NICE Update Bulletin June 2015 (Part 2 –issued 25th June) for guidance issued after June 4th 2015

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)	**Omalizumab for previously treated chronic spontaneous urticaria TA339** **Recommendations** 1.1 Omalizumab is recommended as an option as add-on therapy for treating severe chronic spontaneous urticaria in adults and young people aged 12 years and over only if: • the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more • the person's condition has not responded to standard treatment with H_1-antihistamines and leukotriene receptor antagonists • omalizumab is stopped at or before the fourth dose if the condition has not responded • omalizumab is stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission, and is restarted only if the condition relapses • omalizumab is administered under the management of a secondary care specialist in dermatology, immunology or allergy • the company provides omalizumab with the discount agreed in the patient access scheme. 1.2 People whose treatment with omalizumab 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** Omalizumab is a monoclonal antibody that targets IgE, it is available as a 150 mg solution for subcutaneous injection in a pre-filled syringe, and the recommended dose is 300 mg (as 2 injections) once every 4 weeks. In the summary of product characteristics, prescribers are advised to periodically reassess patients for the need for continued treatment. It also notes that clinical trial experience of long-term treatment beyond 6 months in this indication is limited. **Financial factors** The estimated cost of the implementing the guidance is £20.3m for the population of England which equates to approximately £284K for NEW Devon. This cost is before taking into account the discount available in the patient access scheme. The additional population receiving omalizumab is estimated to be 3,900 people per year in England from year 5 following implementation, this equates to approximately 55 people per year in NEW Devon CCG. **Vedolizumab for treating moderately to severely active ulcerative colitis TA342** **Recommendations** 1.1 Vedolizumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active ulcerative colitis in adults only if the company provides vedolizumab with the discount agreed in the patient access scheme. 1.2 Vedolizumab should be given until it stops working or surgery is needed. At 12

	months after the start of treatment, people should be reassessed to see whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to see whether continued treatment is justified. **The technology** Vedolizumab is a humanised monoclonal antibody. It targets $\alpha_4\beta_7$ integrin, which is expressed in certain white blood cells that are found in the gut. $\alpha_4\beta_7$ integrin is responsible for recruiting these cells to inflamed bowel tissue. Vedolizumab therefore specifically targets the gut. The marketing authorisation states that vedolizumab is indicated 'for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, or lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha antagonist'. The recommended dosage of vedolizumab is 300 mg given by intravenous infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter. Continued therapy for people with ulcerative colitis should be carefully reconsidered if no evidence of therapeutic benefit is observed by week 10. **Financial factors** The NHS list price of vedolizumab is £2,050 per 300 mg vial (excluding VAT). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of vedolizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. This gives an annual cost of £16,913 in the first year and £13,325 in subsequent years. Other biologics used for this indication range in price from approximately £7,500 to £10,700 for the first year. Significant expenditure above what is expected could occur if the treatment is not used in close alignment to the NICE recommendations.
Highly specialized technology guidance (HSTs)	**None published so far**

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)	**Suspected cancer: recognition and referral NG12** **Background information** More than 300,000 new cancers (excluding skin cancers) are diagnosed annually in the UK, across over 200 different cancer types. Each of these cancer types has different presenting features, though they sometimes overlap. Approximately one-third of the population will develop a cancer in their lifetime. There is considerable variation in referral and testing for possible cancer, which cannot be fully explained by variation in the population. Taking into account the financial and clinical costs of broadening the recommendations, the NICE guideline development Group agreed to use a 3% PPV threshold value to underpin the recommendations for suspected cancer pathway referrals and urgent direct access investigations, such as brain scanning or endoscopy. Certain exceptions to a 3% PPV threshold were agreed. Recommendations were made for children and young people at below the 3% PPV threshold, although no explicit threshold value was set. The previous guideline, referral guidelines for suspected cancer (NICE guideline CG27 published date June 2005) used a disparate range of percentage risks of cancer

in the recommendations. Few corresponded with a positive predictive value (PPV) of lower than 5%.

The recommendations in full cover

1.1 Lung and pleural cancers

1.2 Upper gastrointestinal tract cancers

1.3 Lower gastrointestinal tract cancers

1.4 Breast cancer

1.5 Gynaecological cancers

1.6 Urological cancers

1.7 Skin cancers

1.8 Head and neck cancers

1.9 Brain and central nervous system cancers

1.10 Haematological cancers

1.11 Sarcomas

1.12 Childhood cancers

1.13 Non site specific symptoms

Financial factors

The NICE costing statement states that the guideline is anticipated to increase the number of diagnostics tests and referrals for suspected cancer significantly and this will have cost implications. However at the same time benefits are anticipated from earlier diagnosis of cancer, a reduction in the number of patients with cancer identified through emergency admission to hospital and from optimised diagnostic processes. This may require significant investment in cancer services by commissioners.

The tumour groups for which a significant resource impact is estimated are:

- lung and pleural cancers
- upper gastrointestinal tract cancer
- lower gastrointestinal tract cancer.

The guideline is anticipated to increase demand on providers for additional capacity to undertake more diagnostics tests. Services currently report that many have too little capacity to meet existing demand.

Workplace policy and management practices to improve the health and wellbeing of employees NG13

Background information

This guideline makes recommendations on improving the health and wellbeing of employees, with a particular focus on organisational culture and context, and the role of line managers. The aim is to:

•promote leadership that supports the health and wellbeing of employees

•help line managers to achieve this

•explore the positive and negative effect an organisation's culture can have on people's health and wellbeing

•provide a business case and economic modelling for strengthening the role of line managers in ensuring the health and wellbeing of employees.

The guideline is for employers, senior leadership and managers (including line managers) and employees. It will also be of interest to those working in human resources, learning and development teams, professional trainers and educators, occupational health, health and safety, trade unions and professional bodies. In addition, it may be of interest to other members of the public

	The recommendations in full cover 1 Organisational commitment 2 Physical work environment 3 Mental wellbeing at work 4 Fairness and justice 5 Participation and trust 6 Senior leadership 7 Role of line managers 8 Leadership style of line managers 9 Training of line managers 10 Job design 11 Monitoring and evaluation **Financial factors** The NICE costing statement for this guidance states that for some organisations, implementing the guideline could lead to significant gains in productivity for a relatively small cost. These are likely to vary widely and this may not be the case for all organisations. **Venous thromboembolism in adults admitted to hospital: reducing the risk CG92** **The recommendations in full cover** 1.1 Assessing the risks of VTE and bleeding 1.2 Reducing the risk of VTE 1.3 Using VTE prophylaxis 1.4 Medical patients 1.5 Surgical patients 1.6 Other patient groups 1.7 Patient information and planning for discharge **Key priorities for implementation** • Assessing the risks of VTE and bleeding • Reducing the risk of VTE • Patient information and planning for discharge **Financial factors** The NICE costing statement states that following review of this guidance in 2015 no significant costs are anticipated as a result of implementation of the update of this guidance.
Interventional Procedures Guidance (IPGs)	**Hysteroscopic morcellation of uterine leiomyomas (fibroids) IPG522** **Recommendations** 1.1 Current evidence on the efficacy of hysteroscopic morcellation of uterine leiomyomas (fibroids) is limited in quality and quantity. Evidence on safety shows potential for serious complications. **Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.** 1.2 Clinicians wishing to do hysteroscopic morcellation of uterine leiomyomas (fibroids) should: •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 particular they should explain the options for treatment and the reasons for considering hysteroscopic morcellation. In addition, the use of NICE's information for the public is recommended.

•Audit and review clinical outcomes of all patients having hysteroscopic morcellation of uterine leiomyomas (see section 7.2).

1.3 Hysteroscopic morcellation of uterine leiomyomas (fibroids) should only be done by clinicians with specific training in this technique.

1.4 NICE encourages further research into hysteroscopic morcellation of uterine leiomyomas (fibroids) which could include data collection with publication of the findings, particularly of safety outcomes. Patient selection should be clearly described. Outcomes should include symptom relief, quality of life, recurrence rates and information about fertility and subsequent pregnancies. All complications should be documented. NICE may update the guidance on publication of further

The procedure

A hysteroscope is inserted into the uterus through the cervix and saline is pumped through a small channel in the hysteroscope to distend the uterus. A specially designed morcellator is introduced via the hysteroscope and used to cut and simultaneously aspirate the leiomyoma tissue. The aspirated tissue can be collected for histological analysis.

Electrotherapy for the treatment of haemorrhoids IPG525

Recommendations

Current evidence on the efficacy and safety of electrotherapy for the treatment of grade I to III haemorrhoids is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments for lower grade haemorrhoids. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful, and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.

The procedure

A proctoscope is inserted into the anus to identify a haemorrhoid. A probe with metal contact points is then placed at the base of the haemorrhoid and a direct electric current is delivered. The electric current is controlled by a handpiece attached to the probe. The time for which the electric current is applied depends on the grade of the haemorrhoid and on the dose of direct current. The aim of the direct current application is to cause thrombosis of the feeding vessels and to cause the haemorrhoid to shrink. The precise mechanism of action is not known. More than 1 haemorrhoid may be treated at each session, depending on the need and tolerance of the patient.

Cyanoacrylate glue occlusion for varicose veins IPG526

Recommendations

1.1 Current evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins 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 use cyanoacrylate glue occlusion for varicose veins should:

•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 cyanoacrylate glue occlusion

for varicose veins (a national register is currently under development).

1.3 Patient selection should be done by clinicians who can offer a range of treatment options in addition to cyanoacrylate glue occlusion.

1.4 This procedure should only be done by clinicians with specific training in this technique.

1.5 NICE may update the guidance on publication of further evidence

The procedure

Cyanoacrylate glue occlusion aims to close varicose veins by adherence then fibrosis of the lumen, without the need for tumescent anaesthesia. An introducer sheath is inserted into the distal great saphenous vein in the affected leg and, using ultrasound guidance, a delivery catheter is advanced into position just before the saphenofemoral junction. The proximal vein is compressed and a measured dose of cyanoacrylate glue is delivered through the tip of the catheter to seal the vein. The catheter is withdrawn in stages and the steps repeated to close the vein.

Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache IPG527

Recommendations

1.1 Current evidence on the efficacy of implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache, in the short term (up to 2 months), is adequate. With regard to safety, a variety of complications have been documented, most of which occur early and resolve; surgical revision of the implanted system is sometimes needed. **Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.**

1.2 Clinicians wishing to implant a sphenopalatine ganglion stimulation device for chronic cluster headache should:

•Inform the clinical governance leads in their NHS trusts.

•Ensure that patients understand the uncertainty about the procedure's safety and long-term efficacy and provide them with clear written information. Patients should be informed about other treatment options. In addition, the use of NICE's information for the public is recommended.

•Audit and review clinical outcomes of all patients having sphenopalatine ganglion stimulation (see section 7.2).

1.3 The selection of patients for implantation of a sphenopalatine ganglion stimulation device and their management should be done by multidisciplinary teams specialising in refractory headache.

1.4 Clinicians should enter details about all patients being implanted with a sphenopalatine ganglion stimulation device onto the national Neuromodulation register hosted by the National Institute for Cardiovascular Outcomes Research (NICOR). Clinical outcomes should also be reviewed locally.

1.5 NICE encourages further research on sphenopalatine ganglion stimulation for chronic cluster headache. Reported outcomes should include long-term efficacy and device durability

The procedure

Implantation of the neurostimulator device is performed with the patient under general anaesthesia. A small incision is made adjacent to the maxillary first or second molar on the affected side. Under X-ray control, the lead of the neurostimulator device is advanced to place stimulating electrodes in the pterygopalatine fossa. After implantation, the device is tested to assess electrode functionality and the patient's physiological responses to stimulation.

Medical Technologies Guidance	**None published so far**
Diagnostics Guidance	**None published so far**
NICE Quality Standards	**Osteoarthritis QS87** This quality standard covers the assessment and management of osteoarthritis in adults aged 18 years and over. It does not cover the replacement of hip, knee or shoulder joints in adults with osteoarthritis, because this will be included in a future NICE guideline and quality standard. **Personality disorders: borderline and antisocial QS88** This quality standard covers treatment and management of borderline and antisocial personality disorders. For borderline personality disorder, this quality standard applies to adults aged 18 and over and young people post puberty. For antisocial personality disorder, this quality standard applies only to adults aged 18 and over. **Pressure ulcers QS89** This quality standard covers treatment and management of borderline and antisocial personality disorders. For borderline personality disorder, this quality standard applies to adults aged 18 and over and young people post puberty. For antisocial personality disorder, this quality standard applies only to adults aged 18 and over. **Urinary tract infections in adults QS90** This quality standard covers the management of suspected community-acquired bacterial urinary tract infection in adults aged 16 years and over. This includes women who are pregnant, people with indwelling catheters and people with other diseases or medical conditions such as diabetes. **Prostate cancer QS91** This quality standard covers the care of men referred to secondary care with suspected or diagnosed prostate cancer, and men having follow-up for prostate cancer in primary care. It does not cover the recognition and referral of men with suspected prostate cancer in primary care. This topic is expected to be covered by a quality standard on suspected cancer.
Commissioning Guides	**NICE support for commissioning for personality disorders: borderline and antisocial SFCQS88**
Public health briefings for local government	**None published so far**

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