amino acid decarboxylase deficiency HST26

Recommendations

Eladocagene exuparvovec is **recommended**, within its marketing authorisation, as an option for treating aromatic L-amino acid decarboxylase (AADC) deficiency in people 18 months and over with a clinical, molecular and genetically confirmed diagnosis of AADC deficiency with a severe phenotype. Eladocagene exuparvovec is only recommended if the company provides it according to the commercial arrangement.

The Technology

AADC deficiency is a rare genetic disorder that causes a wide range of debilitating symptoms. Normal motor development in young children (such as head control, sitting and walking with help) is particularly affected. Severe AADC deficiency is associated with a high risk of death in childhood. It also has a substantial effect on the quality of life of the person with the condition, and their family and carers. Current treatments only manage the symptoms of AADC. There are no specific treatments for the condition.

The disease is reported to have a worldwide incidence of 1 in 55,000,000 with about 150-200 people diagnosed in 30 countries. No UK incidence rate has been reported but there are believed to be less than 10 people with AADC deficiency in the UK.

Eladocagene exuparvovec is a single-use gene replacement therapy for people with AADC-deficiency. It is made of a viral vector that has been modified to contain a AADC gene that aims to enable the nerve cells to restore the function of AADC and improve symptoms. The gene therapy is injected via a surgical procedure into an area of the brain called the putamen. Eladocagene exuparvovec uses a viral vector (AAV2), containing the human gene that encodes the AADC enzyme.

Financial Factors

This technology is commissioned by NHS England.

The clinical evidence suggests that eladocagene exuparvovec improves motor development and that these improvements will last. But the results are uncertain because the studies are very small and provide limited long-term data and limited information about non-motor outcomes.

Even taking this uncertainty into account, the cost-effectiveness estimates for eladocagene exuparvovec are within the range that NICE considers an effective use of NHS resources for highly specialised technologies. Therefore, eladocagene exuparvovec is recommended for routine use in the NHS.

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

Lumasiran for treating primary hyperoxaluria type 1 HST25

Recommendations

Lumasiran is **recommended**, within its marketing authorisation, as an option for treating primary hyperoxaluria type 1 (PH1) in people of all ages. It is recommended only if the company provides lumasiran according to the commercial arrangement.

The Technology

PH1 is a rare, inherited condition that can significantly affect the quality of life of people with the condition, and their families and carers. In PH1, the liver produces excess oxalate which combines with calcium in the tissues to form toxic crystals. These crystals can cause recurrent kidney stones, kidney damage and in severe cases kidney failure and multiorgan damage. Standard care includes supportive measures, dialysis and a liver–kidney transplant depending on a person's kidney function.

Lumasiran is an RNA interference agent which uses gene silencing to target glycolate oxidase. This reduces oxalate production and therefore has the potential to prevent the build-up of oxalate in people with primary hyperoxaluria type 1 and prevent subsequent complications, such as worsening kidney disease. It is administered as a subcutaneous injection.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence suggests that, after 6 months of treatment, lumasiran plus standard care reduces a person's oxalate levels compared with standard care alone. The impact of PH1 and advanced kidney disease on people's quality of life in the economic model is uncertain. This makes the cost-effectiveness estimates uncertain. Despite this, lumasiran is likely to provide important clinical benefits for people with PH1 and is considered an appropriate use of NHS resources within the context of a highly specialised service. Therefore, lumasiran is recommended for use in the NHS.

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

Onasemnogene abeparvovec for treating presymptomatic spinal muscular atrophy HST24

This guidance partially updates HST15 (published July 2021)

Recommendations

Onasemnogene abeparvovec is **recommended** as an option for treating presymptomatic 5q spinal muscular atrophy (SMA) with a biallelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene in babies aged 12 months and under. It is only recommended if the company provides it according to the commercial arrangement.

The Technology

Spinal muscular atrophy (SMA) is a rare genetic condition that causes muscle weakness and progressive loss of movement. The motor neurones most affected by this condition are those that allow walking, crawling, arm movement, head and neck movement, swallowing and breathing. SMA causes substantial disability and may lead to increased mortality and reduced life expectancy. The most severe types of SMA typically cause death before age 2 years, although people with later-onset types of SMA can live into adolescence or adulthood.

A few children are diagnosed with SMA using genetic testing before symptoms appear if a sibling has been diagnosed with the condition. If untreated, presymptomatic SMA will develop into one of several types of SMA of varying severity and symptoms. There are no routinely commissioned treatments for presymptomatic SMA for use in the NHS. If presymptomatic SMA develops into type 1 SMA, onasemnogene abeparvovec is an available treatment option in certain situations.

In the absence of active treatment, the condition is managed through multidisciplinary supportive care. Supportive care strategies do not affect disease progression but aim to minimise the impact of disability, address complications and improve quality of life. These may involve respiratory, gastroenterology, and orthopaedic care, as well as nutritional support, physiotherapy, assistive technologies, occupational therapy and social care.

Onasemnogene abeparvovec is a single dose gene replacement therapy made of a viral vector that has been modified to contain the primary gene for the human survival motor neuron (SMN) protein, which is lacking or mutated in people with SMA. When injected, the vector is expected to carry the gene into the nerve cells, enabling production of sufficient amounts of SMN. It is administered intravenously. Treatment with onasemnogene abeparvovec is expected to be used exclusively in the context of a highly specialised service.

Financial Factors

This technology is commissioned by NHS England.

Evidence from a clinical trial suggests that onasemnogene abeparvovec is effective for presymptomatic SMA in babies. But it is difficult to estimate how well onasemnogene abeparvovec works, primarily because the trial only included babies aged 6 weeks and under, and treatment before this time point is not always possible in NHS clinical practice. Also, there is a lack of long-term evidence for onasemnogene abeparvovec in presymptomatic SMA.

Despite the high levels of uncertainty, there is evidence that onasemnogene abeparvovec provides substantial health benefits, such as reaching important motor milestones, for babies with presymptomatic SMA. The cost-effectiveness results show a lower overall cost compared with onasemnogene abeparvovec for type 1 SMA and best supportive care for types 2 and 3 SMA for babies aged 6 weeks and under. For babies with presymptomatic SMA aged over 6 weeks to 12 months and under, the cost-effectiveness estimates are still likely to be within the range that NICE considers an effective use of NHS resources for highly specialised technologies. Therefore, onasemnogene abeparvovec is recommended for use in the NHS for presymptomatic SMA in babies aged 12 months and under.

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

Onasemnogene abeparvovec for treating spinal muscular atrophy HST15 (UPDATE)

This guidance was published in July 2021. In April 2023, this guidance was partially updated by HST24.

Recommendations

Onasemnogene abeparvovec is **recommended** as an option for treating 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of type 1 SMA in babies, only if:

- they are 6 months or younger, or
- they are aged 7 to 12 months, and their treatment is agreed by the national multidisciplinary team.

It is only recommended for these groups if:

- permanent ventilation for more than 16 hours per day or a tracheostomy is not needed
- the company provides it according to the commercial arrangement.

For babies aged 7 to 12 months, the national multidisciplinary team should develop auditable criteria to enable onasemnogene abeparvovec to be allocated to babies in whom treatment will give them at least a 70% chance of being able to sit independently.

This recommendation has been updated and replaced by NICE highly specialised technologies guidance on onasemnogene abeparvovec for treating presymptomatic spinal muscular atrophy (HST24).

The Technology

Spinal muscular atrophy (SMA) is a rare genetic condition that causes muscle weakness and progressive loss of movement. The motor neurones most affected by this condition are those that allow walking, crawling, arm movement, head and neck movement, swallowing and breathing. SMA causes substantial disability and may lead to increased mortality and reduced life expectancy. The most severe types of SMA typically cause death before age 2 years, although people with later-onset types of SMA can live into adolescence or adulthood.

SMA is a heterogeneous condition, which is often grouped into 5 main types, based on the age of onset of symptoms and how much motor function the person has.

The types of SMA decrease in severity from type 0, in which symptoms arise before birth and babies survive for only a few weeks, to type 4 (adult-onset) which is associated with mild motor impairment and a normal life span. Types 0 and 4 are rarely diagnosed. In SMA type 1, symptoms arise before age 6 months and babies are unable to sit independently; babies with SMA have low muscle tone and severe muscle weakness which affects movement, swallowing and breathing. In type 2 SMA, the onset of symptoms is between age 7 and 18 months, and people with this condition are often severely disabled and unable to walk unaided. Type 3 SMA is a heterogeneous condition, with a varying degree of muscle weakness appearing between age 18 months and 18 years; most people with type 3 SMA can walk or sit unaided at some point, but many lose mobility over time.

No active treatments are currently routinely available for SMA and the condition is managed through multidisciplinary supportive care. Supportive care strategies do not affect disease progression but aim to minimise the impact of disability, address complications and improve quality of life. These may involve respiratory, gastroenterology, and orthopaedic care, as well as nutritional support, physiotherapy, assistive technologies, occupational therapy and social care.

Onasemnogene abeparvovec is a single dose gene replacement therapy made of a viral vector that has been modified to contain the primary gene for the human survival motor neuron (SMN) protein, which is lacking or mutated in people with SMA. When injected, the vector is expected to carry the gene into the nerve cells, enabling production of sufficient amounts of SMN. It is administered intravenously. Treatment with onasemnogene abeparvovec is expected to be used exclusively in the context of a highly specialised service.

Financial Factors

This technology is commissioned by NHS England.

For babies with type 1 SMA who are 6 months or younger at the start of treatment and who do not need permanent ventilation for more than 16 hours per day or a tracheostomy, evidence from clinical studies suggests that onasemnogene abeparvovec is effective. But the studies are small and do not compare onasemnogene abeparvovec with other treatments, so it is difficult to establish how well it works. Also, there is very limited evidence for babies with type 1 SMA who are older than 6 months at the start of treatment. However, clinical experts advise that some babies aged between 7 and 12 months would be expected to have similar benefit to those 6 months and younger. There is also a lack of long-term evidence, and no evidence in more progressed type 1 SMA.

Because of the uncertainty in the clinical data, the cost-effectiveness estimates for onasemnogene abeparvovec for treating type 1 SMA are uncertain. However, they are likely to be within the range that NICE considers an effective use of NHS resources for highly specialised technologies for:

- babies 6 months and younger
- babies aged 7 to 12 months if it is likely that they will have a similar benefit from treatment with onasemnogene abeparvovec as younger babies.

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

NICE Guidelines (NGs)

Hypertension in pregnancy: diagnosis and management NG133 (UPDATE)

This guideline covers diagnosing and managing hypertension (high blood pressure), including pre-eclampsia, during pregnancy, labour and birth. It also includes advice for women with hypertension who wish to conceive and women who have had a pregnancy complicated by hypertension. It aims to improve care during pregnancy, labour and birth for women and their babies.

April 2023: NICE updated recommendations on when to offer placental growth factor (PLGF)-based testing for pre-eclampsia, in line with DG49 on PLGF-based testing for pre-eclampsia.

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.

April 2023: NICE have reviewed the evidence and made new recommendations and recommendations for research on arm and shoulder mobility.

Metastatic malignant disease of unknown primary origin in adults: diagnosis and management CG104 (UPDATE)

This guideline covers diagnosing and managing secondary cancer in people aged 18 and over when the site of the primary cancer is unknown. This includes people who have had treatment for cancer before. It aims to improve quality of life by offering advice on tests for identifying the site of the primary cancer and options for managing the person's condition.

This guideline covers carcinomas only and does not cover, for example, lymphoma, melanoma and sarcoma.

April 2023: NICE withdrew recommendations on gene-expression-based profiling and added a link to the NHS Genomic Medicine Service's national genomic test directory.

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)

Endoscopic ultrasound-guided biliary drainage for biliary obstruction IPG761

Recommendations

Evidence on the safety and efficacy of endoscopic ultrasound-guided biliary drainage (EUS-BD) for biliary obstruction *caused by distal malignant disease* is adequate to support using this procedure. This is provided that **standard arrangements** are in place for clinical governance, consent and audit.

Evidence on the safety and efficacy of EUS-BD for biliary obstruction *caused by malignant hilar or benign disease* is inadequate in quality and quantity. So, this procedure should be used only in **research**.

Further research should report details of patient selection, where the obstruction is, and whether this procedure has been done after failed endoscopic retrograde cholangiopancreatography.

Patient selection should be done by a multidisciplinary team or, in an emergency, only after agreement with an experienced hepatobiliary team.

This procedure should only be done in specialised centres by a clinician with specific training and experience in the procedure.

The Condition

Biliary obstruction involves blockage of any duct that carries bile from the liver to the gallbladder or from the gallbladder to the small intestine. It may have benign or malignant causes and can lead to symptoms including jaundice, nausea and abdominal pain, itching, pale stools and dark urine.

Current standard management of biliary obstruction usually includes stenting using endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic biliary drainage (PTBD). For malignant obstruction, treatment may also include chemotherapy, biological therapy, photodynamic therapy and radiofrequency ablation.

The Procedure

Endoscopic ultrasound-guided biliary drainage (EUS-BD) is an alternative procedure when ERCP is not possible; ERCP fails in a small proportion of people because of the nature of the obstruction or their anatomy (which may be altered because of disease progression or previous surgery). EUS-BD is also a minimally invasive alternative to PTBD, which is conventionally offered when ERCP has failed. The aim of the procedure is to reduce biliary obstruction and allow the biliary tract to drain.

EUS-BD may be done under conscious sedation or general anaesthesia. It involves inserting an echoendoscope through the mouth and oesophagus into the stomach or duodenum. Using ultrasound guidance, the biliary tract is punctured with a needle. A contrast agent may be injected to enhance imaging.

A guidewire is then passed into the biliary tract at the site of the puncture, which is dilated to create a fistula. Finally, a metal or plastic stent is deployed into the biliary tract to allow biliary drainage into the stomach or small intestine. Stent delivery systems may also be used to do EUS-BD without needle puncture, dilation or insertion of a guidewire.

EUS-BD can be done using several different techniques and stents can be deployed through multiple access routes. The choice of technique depends on the cause of the biliary obstruction and the anatomy of the person having the procedure.

Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea IPG760

Recommendations

Evidence on the safety and efficacy of daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea is inadequate in quality and quantity. So, this procedure should be used only in **research**.

Further research should include suitably powered randomised controlled trials and analysis of observational data, to assess efficacy, safety and adherence. Research should report details of patient selection, duration of treatment and effect, effect on snoring and sleep apnoea, quality of life and complications.

The Condition

Obstructive sleep apnoea (OSA) is a condition in which the upper airway narrows or closes during sleep when the throat muscles intermittently relax. This causes reduced breathing (hypopnoea) or breathing to temporarily stop (apnoea). OSA can lead to major neurocognitive and cardiovascular sequelae.

Management of OSA includes lifestyle changes (such as weight loss), continuous positive airway pressure, oral devices (mandibular advancement devices), neuromuscular electrical stimulation and upper airway surgery.

The Procedure

In this procedure, an intraoral removable device is used to deliver neuromuscular electrical stimulation to the intrinsic and extrinsic (genioglossus) muscles of the tongue. The aim is to improve tongue endurance and reduce airway obstruction during sleep.

A mouthpiece with an electrode array that fits onto the tongue is placed in the mouth by the person during the daytime while they are awake. Bipolar biphasic current is then delivered for about 20 minutes with predetermined low frequency stimulation and rest periods. The mouthpiece is removed once the session is complete. The intensity of the stimulation is controlled by the person, for example by using a smartphone app. An entire therapy usually lasts about 6 weeks, with a 20-minute daytime session each day while awake.

Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases IPG759

Recommendations

Evidence on the safety and efficacy of radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases is adequate to support using this procedure provided that **standard arrangements** are 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.

Patient selection should be done by a multidisciplinary team. The procedure should only be done by clinicians with training and expertise in kyphoplasty or vertebroplasty techniques.

The Condition

Spinal metastases can affect quality of life by causing severe pain, functional impairment, vertebral fractures, nerve root impingement, spinal cord compression and hypercalcaemia.

Treatment for spinal metastases is always palliative. It aims to reduce pain, improve and maintain function, provide mechanical stability and prevent further local tumour progression. Current treatment options include a combination of medical therapies, orthotic support, radiation therapy and minimally invasive localised percutaneous procedures such as cryoablation, photodynamic therapy, microwave ablation and radiofrequency ablation. These techniques may also be used with kyphoplasty or vertebroplasty to improve structural or mechanical stabilisation after tumour ablation. Open surgery (or surgery combined with radiotherapy) may be suitable for some people with spinal cord compression and vertebral fractures.

The Procedure

Radiofrequency ablation is a procedure for palliative treatment of spinal metastases. It is usually done in a day-case setting using a transpedicular or parapedicular approach under general anaesthesia or local anaesthesia with sedation. The approach is either percutaneous, endoscopic or surgical.

Under imaging guidance (fluoroscopy, CT or MRI), a radiofrequency probe is inserted into the spinal tumour. The radiofrequency probe is attached to a radiofrequency generator, which creates high-frequency, alternating current pulses that heat and destroy the tumour. This creates a cavity in the vertebral body. In this procedure, percutaneous vertebroplasty or balloon kyphoplasty is done at the same time with the aim of preventing subsequent fractures in the treated vertebrae.

Radiofrequency ablation is not usually done if the spinal metastases are close to neurological structures because of the risk of neurological injury.

Radiofrequency ablation for palliation of painful spinal metastases IPG758

Recommendations

Evidence on the safety and efficacy of radiofrequency ablation for palliation of painful spinal metastases is limited in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do radiofrequency ablation for palliation of painful spinal metastases should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people and their families and carers understand the procedure's safety and efficacy, and any uncertainties about these.
- 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.
- 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 multidisciplinary team. The procedure should only be done by clinicians with training and expertise in vertebral interventions.

NICE encourages further research into the procedure. This should report details of patient selection, type of tumour and interventional procedures used.

The Condition

Spinal metastases can affect quality of life by causing severe pain, functional impairment, vertebral fractures, nerve root impingement, spinal cord compression and hypercalcaemia.

Treatment for spinal metastases is always palliative. It aims to reduce pain, improve and maintain function, provide mechanical stability and prevent further local tumour progression. Current treatment options are as described in IPG759 above.

The Procedure

Radiofrequency ablation is a procedure for palliative treatment of spinal metastases. It is usually done in a day-case setting using a transpedicular or parapedicular approach under general anaesthesia or local anaesthesia with sedation. The approach is either percutaneous, endoscopic or surgical.

Under imaging guidance (fluoroscopy, CT or MRI), a radiofrequency probe is inserted into the spinal tumour. The radiofrequency probe is attached to a radiofrequency generator, which creates high-frequency alternating current pulses that heat and destroy the tumour.

Radiofrequency ablation is not usually done if the spinal metastases are close to neurological structures because of the risk of neurological injury.

This is a standalone radiofrequency ablation procedure and not an adjunct to vertebroplasty or kyphoplasty.

Maximal cytoreductive surgery for advanced ovarian cancer IPG757

This guidance replaces IPG470 (published November 2013).

Recommendations

Evidence on the safety and efficacy of maximal cytoreductive surgery for advanced ovarian cancer is adequate to support using this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

Patient selection should be done by a specialist gynaecological cancer multidisciplinary team, which may include surgeons from other specialities.

The procedure should be done by a team of surgeons with appropriate expertise. The procedure should only be done in accredited specialised units.

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.

The Condition

Early symptoms of ovarian cancer can be similar to those of other pelvic or abdominal conditions and include persistent bloating, pain in the pelvis and lower abdomen, urinary frequency and urinary urgency. Ovarian cancer is usually at stage 3 or 4 when it is diagnosed and the outcome is generally poor. The stage of the disease at diagnosis is the most important factor affecting outcome and is defined by the International Federation of Gynaecology and Obstetrics (FIGO) system:

- Stage 1 (A to C): the tumour is confined to the ovary.

- Stage 2 (A, B): the tumour involves 1 or both ovaries and has extended into the pelvis.
- Stage 3 (A to C): the tumour involves 1 or both ovaries with microscopically confirmed peritoneal metastasis outside the pelvis, or regional lymph node metastasis (if cancer cells are found only in fluid taken from inside the abdomen the cancer is stage 2).
- Stage 4 (A, B): there is distant metastasis beyond the peritoneal cavity (if ovarian cancer is only found on the surface of the liver and not within the liver itself, then the cancer is stage 3).

The FIGO stage does not fully take into account the tumour load and disease extent in advanced disease.

NICE's guideline on the recognition and initial management of ovarian cancer (CG122) describes the initial management options. The main treatments for advanced ovarian cancer are surgery to remove all macroscopic residual disease and chemotherapy. Standard surgery usually involves, as a minimum, bilateral salpingo-oophorectomy, total abdominal hysterectomy and omentectomy. Maximal cytoreductive surgery uses additional surgical procedures, including upper abdominal surgery, with the aim of achieving no residual disease. The most important factors affecting outcomes after surgery are responsiveness to platinum-based chemotherapy and the amount of residual disease.

Conventional imaging techniques cannot accurately predict the distribution or volume of disease before surgery. Therefore, the only definitive assessment of the distribution or volume of disease found in the abdomen and pelvis is done at the time of surgery. Currently, no objective tools exist to select people for surgery and a decision for surgery will depend on many factors, including fitness, patient choice, availability of surgeons with appropriate expertise and resource levels.

The Procedure

The aim of maximal cytoreductive surgery for advanced ovarian cancer is to safely remove all identifiable disease, to improve survival, compared with surgery that leaves residual disease. It is a development and extension of standard surgery for ovarian cancer.

The precise differences between standard, radical and maximal cytoreduction procedures are not well defined. Surgical complexity scores, such as the Aletti system, have been developed to try to quantify the complexity of surgery. Each procedure that is done during the surgery is allocated a score.

The total score can then be used to categorise the surgery into low complexity (1 to 3), intermediate complexity (4 to 7) or high complexity (8 and above).

Focal therapy using high-intensity focused ultrasound for localised prostate cancer IPG756

This guidance replaces IPG424 (published April 2012).

Recommendations

Evidence on the safety of focal therapy using high-intensity focused ultrasound for localised prostate cancer is adequate, but evidence on its efficacy is limited. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do high-intensity focused ultrasound for localised prostate cancer should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers, as appropriate) clear written information to support shared decision making, including NICE's information for the public. Use the recommendations in NICE's guideline on diagnosing and managing prostate cancer (NG131) for information on treatment options and decision support.
- Ensure that people (and their families and carers, as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 multidisciplinary team.

Further research could include registry data or randomised trials. It should include details of patient selection, including size and classification of tumour, technique used and long-term outcomes such as quality of life.

The Condition

Prostate cancer can cause some lower urinary tract symptoms such as frequency, urgency, hesitancy, terminal dribbling and an overactive bladder. Localised prostate cancer is confined to the prostate and has not spread to nearby tissues or other parts of the body.

NICE's guideline on prostate cancer (NG131) describes how to diagnose and manage prostate cancer. Decisions on treatment are based on imaging, tumour staging, risk assessment and prostate-specific antigen (PSA) levels. For some people, localised prostate cancer grows slowly or not at all and treatment may not be necessary. In such cases, watchful waiting or active surveillance strategies may be appropriate.

If treatment is needed, several options are available. These include radical treatments (such as radical prostatectomy, external beam radiotherapy and radical brachytherapy), focal treatments (such as focal high-intensity focused ultrasound [HIFU], focal cryoablation, irreversible electroporation, focal laser ablation and focal brachytherapy) and adjunctive treatments (such as chemotherapy and androgen deprivation therapy).

The Procedure

Imaging and biopsy mapping are used to confirm that the tumour is suitable for focal therapy and to show its precise location. With the person under spinal or general anaesthesia, the bladder is catheterised using a urethral or supra-pubic catheter and the HIFU probe is inserted transrectally.

Ultrasound imaging guidance is used to position the probe and to monitor the procedure. Pulses of HIFU are directed at the targeted part of the prostate, inducing tumour necrosis by a thermal effect and causing cavitation until satisfactory ablation of the target area is judged to have occurred. This procedure differs from standard whole-gland HIFU in that only some of the prostate is treated. Transurethral resection of the prostate may be done at the same time as focal HIFU to reduce urinary symptoms.

Percutaneous thoracic duct embolisation for persistent chyle leak IPG755

Recommendations

Evidence on the safety and efficacy of percutaneous thoracic duct embolisation for persistent chyle leak is limited in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do percutaneous thoracic duct embolisation for persistent chyle leak should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers, as appropriate) clear written information to support shared decision making, including NICE's information for the public.

- Ensure that people (and their families and carers, as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 team experienced in managing the condition, including a dietitian.

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

NICE encourages further research into percutaneous thoracic duct embolisation for persistent chyle leak. Research should include details of patient selection, size and position of the leak, approaches used, and short- and long-term efficacy and safety outcomes.

The Condition

Chyle leak or discharge can occur as a result of thoracic duct injury. Injury can happen during surgery, from trauma or from disease such as cancer. Chyle leak can cause delayed wound healing, dehydration, malnutrition, electrolyte imbalance, breathing problems and immunosuppression.

Small chyle leaks are usually treated with medicines and by managing nutrition (including by modifying diet or with total parenteral nutrition) to reduce chyle secretion and relieve symptoms. Persistent high-volume leaks may need drainage or percutaneous or open surgical repair (such as thoracic duct ligation).

The Procedure

Thoracic duct embolisation is a percutaneous image-guided closure of the thoracic duct and is done under general or local anaesthesia. It is a 3-step process consisting of intranodal inguinal lymphangiography followed by percutaneous transabdominal catheterisation of the thoracic duct or cisterna chyli and then embolisation of the thoracic duct.

Under fluoroscopic or ultrasound guidance, an oil-based contrast medium is injected into inguinal lymph nodes. This progresses slowly through the network of pelvic and retroperitoneal lymphatic vessels and allows the thoracic duct and cisterna chyli to be visualised. Then, through transabdominal access under imaging guidance, the target thoracic duct or cisterna chyli is accessed with a guidewire using a needle. A microcatheter is advanced over the guidewire into the thoracic duct, then the guidewire is removed. Contrast medium is injected through the catheter to define the source of the leak and the thoracic duct anatomy. The target thoracic duct and its branches are embolised proximally to the leak with a combination of microcoils and cyanoacrylate glue.

Medical Technologies Guidance (MTGs)

AposHealth for knee osteoarthritis MTG76

Recommendations

AposHealth is **recommended** as a cost-saving option to manage knee osteoarthritis in adults only if:

- non-surgical standard care has not worked well enough and
- their condition meets the referral criteria for total knee replacement surgery but they do not want surgery and
- data is collected on the person's quality of life, health resource use and if they have knee replacement surgery in the long term.

Further research is recommended on AposHealth for:

- people with knee osteoarthritis that meets the referral criteria for total knee replacement surgery but who cannot have surgery because it would be unsafe
- people whose condition does not meet the referral criteria for total knee replacement surgery.

The Technology

Knee osteoarthritis is the most common form of osteoarthritis. It typically presents with joint symptoms such as pain and stiffness. Symptoms vary from mild and intermittent, to more persistent or severe. Knee osteoarthritis is more common in women, people living in deprived areas, people aged 45 and over and people who are obese. It is estimated that 1 in 5 people over 45 years have knee osteoarthritis in England.

Treatment of knee osteoarthritis depends on the severity of symptoms. Current treatment options include pharmacological and non-pharmacological treatments.

Non-pharmacological core treatments for osteoarthritis are therapeutic exercise and weight loss, along with information and support. Other non-pharmacological treatment options include manual therapy and devices.

Pharmacological treatment options include topical and oral non-steroidal anti-inflammatories to relieve pain and inflammation. Intra-articular corticosteroid injections should be considered when other pharmacological treatments are ineffective or unsuitable, or to support therapeutic exercise. However, these treatments only provide short-term relief and may become less effective as the severity of knee osteoarthritis increases.

Referral for knee surgery should be considered for people who experience joint symptoms (such as pain, stiffness, reduced function or progressive joint deformity) that have a substantial impact on their quality of life and if non-surgical management is ineffective or unsuitable. Clinical assessment should be used when deciding to refer someone for joint replacement, instead of systems that numerically score severity of disease.

AposHealth is intended for use by adults with knee osteoarthritis who have had non-surgical standard care that has not worked well enough.

AposHealth is a non-invasive device worn on the feet. The device consists of a pair of AposHealth shoes with 2 curved pods (pertupods) on the heel and forefoot of each shoe. The pertupods are securely attached to tracks on the bottom of the shoe with screws. Positioning of the pertupods is done by trained healthcare professionals and can be aided by gait analysis software or hardware.

The AposHealth 4-step treatment plan lasts 1 year and consists of an initial patient assessment, personalisation of the device, at-home treatment and ongoing monitoring. The at-home treatment step involves the person wearing the device for short periods of time during daily activities, for a total of up to 60 minutes per day. People should be offered 1 to 2 follow ups per year after the treatment plan as part of ongoing monitoring if continuing to use AposHealth.

Financial Factors

This technology is commissioned by ICBs.

Potential cost savings from AposHealth mainly come from a reduction in non-surgical standard care resource use and a reduction in knee replacement surgery. This cost could be avoided if AposHealth prevent progression to the requirement for surgery.

In addition to the savings from reduced surgery, the use of AposHealth may also save costs associated with surgery complications, and revision of knee surgery and rehabilitation. Also, available evidence further suggests a 15% reduction in healthcare resource use such as GP appointments.

Non-surgical standard care includes many different elements of healthcare resources, and it is not clear what elements of non-surgical standard care resources are avoided when using AposHealth. Because the evidence for the potential cost savings is limited, further data collection is recommended to understand if cost savings are made once AposHealth is used in the NHS.

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
Oesophago-gastric cancer: assessment and management in adults	02/05/2023
Otitis media with effusion in under 12s	12/05/2023
Myeloma	12/05/2023
Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia	24/05/2023
Cryotherapy for Chronic Rhinitis	24/05/2023
Stroke rehabilitation in adults	31/05/2023