NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: September 2021

Hyperlinks to the relevant NICE web page are included below.

NICE rapid COVID-19 guidelines

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

This guideline covers the management of COVID-19 for children, young people and adults in all care settings. It brings together existing NICE recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily.

September 2021: NICE added new recommendations on non-invasive respiratory support and doxycycline, and updated existing recommendations on heparins.

Technology Appraisals (TAs)

Vericiguat for treating chronic heart failure with reduced ejection fraction *(terminated appraisal)* TA731

NICE is **unable to make a recommendation** on vericiguat for treating chronic heart failure with reduced ejection fraction in adults because Bayer did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours *(terminated appraisal)* TA730

NICE is **unable to make a recommendation** on avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours in adults because Blueprint Medicines did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Sapropterin for treating hyperphenylalaninaemia in phenylketonuria TA729

Recommendations

Sapropterin is **recommended** as an option for treating hyperphenylalaninaemia that responds to sapropterin (response as defined in the summary of product characteristics) in people with phenylketonuria (PKU), only if they are:

- under 18 and a dose of 10 mg/kg is used, only using a higher dose if target blood phenylalanine levels cannot be achieved at 10 mg/kg
- aged 18 to 21 inclusive, continuing the dose they were having before turning 18 or at a maximum dose of 10 mg/kg
- pregnant (from a positive pregnancy test until birth).

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

This recommendation is not intended to affect treatment with sapropterin 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

Phenylketonuria is an autosomal recessive genetic disorder caused by the deficiency of an enzyme called phenylalanine hydroxylase. Phenylalanine hydroxylase breaks down phenylalanine into tyrosine and in the absence of this, phenylalanine accumulates in the blood, resulting in brain damage. This is characterised by irreversible intellectual disability, motor deficits, skin lesions, autism, seizures, psychological, social and behavioural problems.

Phenylketonuria is typically diagnosed at birth. Since the introduction of the new-born screening programmes, all babies born in the UK are routinely screened for high phenylalanine levels and neurological damage can largely be prevented by following a strict phenylalanine restricted (low protein) diet. This is a severely restrictive diet excluding all natural proteins (such as meat, fish, eggs, cheese, pulses, seeds, flour, bread and pasta). Managing this diet is a substantial burden to both people with phenylketonuria and their carers and families. The diet is associated with eating disturbances and side effects such as gastrointestinal symptoms. Many people do not adhere to dietary treatment because it is very challenging and difficult to manage while living a normal life.

When phenylketonuria manifests in adults it is typically characterised by a decline in executive function, depression, anxiety disorders, phobias and low self-esteem. Adults with phenylketonuria may also develop comorbidities impacting cardio-vascular and metabolic functions. It is especially important to maintain low levels of phenylalanine during pregnancy and pre-conception to avoid its harmful effects on the fetus, which

can include congenital heart disease, microcephaly, developmental delay and miscarriage.

It is estimated that about 4,400 people have phenylketonuria in England. The rate of positive tests for phenylketonuria in babies tested in the new-born blood spot screening programme in 2016 to 2017 was 0.0137%.

The only treatment for PKU is a diet to manage phenylalanine and overall protein intake (protein-restricted diet) and prescribed supplements.

Sapropterin dihydrochloride is a synthetic form of BH4, a cofactor that increases the activity of phenylalanine hydroxylase, and therefore helps convert phenylalanine into tyrosine, resulting in decreased blood phenylalanine levels. It is administered orally.

Sapropterin, plus a protein-restricted diet, is used for people whose PKU has been shown to respond to it. The aim of treatment is to maintain satisfactory blood phenylalanine levels to reduce PKU symptoms and complications, and potentially allow a less restricted diet.

Sapropterin has a marketing authorisation in the UK for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment.

Financial factors

This technology is commissioned by NHS England.

Taking uncaptured benefits and the clinical evidence into account, cost-effectiveness estimates are acceptable at the upper limit of what NICE considers an acceptable use of NHS resources. Sapropterin is therefore recommended for people under 18.

The maximum age at which sapropterin can be considered a cost-effective use of NHS resources is 21. However, for this use to be cost effective people would need to continue the dose they were having when they were under 18. In practice this may mean that some young adults may need more dietary control alongside sapropterin between the ages of 18 and 21 (inclusive) than they would with a higher dose. Sapropterin is recommended for people aged 18 to 21, continuing the dose they were having before turning 18.

The benefits for the pregnant woman with PKU who has the treatment are included in the cost-effectiveness analysis, but benefits for the unborn child have not been included. Taking the benefits for both these individuals into account, the cost-effectiveness estimates are likely to be within what NICE considers acceptable. Sapropterin is recommended during pregnancy until birth.

Sapropterin is not recommend for adults after they reach the age of 22 as the cost-effectiveness estimates are substantially higher than what NICE considers an acceptable use of NHS resources.

Midostaurin for treating advanced systemic mastocytosis TA728

Recommendations

Midostaurin monotherapy is **recommended**, within its marketing authorisation, as an option for treating aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia in adults. It is recommended only if the company provides midostaurin according to the commercial arrangement.

The technology

Mastocytosis is a condition caused by excessive amounts of mast cells gathering in body tissues, such as the skin, organs and bones. In many cases, mastocytosis is caused by a mutation in the KIT gene. Mastocytosis is generally classified as cutaneous (affecting the skin) or systemic (affecting the internal organs). The mast cells release large amounts of histamine and other mediators into the blood, causing symptoms such as skin rash, itchy skin, hot flushes, vomiting, diarrhoea and anaphylaxis. In advanced systemic mastocytosis, mast cells accumulate in internal organs and can cause organ damage, bone fractures and anaemia. The wide-ranging symptoms can be disabling or even life-threatening. The systemic condition mainly affects adults. It is estimated that around 1 in 10,000 people have systemic mastocytosis.

The aim of treatment for advanced systemic mastocytosis is to decrease the number of mast cells and to control symptoms. Therefore, treatment depends on the symptoms experienced by each person. Treatment may include interferon alpha, cladribine, imatinib (for disease without the KIT mutation), nilotinib or dasatinib. Treatment for systemic mastocytosis with an associated blood (haematological) disease will also include treatment for the associated condition.

Midostaurin is a multi-targeted kinase inhibitor, which inhibits FLT3, KIT and other receptor tyrosine kinases. It is administered orally. Midostaurin has a marketing authorisation for treating adults with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm or mast cell leukaemia.

Financial factors

This technology is commissioned by NHS England.

Evidence suggests that midostaurin is more effective than current treatments, but this is uncertain because it was not compared directly with these. Also, better quality comparative evidence is unlikely to become available.

Midostaurin meets NICE's criteria for a life-extending treatment at the end of life, which means that higher cost-effectiveness estimates can be considered. This means that, despite the uncertainty about the clinical evidence, the cost-effectiveness estimates are within the range that NICE considers acceptable.

The list price of midostaurin is £5,609.94 for a 56-pack of 25 mg capsules, which equates to an annual cost of £292,719 at the standard dose of 100 mg twice daily.

Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma *(terminated appraisal)* TA727

NICE is **unable to make a recommendation** on isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma because Sanofi did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma *(terminated appraisal)* TA726

NICE is **unable to make a recommendation** on daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma because Janssen did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy TA725

Recommendations

Abemaciclib plus fulvestrant is **recommended** as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in adults who have had endocrine therapy only if:

- exemestane plus everolimus is the most appropriate alternative to a cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor and

- the company provides abemaciclib according to the commercial arrangement.

The technology

Breast cancer arises from the tissues of the ducts or lobules of the breast. The cancer is said to be 'advanced' if it has spread to other parts of the body such as the bones, liver, and lungs (metastatic cancer), or if it has grown directly into nearby tissues and cannot be completely removed by surgery.

Approximately 13% of women with breast cancer have advanced disease when they are diagnosed, and around 35% of people with early or locally advanced disease will progress to metastatic breast cancer in the 10 years following diagnosis.

Current treatments for advanced breast cancer aim to relieve symptoms, prolong survival and maintain a good quality of life with minimal adverse events. Treatment depends on whether the cancer cells have particular receptors (hormone receptor status or HER2 status), the extent of the disease, and previous treatments.

NICE clinical guideline 81 (CG81) recommends first-line treatment with endocrine therapy for most people with advanced hormone receptor-positive breast cancer. But for people whose disease is life-threatening or requires early relief of symptoms, CG81 recommends chemotherapy.

Abemaciclib is an inhibitor of cyclindependent kinases 4 and 6, which prevents DNA synthesis by prohibiting progression of the cell cycle from G1 to S phase. It is administered orally. Abemaciclib in combination with fulvestrant has a marketing authorisation in the UK for treating hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer.

Financial factors

These technologies are commissioned by NHS England.

Cost-effectiveness estimates vary. But, even with the uncertainty around the estimates, abemaciclib plus fulvestrant is considered a cost-effective use of NHS resources.

Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer TA724

Recommendations

Nivolumab plus ipilimumab and 2 cycles of platinum-doublet chemotherapy is **not recommended**, within its marketing authorisation, for untreated metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations.

This recommendation is not intended to affect treatment with nivolumab plus ipilimumab and 2 cycles of platinum-doublet chemotherapy 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

Lung cancer falls into 2 main histological categories: 85-90% are non-small cell lung cancers (NSCLC) and 10-15% are small-cell lung cancers. NSCLC can be further classified into squamous cell carcinoma and non-squamous cell carcinoma.

Most lung cancers are diagnosed at an advanced stage, when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage III) or to other parts of the body (metastatic disease; stage IV).

For the majority of people with NSCLC, the aims of treatment are to prolong survival and improve quality of life. Treatment choices are influenced by the presence of biological markers (such as mutations in epidermal growth factor receptor-tyrosine kinase (EGFR), anaplastic-lymphoma-kinase (ALK) or programmed death-ligand (PD-L1) status), histology (squamous or nonsquamous) and previous treatment experience.

Standard care for untreated metastatic NSCLC that has no EGFR or ALK mutations is usually immunotherapy plus platinum-doublet chemotherapy. People have different

treatments depending on their PD-L1 tumour proportion score and whether they have squamous or non-squamous NSCLC.

Nivolumab is a fully humanised IgG4 monoclonal antibody which targets and blocks the PD-L1 receptor, to promote an anti-tumour immune response. It is administered intravenously.

Ipilimumab is a recombinant human antiCTLA-4 monoclonal antibody which blocks the effects of CTLA-4 to enhance T-cell mediated immune responses to tumour cells. It is administered intravenously.

Financial factors

These technologies are commissioned by NHS England.

The cost-effectiveness estimates for nivolumab combination compared with platinum-doublet chemotherapy, atezolizumab combination and pembrolizumab monotherapy are higher than what NICE considers an acceptable use of NHS resources. The cost-effectiveness estimates compared with pembrolizumab plus pemetrexed and platinum chemotherapy are uncertain because of problems with the analysis

Bimekizumab for treating moderate to severe plaque psoriasis TA723

Recommendations

Bimekizumab is **recommended** as an option for treating plaque psoriasis in adults, only if:

- the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
- the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
- the company provides the drug according to the commercial arrangement.

Stop bimekizumab treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:

- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

The least expensive treatment should be chosen if patients and their clinicians consider bimekizumab to be one of a range of suitable treatments (taking into account availability of biosimilar products, administration costs, dosage, price per dose and commercial arrangements).

It should be taken into account how skin colour could affect the PASI score and any appropriate clinical adjustments should be made.

Any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI should be considered and any appropriate adjustments made.

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

The technology

Plaque psoriasis is an inflammatory skin condition characterised by an accelerated rate of turnover of the upper layer of the skin (epidermis). This leads to an accumulation of skin cells forming raised plaques on the skin. These plaques can be flaky, scaly, itchy and red or a darker colour to the surrounding skin. Plaque psoriasis may affect the scalp, elbows, limbs and trunk and sometimes the face, groin, nails, armpits or behind the knees.

There is no cure for psoriasis but there is a wide range of topical and systemic treatments that can manage the condition. Most treatments reduce the severity of psoriasis flares rather than prevent episodes. Psoriasis has to be treated continually and on a long-term basis.

Bimekizumab is a monoclonal antibody which binds to and selectively neutralises IL-17A and IL-17F. It is administered by subcutaneous administration. Bimekizumab is an alternative to other biological treatments already recommended by NICE for treating severe plaque psoriasis in adults.

Evidence from clinical trials shows that bimekizumab is more effective than adalimumab, secukinumab and ustekinumab. Indirect comparisons suggest that bimekizumab is similarly or more effective than other biological treatments.

Financial factors

This technology is commissioned by CCGs.

The list price of bimekizumab is £2,443 per 320 mg dose (two 160 mg prefilled syringes or prefilled pens; excluding VAT).

The company has a commercial arrangement. This makes bimekizumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

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)

Transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair IPG707

Recommendations

Evidence on the safety of transapical transcatheter mitral valve-in-ring implantation after failed mitral valve repair surgery is adequate and shows some serious but well recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making.
- Ensure that patients have been told and understand about all alternative treatment options and their advantages and disadvantages.

- Enter details about all patients having transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair onto a national registry when 1 is available.

- Audit and review clinical outcomes of all patients 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 every patient having this procedure.

- Regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.

The procedure is technically challenging and should only be done in specialised centres, and only by clinician teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care.

Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

NICE encourages further research into transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair. Studies should include details on patient selection, type and size of valve used, functional outcomes (New York Heart Association functional class, mitral valve regurgitation), quality of life, patient-reported outcome measures, survival and complications. Studies should report long-term follow up of clinical outcomes and valve durability. NICE may update this guidance on publication of further evidence.

The condition

The mitral valve allows blood to flow from the left atrium to the left ventricle. Mitral valve regurgitation happens when the valve does not close properly and blood flows back into the atrium from the ventricle. The heart has to work harder to pump blood from the left ventricle to the aorta, resulting in an enlarged left ventricle. If not treated,

this can lead to shortness of breath, fatigue and palpitations (because of atrial fibrillation) and eventually heart failure.

If symptoms of mitral valve regurgitation are severe enough, mitral valve annulus surgical repair may be done by open heart surgery in patients who are well enough for this kind of operation. A surgical valve annulus repair may fail over time and can result in the need for further intervention.

The procedure

The standard treatment after a failed mitral valve annuloplasty is repeat open-heart surgery. Repeat open heart surgery is associated with a higher risk of morbidity and mortality than primary surgery. Transapical transcatheter mitral valve-in-ring implantation is a less invasive alternative. It avoids the need for cardiopulmonary bypass and can be used to treat failed annuloplasty rings originally placed during open heart surgery.

The procedure is usually done with the patient under general anaesthesia and using imaging guidance including fluoroscopy, angiography and transoesophageal echocardiography. Prophylactic antibiotics and anticoagulants are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used.

The mitral valve is accessed surgically through an apical puncture of the left ventricle using an anterior or left lateral mini thoracotomy (transapical approach). A guidewire is placed across the existing native mitral valve and into a pulmonary vein. A balloon catheter delivery system is then advanced over the guidewire into the left atrium. The inner diameter of the mitral valve annulus is measured using transoesophageal echocardiography to establish the size of bioprosthetic valve needed. Using the delivery system, the bioprosthetic valve is then introduced, manipulated into position (to align the valve with the mitral annulus) and slowly deployed within the surgically implanted mitral valve ring under fluoroscopic and echocardiographic guidance. Often, rapid ventricular pacing is used to reduce movement of the heart. After valve deployment, the catheter delivery system, guidewires and pacing wires are removed from the left ventricle and the left ventricular puncture and chest incisions are closed. Valve performance is then assessed using echocardiography and fluoroscopy.

Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis IPG706

Recommendations

Evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well-recognised complications. Evidence on its efficacy is limited in quality. So, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers, as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients have been told and understand about all alternative treatment options and their advantages and disadvantages.
- Enter details about all patients having transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis onto a national registry when 1 is available.
- Audit and review clinical outcomes of all patients 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 every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.

The procedure is technically challenging and should only be done in specialised centres, and only by clinical teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care.

Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Studies should include details on patient selection, type and size of valve used, functional outcomes

(New York Heart Association functional class, mitral valve regurgitation), quality of life, patient-reported outcome measures, survival and complications. Studies should report long-term follow up of clinical outcomes and valve durability. NICE may update this guidance on publication of further evidence.

The condition

Mitral valve replacement is where an artificial prosthetic valve (bioprosthetic or mechanical) is inserted by open heart surgery. It is most commonly done for severe symptomatic mitral regurgitation but may also be done in patients with severe mitral valve stenosis or a combination of both. Symptoms of severe mitral valve disease typically include shortness of breath, fatigue and palpitations (because of atrial fibrillation).

Bioprosthetic valves have some advantages over mechanical valves, but they are more likely to degenerate and fail over time. This can result in severe stenosis or regurgitation, needing replacement of the bioprosthetic valve.

The procedure

The standard treatment for a failed bioprosthetic valve is repeat open-heart surgery to replace the valve. Repeat open heart surgery is associated with a higher risk of morbidity and mortality than primary surgery. Transapical transcatheter mitral valve-in-valve implantation is a less invasive alternative when repeat open heart surgery is considered to have a high risk. It avoids the need for routine cardiopulmonary bypass and can be used to treat failed bioprosthetic mitral valves originally placed during open heart surgery.

The procedure is done with the patient under general anaesthesia and using imaging guidance including fluoroscopy, angiography and transoesophageal echocardiography (TEE). Prophylactic antibiotics and anticoagulants are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used.

The mitral valve is accessed surgically through an apical puncture of the left ventricle using an anterior or left lateral mini thoracotomy (transapical approach). A guidewire is placed across the existing mitral prosthetic valve and into a pulmonary vein. A balloon catheter delivery system is then advanced over the guidewire. When there is severe prosthetic mitral valve stenosis a balloon valvuloplasty may be done first. The inner diameter of the degenerated valve is measured using TEE to establish the size of the new bioprosthetic valve needed. Using the delivery system, the new bioprosthetic valve is then introduced, manipulated into position and slowly deployed within the degenerated mitral valve under fluoroscopic and TEE guidance. Often rapid ventricular pacing is used to reduce movement of the heart. After valve deployment, the catheter delivery system, guidewires and pacing wires are removed and the left ventricular puncture and chest incisions are closed. Valve performance is then assessed using echocardiography and fluoroscopy.

Lateral elbow resurfacing for arthritis IPG705

Recommendations

Evidence on the safety and efficacy of lateral elbow resurfacing for arthritis 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 wishing to do lateral elbow resurfacing for arthritis should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Enter details about all patients having the procedure onto the National Joint Registry. Clinicians should also audit and review their outcomes locally.
- 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 every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

The procedure should only be done in specialist centres by surgeons who do elbow arthroplasty regularly and have training in this specific technique.

Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

Further research, which could include case series with long-term follow up, should report range of motion, patient-reported outcomes and complications.

NICE may update the guidance on publication of further evidence.

The condition

Rheumatoid arthritis is the most common form of arthritis in the elbow. Osteoarthritis that needs surgery is less common in the elbow than in weight-bearing joints, such as the knee and hip. Symptoms include pain, swelling and stiffness in the elbow.

The procedure

Treatment for elbow arthritis depends on the severity of the disease. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, and physiotherapy and prescribed exercise to improve function and mobility. When symptoms are severe, surgery may be indicated. Options include arthroscopic debridement, interposition arthroplasty, replacement or excision of the radial head, or total elbow replacement.

Lateral resurfacing of the elbow for arthritis is usually done under general anaesthesia. An incision is made through muscle tendon to access the elbow joint, and the articular surfaces prepared. The capitellum of the humerus is reamed using a surface cutter, and a peg hole is created. A trial component is inserted. A guidewire is inserted into the radial head, then the surface is shaped with a cutter to produce a concave face. A peg hole is then created in the radial head and a trial component inserted. Once the trial components have been tested for stability and range of movement the definitive components are implanted and the joint reduced. The soft tissues are repaired, and the skin is closed with sutures. A cast or splint may be used for 4 to 6 weeks.

A potential advantage of this procedure over a total elbow replacement is that it preserves the natural inner compartment of the elbow. Movements are therefore likely to be more like a natural elbow joint.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

Workplace health: long-term sickness absence and capability to work QS202

This quality standard covers how to help people return to work after long-term sickness absence, reduce recurring sickness absence, and help prevent people moving from short-term to long-term sickness absence. It covers everyone aged over 16 in full-time or part-time employment (paid or unpaid). It describes high-quality care in priority areas for improvement.

End of life care for adults QS13 (update)

This quality standard covers care for adults (aged 18 and over) who are approaching the end of their life. This includes people who are likely to die within 12 months, people with advanced, progressive, incurable conditions and people with life-threatening acute conditions. It also covers support for their families and carers. It includes care provided by health and social care staff in all settings. It describes high-quality care in priority areas for improvement.

September 2021: This guidance was updated and replaced the previous version published in 2011. The topic was identified for update following the annual review of quality standards. The review identified changes in the priority areas for improvement and new NICE guidance on end of life care for adults and supporting adult carers.

It does not include the care of people in the last days of life, which is covered by NICE's quality standard on care of dying adults in the last days of life.

Current NICE consultations

Title / link	End date of consultation
Otitis media with effusion in under 12s: surgery	06/10/2021
Pernicious anaemia	06/10/2021
Odevixibat for treating progressive familial intrahepatic cholestasis [ID1570]	07/10/2021
Colorectal cancer (QS update)	11/10/2021
GID-MT561 ClearGuard HD Antimicrobial Barrier Cap for preventing haemodialysis catheter-related bloodstream infections	11/10/2021
Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies [ID1557]	12/10/2021
Type 2 diabetes in adults: management (update)	14/10/2021
Stereotactic radiosurgery for trigeminal neuralgia	18/10/2021
Microwave ablation for treating primary lung cancer and metastases in the lung	18/10/2021
Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine	18/10/2021
Mental wellbeing at work	29/10/2021