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Type	Guidance title and reference number
Technology Appraisals (TAs)	**Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears TA369** **Recommendations** 1.1 Ciclosporin **is recommended as an option**, within its marketing authorisation, for treating severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes. **The technology** Ciclosporin is a sterile, positively charged, oil-in water, unpreserved ophthalmic emulsion that contains ciclosporin (CsA). Its formulation contains an excipient, cetalkonium chloride, which is specifically designed to prolong the time each eye drop stays on the epithelial layer of the eye. Ciclosporin has an anti-inflammatory effect on the cornea and the lacrimal (tear) gland. Following administration, ciclosporin blocks the expression of pro-inflammatory cytokines and subsequently enters corneal and conjunctival infiltrated T-cells, activating them. It has a marketing authorisation in the UK for treating 'severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes'. Ciclosporin is administered as an eye drop of 1 mg/ml once daily at bed time. **Financial factors** The acquisition cost of a monthly course of ciclosporin is £72 (excluding VAT). Costs may vary in different settings because of negotiated procurement discounts. **Bortezomib for previously untreated mantle cell lymphoma TA370** **Recommendations** 1.1 Bortezomib **is recommended**, within its marketing authorisation, as an option for previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable. **The technology** Bortezomib is a highly selective proteasome inhibitor specifically designed to inhibit the chymotrypsin-like activity of the 26S proteasome in mammalian cells. This proteasome is a large protein complex that degrades unneeded or damaged proteins tagged with ubiquitin. The ubiquitin–proteasome pathway plays an essential role in many cellular processes, including the cell cycle. Bortezomib has a marketing authorisation for treating adults with previously untreated mantle cell lymphoma for whom haematopoietic stem cell transplantation is unsuitable. **Financial factors** Bortezomib costs £762.38 for a 3.5-mg vial (excluding VAT; British national formulary [BNF] edition 70). It is estimated that the annual cost of implementing this technology for the population of England will be £3.8 million, treating 163 patients at full implementation. Bortezomib is a high-cost chemotherapy drug and is therefore charged in addition to the tariff. **Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane TA371**

Recommendations

1.1 Trastuzumab emtansine is **not recommended**, within its marketing authorisation, for treating adults with human epidermal growth factor 2 (HER2) positive, unresectable locally advanced or metastatic breast cancer previously treated with trastuzumab and a taxane.
1.2 People currently receiving treatment initiated within the NHS with trastuzumab emtansine that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

The technology

Trastuzumab emtansine (Kadcyla, Roche) is an antibody–drug conjugate consisting of trastuzumab linked to maytansine, which is a cytotoxic agent. Because the antibody targets human epidermal growth factor receptor 2 (HER2), and HER2 is overexpressed in breast cancer cells, the conjugate delivers the toxin directly to the cancer cells. Trastuzumab emtansine, as a single agent, has a UK marketing authorisation 'for the treatment of adult patients with HER2 positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.
Patients should have either:

- received prior therapy for locally advanced or metastatic disease, or
- developed disease recurrence during or within 6 months of completing adjuvant therapy'.

Trastuzumab emtansine is administered intravenously. The recommended dose of trastuzumab emtansine is 3.6 mg/kg body weight administered every 3 weeks (21 day cycle). Patients should have treatment until the disease progresses or unacceptable toxicity occurs.

Financial factors
Trastuzumab emtansine costs £1,641.01 per 100 mg vial and £2,625.62 per 160 mg vial (excluding VAT; MIMS, March–May 2014). The company estimated that the average cost of a course of treatment with trastuzumab emtansine is £90,831 (excluding administration costs), assuming a 3-weekly dose of 3.6 mg/kg, a patient weight of 70.1 kg and an average length of treatment of 14.5 months. Roche has agreed a patient access scheme with the Department of Health. If trastuzumab emtansine had been recommended, this scheme would provide a simple discount to the list price of trastuzumab emtansine, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.

Apremilast for treating active psoriatic arthritis TA372

Recommendations

1.1 Apremilast alone or in combination with disease‑modifying antirheumatic drug (DMARD) therapy is **not recommended** within its marketing authorisation for treating adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or such therapy is not tolerated.

1.2 People whose treatment with apremilast was started within the NHS before this guidance was published should be able to continue treatment until they and their NHS clinician consider it appropriate to stop

The technology

Apremilast (Otezla, Celgene) is a small‑molecule inhibitor of phosphodiesterase 4 (PDE4). Apremilast down‑regulates the inflammatory response by modulating the expression of inflammatory and anti‑inflammatory cytokines and mediators associated with psoriatic arthritis (including tumour necrosis factor [TNF]‑alpha and interleukin [IL]‑23). Its UK marketing authorisation states that apremilast 'alone or in combination with disease‑modifying antirheumatic drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy'

Financial factors

The cost of 12 months of treatment with apremilast is estimated at £7,140.18 (company submission). Costs may vary in different settings because of negotiated procurement discounts.

Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis TA373

Recommendations

1.1 Abatacept, adalimumab, etanercept and tocilizumab **are recommended,** within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is:

•for abatacept, people 6 years and older whose disease has responded inadequately to other disease-modifying anti-rheumatic drugs (DMARDs) including at least 1 tumour necrosis factor (TNF) inhibitor

•for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD

•for etanercept, people 2 years and older whose disease has responded inadequately to, or who are intolerant of, methotrexate

•for tocilizumab, people 2 years and older whose disease has responded inadequately to previous therapy with methotrexate.

Abatacept and tocilizumab are recommended only if the companies provide them with the discounts agreed in the patient access schemes for these technologies.

1.2 Adalimumab and etanercept are recommended, within their marketing authorisations, as options for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) and 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy.

1.3 Etanercept is recommended, within its marketing authorisation, as an option for treating psoriatic JIA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate.

1.4 When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.

The technology

Abatacept is a fusion protein that inhibits the activation of T cells. It is administered by intravenous infusion.

Adalimumab is an antibody that inhibits TNF. It is administered by subcutaneous injection

Etanercept is a human tumour necrosis factor receptor p75 Fc fusion protein that inhibits TNF. It is administered by subcutaneous injection

Tocilizumab is an antibody that inhibits the action of interleukin-6. It is administered by intravenous infusion.

Financial factors

The technologies are commissioned by NHS England.

The companies that hold the marketing authorisations for abatacept and tocilizumab have each agreed a patient access scheme with the Department of Health. There is no patient access scheme for adalimumab and etanercept. It is unlikely that the guidance will result in a significant change in resource use in the NHS because it is considered that the recommendations are consistent with current clinical practice. Therefore no

costing template has been produced.

Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy TA374

Recommendations

1.1 Erlotinib **is recommended as an option for** treating locally advanced or metastatic non-small-cell lung cancer that has progressed in people who have had non-targeted chemotherapy because of delayed confirmation that their tumour is epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive, only if the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 258.

1.2 Erlotinib **is recommended as an option** for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours of unknown EGFR-TK mutation status, only if:

•the result of an EGFR-TK mutation diagnostic test is unobtainable because of an inadequate tissue sample or poor-quality DNA and

•the treating clinician considers that the tumour is very likely to be EGFR-TK mutation-positive and

•the person's disease responds to the first 2 cycles of treatment with erlotinib and

•the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 258.

1.3 Erlotinib **is not recommended** for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative.

1.4 Gefitinib **is not recommended** for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive.

1.5 People whose treatment with erlotinib or gefitinib is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

The technology

Erlotinib is an inhibitor of epidermal growth factor receptor tyrosine kinase (EGFR-TK). It blocks the signal pathways involved in cell proliferation and helps to slow the growth and spread of tumours. Erlotinib has a UK marketing authorisation for the 'treatment of patients with locally advanced or metastatic non-small-cell lung cancer after the failure of at least 1 prior chemotherapy regimen'.

Financial factors

Gefitinib is given orally at a recommended dosage of 250 mg once daily. The cost for a 30-tablet pack of 250-mg tablets is £2,167.71. Costs may vary in different settings because of negotiated procurement discounts.

This technology is commissioned by NHS England. It is unlikely that the guidance will result in a significant change in resource use in the NHS. The updated recommendations for erlotinib reduce the population eligible for treatment.

Highly specialized technology guidance (HSTs)	**Elosulfase alfa for treating mucopolysaccharidosis type Iva HST2** **Recommendations** Elosulfase alfa, within its marketing authorisation, **is recommended** for funding for treating mucopolysaccharidosis type IVa (MPS IVa) according to the conditions in the managed access agreement for elosulfase alfa. **The technology** Elosulfase alfa is a recombinant form of the human N-acetylgalactosamine-6-sulfatase enzyme. It is intended to replace the enzyme lacking in people with mucopolysaccharidosis type IVa (MPS IVa). Elosulfase alfa has a marketing authorisation in the UK for treating MPS IVa in people of all ages. It is given by intravenous infusion, over 4 hours, once a week. The recommended dosage is 2 mg/kg body weight each week, and treatment is anticipated to continue for life. **Financial factors** Elosulfase alfa is available in 5 ml vials containing 5 mg of elosulfase alfa, at a net price of £750 per vial (excluding VAT). NICE estimates that the average cost per year for elosulfase alfa is £394,680 per patient (based on the recommended dosage of 2 mg/kg/week and an average body weight of 25.3 kg). The company has proposed a patient access scheme, in which elosulfase alfa would be provided at a discounted cost; the discount is commercial in confidence and so cannot be reported here. The managed access agreement includes further commercial arrangements between the company and NHS England for the duration of the agreement.

Note: From January 2015 NICE has decided to use a single set of methods and processes to develop all NICE guidelines, whether they are clinical, public health, social care, safe staffing or medicines practice.

Technology appraisals, interventional procedures, medical technologies and diagnostics guidance; and quality standards and advice products, are unaffected by this change.

NICE Guidelines (NGs)	**Transition between inpatient hospital settings and community or care home settings for adults with social care needs NG27** **Background** A range of health, social care and other services are involved when adults with care and support needs move into or out of hospital from community or care home settings. Families and carers also play an important part. Problems can occur if services and support are not integrated. For example, if hospital admissions are not coordinated. This can result in delayed transfers of care, re-admissions, poor care and avoidable admissions to residential or nursing care. This guideline considers how person-centred care and support should be planned and delivered during admission to, and discharge from, hospital. It addresses how services should work together and with the person, their family and carers, to ensure transitions are timely, appropriate and safe. **Recommendations** The guideline includes recommendations on: •person-centred care and communication and information sharing •before admission to hospital including developing a care plan and explaining what type of care the person might receive •admission to hospital including the establishment of a hospital-based multi-disciplinary team •during hospital stay including recording medicines and assessments and regularly reviewing and updating the person's progress towards discharge •discharge from hospital including the role of the discharge coordinator

•supporting infrastructure

•training and development for people involved in the hospital discharge process.

Implementation getting started

This section highlights 3 areas of the transition between inpatient hospital settings and community or care home settings for adults with social care needs that were identified as a focus for implementation. It explains the reasons why the change needs to happen

The challenge: improving understanding of person-centred care
The challenge: ensuring health and social care practitioners communicate effectively
The challenge: changing how community- and hospital-based staff work together to ensure coordinated, person-centred support.

Financial factors

The NICE costing statement states that overall implementing the guideline will be cost saving. Implementing the guideline is likely to have resource implications (both costs and savings) for health and social care commissioners and for providers, and we advise them to assess these locally. Based on assumptions in the economic analysis, implementing the recommendation would lead to an average reduction in expenditure of around £950 per person per year.

Type 2 diabetes in adults: management NG28

Background

Type 2 diabetes is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Type 2 diabetes is commonly associated with obesity, physical inactivity, raised blood pressure, disturbed blood lipid levels and a tendency to develop thrombosis, and therefore is recognised to have an increased cardiovascular risk. It is associated with long-term microvascular and macrovascular complications, together with reduced quality of life and life expectancy. In 2013, over 3.2 million adults were diagnosed with diabetes, with prevalence rates of 6% and 6.7% in England and Wales respectively.

Since the publication of the 2009 guideline, availability of new evidence and several key developments have prompted an update in the following areas: managing blood glucose levels, antiplatelet therapy and erectile dysfunction. In particular, reasons included safety concerns surrounding some blood glucose lowering medicines, new evidence on new dipeptidyl peptidase-4 (DPP-4) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, new indications and licensed combinations for licensed class members and the potential impact of drugs coming off patent on health-economic issues.

Recommendations

1.1 Individualised care

1.2 Patient education

1.3 Dietary advice

1.4 Blood pressure management

1.5 Antiplatelet therapy

1.6 Blood glucose management

1.7 Managing complications

Key priorities for implementation

- Patient education
- Dietary advice
- Blood pressure management
- Blood glucose management
- Drug treatment

Financial factors

The NICE resource impact report states that it is anticipated that implementation of the recommendations may have a resource impact. This is because the original guideline recommended a sulfonylurea as the second drug choice after metformin (either as initial drug treatment when metformin is contraindicated or not tolerated or in addition to metformin at first intensification). The updated recommendations give an equal weighting to dipeptidyl peptidase-4 (DPP-4) inhibitors, pioglitazone and sulfonylureas.

Treatment with sulfonylureas is estimated to have an average cost of £84 per patient per year compared with an estimated average cost of £431 for DPP-4 inhibitors. CCGs should monitor prescribing patterns in this area accordingly. The people affected by the new recommendations each year are likely to be those newly diagnosed with type 2 diabetes and those having their treatment intensified. Therefore implementation is likely to occur over several years.

Intravenous fluid therapy in children and young people in hospital NG29

Background

There is a wide variation in the charts used to prescribe fluids and to record fluid and electrolyte status. Monitoring children and young people is often challenging: it may be difficult to assess urine output accurately, and blood tests can be painful, distressing and difficult to repeat. Assessment and monitoring is often suboptimal, and fluid and electrolyte status may not be recorded accurately. Clinical staff need to ensure that appropriate identification, treatment and monitoring of changes in fluid and electrolyte status is maintained and documented. There is a need for a standardised approach to assessing patients' fluid and electrolyte status and prescribing IV fluid therapy in the NHS. This guidance represents a major opportunity to improve patient safety for children and young people having IV fluid therapy in hospital.

Recommendations

- principles and protocols for intravenous fluid therapy
- assessment and monitoring
- fluid resuscitation
- routine maintenance
- replacement and redistribution
- managing hypernatraemia and hyponatraemia that develops during intravenous fluid therapy
- training and education

Key priorities for implementation

- Assessment and monitoring
- Fluid resuscitation
- Routine maintenance
- Replacement and redistribution
- Managing hyponatraemia that develops during intravenous fluid therapy

Financial factors

Overall costs are not anticipated to increase, however the use of clinical time and mandatory training may need to be modified. The benefit is anticipated to be a reduction in adverse events and associated costs.

Oral health promotion: general dental practice NG30

Background

Oral health is important to general health and wellbeing. It can also affect people's ability to eat, speak and socialise normally. Poor oral health can lead to absences from school and workplaces. It can also affect the ability of children to learn, thrive and develop. Oral health in England has improved significantly over recent decades. The Adult dental health survey 2009 (Health and Social Care Information Centre) reports that the proportion of adults in England without natural teeth has dropped from 28% to 6% in the past 30 years.

In addition, the number of children with signs of previous decay in permanent teeth has

dropped. In 2013, for example, 46% of young people aged 15 – and 34% of those aged 12 – had 'obvious decay experience' in permanent teeth. This compares with 56% and 43% respectively in 2003.

However, oral health varies widely across England. For example, the prevalence of tooth decay among children aged 5 ranges from 12.5% in Brighton and Hove to 53.2% in Leicester.

Recommendations

1.1 Oral health advice given by dentists and dental care professionals

1.2 How dentists and dental care professionals can adopt a patient-centred approach

Terms used in this guideline

Care of dying adults in the last days of life NG31

Background

Without an evidence-based approach to the care of dying people, there is a danger of placing tradition and familiar policies before the needs of individuals and families. The Liverpool Care Pathway (LCP) for the Care of the Dying Adult and its numerous local derivatives were widely adopted in the NHS and UK hospices until 2014. Although the LCP was designed to bring values of 'good' end of life care from the hospice movement to mainstream hospitals and elsewhere, it met with increasing criticism from the public, healthcare professions and the media.

There were 3 main areas of concern:

•recognising that a person was dying was not always supported by an experienced clinician and not reliably reviewed, even if the person may have had potential to improve

•the dying person may have been unduly sedated as a result of injudiciously prescribed symptom control medicines

•the perception that hydration and some essential medicines may have been withheld or withdrawn, resulting in a negative effect on the dying person.

These were not necessarily a direct consequence of following the LCP, but often happened because of poor or indiscriminate implementation and a lack of staff training and supervision. This guideline responds to a need for an evidence-based guideline for the clinical care of the dying adult throughout the NHS. It is focused on care needed when a person is judged by the multiprofessional clinical team to be within a few (2 to 3) days of death. This is different from other important NHS initiatives labelled 'end of life care' which are aimed at improving care for people in the last year or so of a chronic condition.

Recommendations

1.1 Recognising when a person may be in the last days of life

1.2 Communication

1.3 Shared decision-making

1.4 Maintaining hydration

1.5 Pharmacological interventions

1.6 Anticipatory prescribing

Implementation: getting started

This section highlights 3 areas of the care of dying adults in the last days of life guideline that could have a big impact on practice and be challenging to implement, along with the reasons why change is happening in these areas.

The challenge: recognising dying and communicating effectively
The challenge: maintaining hydration
The challenge: anticipatory prescribing

	Financial factors The NICE resource impact report states that implementing the guideline may lead to costs associated with ensuring appropriate equipment and support is available in the community. Investing in these areas is expected to lead to offsetting savings as a result of reduced admissions to hospital for people in the last few days of life. NHS organisations and local authorities are encouraged to evaluate their own practices against the recommendations in the NICE guideline and to assess costs locally. **Older people: independence and mental wellbeing NG32** In 2014, 17.6% of the population were aged 65 or older. By 2035 this is estimated to rise to almost 1 in 4 (23%). The number of people aged 85 and older has risen the fastest. In 1985 nearly 1.2% of the population was 85 or older. By 2014 this had increased to 2.3%. Older people may experience an age-related disability. Older people are at higher risk of developing chronic health conditions such as diabetes or osteoarthritis (painful and stiff joints). Improving the mental wellbeing of older people and helping them to retain their independence can benefit families, communities and society as a whole. Helping those at risk of poor mental wellbeing or losing their independence may also reduce, delay or avoid their use of health and social care services **Recommendations** 1.1 Principles of good practice 1.2 Group-based activities 1.3 One-to-one activities 1.4 Volunteering 1.5 Identifying those most at risk of a decline in their independence and mental wellbeing **Implementation: getting started** This section highlights 6 areas of the guideline that were identified as a focus for implementation and outlines activities that will support this Area 1: planning and partnerships Area 2: local assets and needs assessment Area 3: local coordination Area 4: getting older people involved in activities Area 5: training Area 6: evaluating effectiveness
Interventional Procedures Guidance (IPGs)	**Insertion of a subretinal prosthesis system for retinitis pigmentosa IPG537** **Recommendations** 1.1 Current evidence on the safety and efficacy of insertion of a subretinal prosthesis system for retinitis pigmentosa is limited in quality and quantity. **Therefore, this procedure should only be used in the context of research**. 1.2 NICE encourages further research on this procedure. Outcomes should include the impact on quality of life and activities of day-to-day living, and durability of implants. NICE may update the guidance on publication of further evidence. **The procedure** Subretinal prosthesis systems aim to restore perception of light, movement, and shapes by surgically implanting a microchip behind the retina. The microchip mimics the function of damaged outer retinal photoreceptors by absorbing light and converting it into retinotopically correct electrical pulses that stimulate the overlying bipolar cell layer. The bipolar cells propagate the signal to downstream retinal cells, which send visual information to the brain **Joint distraction for ankle osteoarthritis IPG538** **Recommendations** 1.1 Current evidence on the safety and efficacy of joint distraction for ankle osteoarthritis is inadequate in quantity and quality. **Therefore, this procedure should**

only be used in the context of research.

1.2 Further research into joint distraction for ankle osteoarthritis should include comparative studies against the natural history of the disease and against other forms of management. Studies should record patient selection, pain relief, functional outcomes, complications, and quality of life in the long term. They should also report the nature and timing of any further surgery on the ankle. Minimising loss to follow-up is of particular importance. NICE may update the guidance on publication of further evidence.

The procedure

With the patient under spinal block or general anaesthesia, an external frame is fitted to the ankle. The frame is secured to the tibia and the foot with pins and wires. The ankle is distracted over several days, gradually increasing the distance between the cartilaginous surfaces of the joint (usually up to about 5 mm). Distraction is usually maintained for about 2–3 months before the frame is removed. During this time, the patient is able to walk.

Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma IPG539

Recommendations

1.1 Current evidence on radiofrequency ablation for symptomatic interdigital (Morton's) neuroma raises no major safety concerns. The evidence on efficacy is limited in quantity and quality. **Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.**

1.2 Clinicians wishing to do radiofrequency ablation for symptomatic Morton's neuroma should:

•Inform the clinical governance leads in their NHS trusts.

•Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

•Audit and review clinical outcomes of all patients having radiofrequency ablation for symptomatic Morton's neuroma (see section 6.2).

1.3 NICE encourages further research into radiofrequency ablation for symptomatic Morton's neuroma. Further research should include details of patient selection and previous treatments. Studies should compare the procedure against other non-surgical treatments, such as steroid injections. Outcome measures should include pain relief, the duration of treatment effect, and the need for subsequent treatments.

The procedure

Radiofrequency ablation (RFA) for symptomatic interdigital (Morton's) neuroma is a percutaneous treatment, which is usually done as an outpatient procedure under local anaesthesia. Using imaging guidance, an RFA probe attached to a generator is inserted into the web space between the toes and into the area of the neuroma.

Electrical stimulation of the lower oesophageal sphincter for treating gastro-oesophageal reflux disease IPG540

Recommendations

1.1 Current evidence on the safety and efficacy of electrical stimulation of the lower oesophageal sphincter for treating gastro-oesophageal reflux disease (GORD) is limited in quantity and quality. **Therefore, this procedure should only be used in the context of research**.

1.2 NICE encourages clinicians to enter patients into controlled clinical trials. These could include crossover and cohort studies, which would allow inclusion of patients for whom other surgical options are unsuitable. These should provide a clear description of patient selection, and details of adjunctive medical and surgical treatments. Outcomes should include GORD symptoms, quality of life and objective measurements of gastric reflux. Efficacy, device durability, the need for surgical treatment for GORD in the longer term (at least 2 years) and all complications should be reported. NICE may update the guidance on publication of further evidence.

The procedure

Electrical stimulation of the lower oesophageal sphincter aims to strengthen a weak or improperly functioning lower oesophageal sphincter muscle, to restore the anti-reflux barrier between the stomach and oesophagus, by using low energy electrical impulses. With the patient under general anaesthesia, 2 electrodes and a lead are implanted into the sphincter muscle using a laparoscope under endoscopic guidance. The lead is passed through the abdominal wall and is secured to a stimulator, which is implanted in a subcutaneous pocket in the abdominal wall.

Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis IPG541

Recommendations

1.1 The current evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis shows the potential for serious complications. However, this is in patients for whom open surgical valve implantation is unsuitable, who have severe symptoms and a high risk of death. The evidence on efficacy shows generally good symptom relief in the short term, but is based on very small numbers of patients. **Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.**

1.2 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 NHS trusts.

•Ensure that patients understand the uncertainty about the procedure's safety and efficacy in the long term, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

•Enter details about all patients having transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis onto the National Institute for Cardiovascular Outcomes Research database (NICOR) and review local clinical outcomes.

1.3 Patient selection should be done by a multidisciplinary team including interventional cardiologists, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient and review their suitability for alternative medical or surgical treatments.

1.4 Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis should only be done by clinicians and teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Units doing these procedures should have both cardiac and vascular surgical support for emergency treatment of complications.

1.5 NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. This may include prospective observational studies. Studies should include details on patient selection, functional outcomes, quality of life, 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 procedure

The procedure is 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.

Repetitive transcranial magnetic stimulation for depression IPG542

Recommendations

1.1 The evidence on repetitive transcranial magnetic stimulation for depression shows

	no major safety concerns. The evidence on its efficacy in the short-term is adequate, although the clinical response is variable. Repetitive transcranial magnetic stimulation for depression may be used with normal arrangements for clinical governance and audit. 1.2 During the consent process, clinicians should, in particular, inform patients about the other treatment options available, and make sure that patients understand the possibility the procedure may not give them benefit. 1.3 NICE encourages publication of further evidence on patient selection, details of the precise type and regime of stimulation used, the use of maintenance treatment and long-term outcomes. **The procedure** Repetitive transcranial magnetic stimulation (rTMS) does not need anaesthesia and can be done on an outpatient basis. A purpose-made electromagnetic coil is held against the scalp with the intention of inducing electric currents in the cerebral cortex. Imaging may be used to help target specific areas of the brain.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Acute heart failure: diagnosis and management in adults QS103** This quality standard covers the care of adults (aged 18 years or older) who have a diagnosis of acute heart failure or are being investigated for acute heart failure. The long-term management of chronic heart failure is not covered in the quality standard because it is covered by a separate NICE guideline (CG108) and quality standard referral (QS9). **Gallstone disease QS104** This quality standard covers diagnosing and managing gallstone disease in adults. **Intrapartum care QS105** This quality standard covers the care of women who go into labour at term (37+0 weeks to 41+6 weeks) and their babies during labour and immediately after the birth. It covers both women who go into labour at low risk of intrapartum complications and women who go on to develop complications. **Bladder Cancer QS106** This quality standard covers diagnosis and management of bladder cancer in adults (18 years and older) referred from primary care. It includes suspected, newly diagnosed and recurrent bladder cancers (urothelial carcinoma, adenocarcinoma, squamous cell carcinoma or small cell carcinoma) and urethral cancers.
Commissioning Guides	**None published so far this month**
Public health briefings for local government	**None published so far this month**

Current NICE consultations with links and start and finish dates for stakeholders to make contribution

Title / link	Start date of consultation	End date of consultation
Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis : Interventional procedure consultation	20/11/2015	18/12/2015
Endoscopic CO2 laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia : Interventional procedure consultation	20/11/2015	18/12/2015
Oesophago-gastric cancer : Draft scope consultation	23/11/2015	18/12/2015
Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine : Interventional procedure consultation	20/11/2015	18/12/2015
People's experience in adult social care services: improving the experience of care for people using adult social care services : Draft scope consultation	23/11/2015	21/12/2015
Transition between inpatient hospital settings and community or care home settings : Topic engagement	07/12/2015	21/12/2015
Antimicrobial stewardship : Quality Standard consultation	26/11/2015	24/12/2015
Hypophosphatasia (paediatric-onset) - asfotase alfa [ID758] : Evaluation consultation	03/12/2015	07/01/2016
Older people with social care needs and multiple long-term conditions : Topic engagement	15/12/2015	08/01/2016
Intravenous fluids therapy in children : Topic engagement	15/12/2015	08/01/2016
Neurological problems : Draft scope consultation	04/12/2015	08/01/2016
Increasing the uptake of HIV testing among people at higher risk of exposure : Call for evidence	09/12/2015	11/01/2016
PlGF based testing to help diagnose suspected pre-eclampsia : Diagnostics consultation : 2	16/12/20150	11/01/2016
Pancreatic cancer : Draft scope consultation	02/12/2015	13/01/2016
Haematological cancers - improving outcomes (update) : Draft guidance consultation	30/11/2015	14/01/2016
Obesity - clinical assessment and management : Quality Standard consultation	14/12/2015	14/01/2016
Heart failure - sacubitril valsartan [ID822] : Appraisal consultation	11/12/2015	15/01/2016
Prostate cancer (metastatic, hormone relapsed, not treated with chemotherapy) - abiraterone acetate (with prednisolone) [ID503] : Appraisal consultation : 2	11/12/2015	15/01/2016
Oral health for adults in care homes : Draft guidance consultation	04/12/2015	19/01/2016
Lung cancer (non-small-cell, squamous, metastatic) - nivolumab (after chemotherapy) [ID811] : Appraisal consultation	16/12/2015	19/01/2016
Venous thromboembolism - reducing the risk (full update) : Draft scope consultation	11/12/2015	20/01/2016

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