NICE Update Bulletin May 2014 for guidance issued Wednesday 28th May 2014

Hyperlinks to the relevant NICE web page are included, to activate link left click on your mouse. Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number
Technology Appraisals (TAs)	**Multiple sclerosis (relapsing-remitting) – alemtuzumab TA312** **Background** Relapsing–remitting multiple sclerosis is a chronic, disabling, neurological condition that, as it progresses, is life altering and has a large negative impact on quality of life and activities of daily living. Currently available first-line treatments for active relapsing–remitting multiple sclerosis need to be injected weekly or several times per week and can be associated with unpleasant side effects (such as injection-site reactions, flu-like symptoms, fatigue and depression) and can significantly affect patients' emotional wellbeing. **Recommendations** Alemtuzumab is **recommended as an option**, within its marketing authorisation, for treating adults with active relapsing–remitting multiple sclerosis. **The technology** Alemtuzumab (Lemtrada, Genzyme) is an antibody that binds to cells of the immune system (B and T cells), causing their destruction. The way in which alemtuzumab slows the decline of active relapsing–remitting multiple sclerosis is not fully understood. Alemtuzumab has a UK marketing authorisation for treating adults with relapsing–remitting multiple sclerosis with active disease defined by clinical or imaging features. The recommended dosage of alemtuzumab is 12 mg/day administered by intravenous infusion for 2 treatment courses. The initial treatment course lasts 5 consecutive days, followed 12 months later by the second treatment course of 3 consecutive days. The price of alemtuzumab is £7,045 per 12 mg vial, which equates to £56,360 for the full course of treatment consisting of 5 daily consecutive 12 mg doses in year 1, followed by 3 daily consecutive 12 mg doses 12 months later in year 2. Costs may vary in different settings because of negotiated procurement discounts. **Psoriatic arthritis (active) – ustekinumab TA313** **Recommendations** 1.1 Ustekinumab is **not recommended** within its marketing authorisation for treating active psoriatic arthritis, that is, alone or in combination with methotrexate in adults when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. 1.2 People currently receiving treatment initiated within the NHS with ustekinumab 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** Ustekinumab (Stelara, Janssen) is a monoclonal antibody that acts as a cytokine inhibitor. It is administered by subcutaneous injection. Ustekinumab has a UK marketing authorisation for use alone or in combination with methotrexate 'for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate'.
Clinical Guidelines (CGs)	• **None published so far this month**

Public Health Guidance	**Overweight and obese adults - lifestyle weight management PH53** This guideline makes recommendations on the provision of effective multi-component lifestyle weight management services for adults who are overweight or obese (aged 18 and over). It covers weight management programmes, courses, clubs or groups that aim to change someone's behaviour to reduce their energy intake and encourage them to be physically active. The aim is to help meet a range of public health goals. These include helping reduce the risk of the main diseases associated with obesity, for example: coronary heart disease, stroke, hypertension, osteoarthritis, type 2 diabetes and various cancers (endometrial, breast, kidney and colon). The focus is on lifestyle weight management programmes that: • accept self-referrals or referrals from health or social care practitioners • are provided by the public, private or voluntary sector • are based in the community, workplaces, primary care or online. Usually known as 'tier 2' services, these programmes are just 1 part of a comprehensive approach to preventing and treating obesity. Clinical judgement will be needed to determine whether they are suitable for people with conditions that increase the risk of, or are associated with, obesity or who have complex needs. **The recommendations in full are** 1 Adopt an integrated approach to preventing and managing obesity 2 Ensure services cause no harm 3 Raise awareness of local weight management issues among commissioners 4 Raise awareness of lifestyle weight management services among health and social care professionals 5 Raise awareness of lifestyle weight management services among the local population 6 Refer overweight and obese adults to a lifestyle weight management programme 7 Address the expectations and information needs of adults thinking about joining a lifestyle weight management programme 8 Improve programme uptake, adherence and outcomes 9 Commission programmes that include the core components for effective weight loss 10 Commission programmes that include the core components to prevent weight regain 11 Provide lifestyle weight management programmes based on the core components for effective weight loss and to prevent weight regain 12 Provide a national source of information on effective lifestyle weight management programmes 13 Ensure contracts for lifestyle weight management programmes include specific outcomes and address local needs 14 Provide continuing professional development on lifestyle weight management for health and social care professionals 15 Provide training and continuing professional development for lifestyle weight management programme staff 16 Improve information sharing on people who attend a lifestyle weight management programme 17 Monitor and evaluate programmes 18 Monitor and evaluate local provision
Medical Technologies Guidance	**None published so far this month**

NICE Quality Standards	**Constipation in children and young people QS62** This quality standard covers the diagnosis and management of idiopathic constipation in children and young people (from birth to 18 years).
Interventional Procedures Guidance (IPGs)	**Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb IPG487** **Recommendations** 1.1 Current evidence on the efficacy and safety of endoscopic thoracic sympathectomy (ETS) for primary hyperhidrosis of the upper limb is **adequate to support the use of this procedure** with normal arrangements for clinical governance, consent and audit. 1. 2 Clinicians wishing to undertake ETS for primary hyperhidrosis of the upper limb should ensure that patients understand the risks of the procedure. In particular they must explain that: • there is a risk of serious complications • hyperhidrosis elsewhere on the body is usual after the procedure: this can be severe and distressing and some patients regret having had the procedure (especially because of subsequent and persistent hyperhidrosis elsewhere) • the procedure sometimes does not reduce upper limb hyperhidrosis. Clinicians should also provide patients considering the procedure with clear written information. 1.3 In view of the risk of side effects this procedure should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments. 1.4 This procedure should only be undertaken by clinicians trained and experienced in thoracic endoscopy, and there should be the capacity to deal with intraoperative complications. 1.5 Further research into ETS for primary hyperhidrosis of the upper limb should include clear information on patient selection and should seek to identify which patient characteristics might predict severe side effects. All complications should be reported. Outcomes should include measurements of efficacy, including quality of life and social functioning both in the short and long term and in particular the frequency and severity of compensatory hyperhidrosis. **The procedure** The aim of endoscopic thoracic sympathectomy (ETS) for primary hyperhidrosis of the upper limb is to relieve primary hyperhidrosis from the palms and axillae permanently by dividing the sympathetic nerves that lie along the sympathetic chain beside the vertebral column. ETS is usually done with the patient under general anaesthesia. Small incisions are made in the axilla and an endoscope is inserted. The lung is partially collapsed. **Chemosaturation via percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic liver cancer IPG488** **Recommendations** 1.1 Current evidence on the efficacy of chemosaturation via percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic liver cancer ('hepatic chemosaturation') is limited in quality and quantity. With regard to safety, there is a significant incidence of serious adverse effects. Therefore, **this procedure should only be performed within the context of research**, which may take the form of observational studies. 1.2 Patient selection should be done by an appropriate multidisciplinary team. 1.3 Hepatic chemosaturation should only be carried out by clinicians with specific training in its use and in techniques to minimise the risk of adverse effects from the procedure. 1.4 Research should document indications for treatment, details of patient selection and details of adjuvant and prior treatments. Outcome measures should include

complications, survival and quality of life. Data from well-designed trials comparing the procedure against other forms of management would be particularly useful, but prospective observational studies may also be of value.

The procedure

The aim of chemosaturation via percutaneous hepatic artery perfusion and hepatic vein isolation is to treat liver cancer by delivering a high dose of chemotherapy directly into the hepatic artery. As the blood leaves the liver it is diverted out of the body through a catheter and filtered to reduce the level of chemotherapy drug before being returned to the circulation. This allows high doses of chemotherapy to be used, which would otherwise not be tolerated because of severe systemic side effects.

Gastroelectrical stimulation for gastroparesis IPG489

This document replaces previous guidance on gastroelectrical stimulation (interventional procedure guidance 103)

Recommendations

1.1 Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is **adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit**.

1.2 During the consent process, clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.

1.3 Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.

1.4 Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

The procedure

Electrical stimulation is delivered via an implanted system that consists of a neurostimulator and 2 leads. Implantation is done with the patient under general anaesthesia by an open or laparoscopic approach. The stimulating electrode of each intramuscular lead is fixed to the muscle of the distal part of the stomach. The connector end of each lead is then attached to the neurostimulator, which is placed in a pocket in the abdominal wall.

Transcutaneous Neuromuscular Electrical Stimulation (NMES) for oropharyngeal dysphagia IPG490

Recommendations

1.1 Current evidence on the efficacy of transcutaneous neuromuscular electrical stimulation (NMES) for oropharyngeal dysphagia is limited in quality. The evidence on safety is limited in both quality and quantity but there were no major safety concerns. Therefore, this procedure **should only be used with special arrangements for clinical governance, consent and audit or research**.

1.2 Clinicians wishing to undertake transcutaneous NMES for oropharyngeal dysphagia should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and 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 transcutaneous NMES for oropharyngeal dysphagia.

1.3 NICE encourages further research into transcutaneous NMES for oropharyngeal dysphagia, which should clearly document the indications for treatment and the details of patient selection. Research should document the timing of initiation of treatment after onset of symptoms, as well as precise information about the procedure technique. Outcome measures should include freedom from tube feeding, quality of life and duration of treatment effect. NICE may review the procedure on publication of further evidence.

The procedure

NMES is usually administered by a speech and language therapist after appropriate diagnosis and patient selection. Therapists need appropriate training to use the procedure. The speech and language therapist places electrodes in selected positions on the patient's neck, through which small electrical currents are then passed.

Transcutaneous neuromuscular electrical stimulation (NMES) is usually used as an adjunct to traditional swallowing therapy for treating oropharyngeal dysphagia. Swallowing therapy uses exercises to improve muscle function. The aim of NMES is to increase the effectiveness of swallowing therapy. Its mechanism of action is thought to include accelerating the development of muscle strength and promoting central or cortical recovery.

Platelet-rich plasma injections for osteoarthritis of the knee IPG491

Recommendations

1.1 Current evidence on platelet-rich plasma injections for osteoarthritis of the knee raises no major safety concerns; however, the evidence on efficacy is inadequate in quality. Therefore **this procedure should only be used with special arrangements for clinical governance, consent and audit or research**.

1.2 Clinicians wishing to undertake platelet-rich plasma injections for osteoarthritis of the knee should take the following actions.

- 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 platelet-rich plasma injections for osteoarthritis of the knee.

1.3 Further research into platelet-rich plasma injections for treating osteoarthritis of the knee should clearly describe patient selection and should take the form of well-designed, controlled studies that compare the procedure against other methods of management. Outcomes should include measures of knee function, patient-reported outcome measures and the timing of subsequent interventions. Studies aimed at assessing possible cartilage repair after platelet-rich plasma injections should include detailed radiographic or MRI imaging before and after the procedure.

The procedure

Blood is taken from the patient and centrifuged to obtain a concentrated suspension of platelets. The final platelet-rich plasma product is injected into the joint space in the knee, usually under ultrasound guidance. Platelet-rich plasma injections aim to promote cartilage repair and relieve osteoarthritic symptoms, potentially delaying the need for joint replacement surgery. Platelets produce growth factors that are thought to stimulate chondrocyte proliferation, leading to cartilage repair.

Bioresorbable stent implantation for treating coronary artery disease IPG492

Recommendations

1.1 Current evidence on the short-term safety and efficacy of bioresorbable stent implantation for treating coronary artery disease is adequate, but the quantity of evidence on the safety and efficacy of the procedure in the long term is inadequate. Therefore this **procedure should only be used with special arrangements for clinical governance, consent and audit or research.**

1.2 Clinicians wishing to undertake bioresorbable stent implantation for treating coronary artery disease should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy in the longer 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 undergoing bioresorbable stent implantation for treating coronary artery disease onto the UK Central Cardiac Audit Database and review clinical outcomes locally.

	1.3 NICE encourages further research into bioresorbable stent implantation for treating coronary artery disease and may review the procedure on publication of further evidence. Details of subsequent antiplatelet therapy should be reported and outcomes should include major adverse cardiac events (MACE) and target vessel revascularisation (defined as any repeat percutaneous intervention or surgical bypass of any segment of the treated vessel), particularly in the long term (at least 2–3 years). Studies on the safety and efficacy of the procedure compared with other types of coronary stent implantation would be useful. **The procedure** The procedure is usually done under local anaesthesia with fluoroscopic image guidance. Bioresorbable stents are designed to be absorbed by the body over time. The aim is to reduce the risk of late complications such as thrombosis that may occur after the use of metal stents, and to reduce the need for long-term antiplatelet drugs, with their risk of bleeding complications.
NICE Pathways	These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.
Commissioning Guides	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
Public health briefings for local government	**Tackling drug use LGB18** This briefing summarises NICE's recommendations for local authorities and partner organisations on tackling drug use. This includes preventing drug use, minimising the harm caused by drugs and helping people to stop taking them. It is particularly relevant to health and wellbeing boards, police and crime commissioners and community safety partnership

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

Title / link	Start date of consultation	Finish date of consultation
Bipolar disorder (update): guideline consultation	17/04/2014	29/05/2014
Inflammatory bowel disease: quality standard consultation	30/04/2014	30/05/2014
Prostate cancer (metastatic, hormone relapsed, not treated with chemotherapy) - abiraterone acetate (with prednisolone): appraisal consultation	14/05/2014	05/06/2014
Transient loss of consciousness: quality standard consultation	08/05/2014	05/06/2014
Promoting mental wellbeing at work: review proposal consultation	22/05/2014	06/06/2014
Myocardial infarction (acute) - Early rule out using high-sensitivity troponin tests: diagnostics consultation	19/05/2014	10/06/2014
Safe nurse staffing of adult wards in acute hospitals - guideline consultation	12/05/2014	10/06/2014
Implementing Vitamin D guidance: draft guideline consultation	13/05/2014	10/06/2014
Implementing Vitamin D guidance: call for evidence	13/05/2014	10/06/2014
Multiple sclerosis (2014): guideline consultation	29/04/2014	10/06/2014
Myelodysplastic syndrome (deletion 5q) - lenalidomide: appraisal consulation 2	20/05/2014	11/06/2014
Workplace interventions to promote smoking cessation: consultaion on the reviw proposal	29/05/2014	12/06/2014
Fertility problems: quality standard consultation	15/05/2014	12/06/2014
Head injury: quality standard consultation	15/05/2014	12/06/2014
Acute heart failure: guideline consultation	02/05/2014	13/06/2014
Seronegative arthropathies: scope consultation	20/05/2014	16/06/2014
Safe staffing for accident and emergency settings: draft scope consultation	20/05/2014	17/06/2014
Consultation on the Methods of Technology Appraisal	27/03/2014	20/06/2014
Intrapartum Care (update): guideline consultation	13/05/2014	24/06/2014
Developing NICE guidelines - the manual	01/04/2014	30/06/2014

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