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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)	**Naloxegol for treating opioid-induced constipation TA345** **Recommendations** Naloxegol is recommended, within its marketing authorisation, as an option for treating opioid induced constipation in adults whose constipation has not adequately responded to laxatives. •An inadequate response is defined as opioid-induced constipation symptoms of at least moderate severity in at least 1 of the 4 stool symptom domains (that is, incomplete bowel movement, hard stools, straining or false alarms) while taking at least 1 laxative class for at least 4 days during the prior 2 weeks. **The technology** Naloxegol (Moventig) is a form of naloxol which has been pegylated (that is, attached to a molecule of polyethylene glycol, or PEG). In this form, it selectively antagonises peripheral opioid receptors to relieve constipation. **Financial factors** The list price for naloxegol, which has been agreed by the Department of Health, is £55.20 per 30-tablet pack of 12.5-mg or 25-mg film-coated tablets. The recommended dose is 25 mg taken orally once daily (or 12.5 mg for people with renal insufficiency). Costs may vary in different settings because of negotiated procurement discounts. The NICE costing statement states that although additional drug costs are anticipated where naloxegol is used in place of conventional laxative treatments, there may be cost savings if it is used as an alternative to methylnaltrexone. If a person's condition responds to treatment with naloxegol, there may be further savings to commissioners on treating opioid-induced constipation because of the avoidance of hospital attendances, or treatments such as enemas. **Aflibercept for treating diabetic macular oedema TA346** **Recommendations** 1.1 Aflibercept solution for injection is recommended as an option for treating visual impairment caused by diabetic macular oedema only if: • the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and • the company provides aflibercept with the discount agreed in the patient access scheme. 1.2 People whose treatment with aflibercept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue aflibercept until they and their NHS clinician consider it appropriate to stop. **The technology** Aflibercept (Eylea) is a soluble vascular endothelial growth factor (VEGF) receptor fusion protein that binds to all forms of VEGF-A, VEGF-B, and the placental growth factor. VEGF is involved in the pathogenesis of diabetic macular oedema (DMO). Aflibercept is given as a single 2 mg intravitreal injection every month for 5 consecutive months, followed by 1 injection every 2 months with no requirement for monitoring between visits. After the first 12 months, the treatment interval may be extended based

on visual and anatomic outcomes. The schedule for monitoring should be determined by the treating physician. Aflibercept should be discontinued if the patient is not benefiting from continued treatment.

Financial factors

The list price of aflibercept is £816.00 per vial (excluding VAT- BNF edition January 2015). The total cost for treating a patient in the first year is £6,936 (based on 8.5 aflibercept injections). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of aflibercept, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.

The NICE costing report states that the implementing the guidance will result in 12 people being treated and a cost of £48,407 (not accounting for VAT or discounts available) per 100,000 population.

Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer TA347

Recommendations

Nintedanib in combination with docetaxel is recommended, within its marketing authorisation, as an option for treating locally advanced, metastatic or locally recurrent non-small-cell lung cancer of adenocarcinoma histology that has progressed after first-line chemotherapy, only if the company provides nintedanib with the discount agreed in the patient access scheme.

The technology

Nintedanib (Vargatef) is a small molecule tyrosine-kinase inhibitor. It blocks 3 receptor classes that promote angiogenesis and tumour growth: vascular endothelial growth factor receptors; fibroblast growth factor receptors; and platelet-derived growth factor receptors α and β. The recommended dose is 200 mg twice daily. This can be reduced to 150 mg or 100 mg twice daily in patients who experience adverse events.

Financial factors

Nintedanib costs £2151.10 for a 30-day pack of 150 mg or 100 mg capsules for oral use (excluding VAT, MIMS online March 2015). The NICE costing statement states that the estimated annual cost (without the discount from the patient access scheme) of implementing this technology for the population of England will be:
£0.2 million in year 1; £0.8 million in year 2; £1.7 million in year 3; and £2.4 million in year 4, assuming the uptake levels in the costing assumptions. The population eligible for treatment is about 600 per year in England. The commissioner for this technology is NHS England.

Everolimus for preventing organ rejection in liver transplantation TA348

Recommendations

1.1 Everolimus is not recommended within its marketing authorisation for preventing organ rejection in people having a liver transplant.

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

The technology

Everolimus (Certican) is an analogue of sirolimus. It is an immunosuppressant that inhibits the mammalian target of rapamycin (mTOR) protein and targets the primary causes of progressive allograft dysfunction (also known as chronic rejection) following an organ transplant. It has a marketing authorisation in the UK for 'the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, everolimus should be used in combination with tacrolimus and corticosteroids'.

Financial factors

The commissioner for this technology is NHS England. Everolimus is not recommended within its marketing authorisation for preventing organ rejection in people having a liver transplant. As a result, no significant resource impact is anticipated.

Dexamethasone intravitreal implant for treating diabetic macular oedema TA349

Recommendations

1.1 Dexamethasone intravitreal implant is recommended as an option for treating diabetic macular oedema only if:

•the implant is to be used in an eye with an intraocular (pseudophakic) lens and

•the diabetic macular oedema does not respond to non‑corticosteroid treatment, or such treatment is unsuitable.

1.2 People whose treatment with dexamethasone intravitreal implant was started within the NHS before this guidance was published, but 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

Dexamethasone intravitreal implant (Ozurdex) contains a corticosteroid. It suppresses inflammation and prevents oedema. Dexamethasone intravitreal implant is given as an injection into the eye. Each implant delivers 700 micrograms dexamethasone to the back of the eye over a period of 6 months or more. The implant remains in the vitreous for up to 270 days before fully dissolving. The summary of product characteristics states that, after initial treatment, re-treatment can be performed after approximately 6 months if the patient experiences decreased vision with or without an increase in retinal thickness with recurrent or worsening diabetic macular oedema.

Financial factors

The list price of dexamethasone intravitreal implant is £870.00 per 700 micrograms (BNF price excluding VAT). Costs may vary in different settings because of negotiated procurement discounts. 595 people in England may be eligible for dexamethasone intravitreal implant each year. The NICE Costing report states that The annual cost of implementing this guidance for the incident population is estimated as £4 million in England. This equates to 1 person per 100,000 population and a cost of £7,845 per annum. There will also be a non-recurring cost for treating the prevalent population not previously treated with fluocinolone. NICE estimate that this will be implemented over 3 years at a cost of £17 million in year 1, £17 million in year 2 and £15 million in year 3. This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts and outsourced services.

Secukinumab for treating moderate to severe plaque psoriasis TA350

Recommendations

1.1 Secukinumab is recommended, within its marketing authorisation, as an option for treating adults with plaque psoriasis only when:

- the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
- the disease has failed to respond to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long‑wave ultraviolet radiation), or these treatments are contraindicated or the person cannot tolerate them
- the company provides secukinumab with the discount agreed in the patient access scheme.

1.2 Secukinumab treatment should be stopped in people whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these people. An adequate response is defined as either:

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

	from when treatment started. 1.3 People whose treatment with secukinumab 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. 1.4 When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate. **The technology** Secukinumab (Cosentyx) is a high-affinity, fully human monoclonal antibody that binds to and neutralises interleukin-17A, which is thought to be involved in the body's autoimmune response in diseases such as psoriasis. Secukinumab is given subcutaneously. The recommended dosage is 300 mg at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at week 4. **Financial factors** The undiscounted price for 2 × 150 mg prefilled pen or syringe is £1218.78 (excluding VAT, 'Monthly Index of Medical Specialities' [MIMS] May 2015). The company has agreed a patient access scheme with the Department of Health. This appears to equate to 16 doses in the first year costing £19,500.48 without vat or discounts applied. The NICE costing report does not give a financial projection per 100,000 population. A costing template has been produced to allow local practice to be taken into account, populating this with default values gives a resource impact of £748K (62 pts receiving secukinumab in future practice) for NEW Devon and £237K (20pts) for SDT. **Cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti-platelet therapy (terminated appraisal) TA351** **Recommendations** NICE is unable to make a recommendation about the use in the NHS of cangrelor for reducing atherothrombotic events in people undergoing percutaneous coronary intervention or awaiting surgery requiring interruption of anti-platelet therapy because no evidence submission was received from The Medicines Company.
Highly specialized technology guidance (HSTs)	**None published so far this month**

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)	**None published so far this month**
Interventional Procedures Guidance (IPGs)	**Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section IPG528** **Recommendations** Current evidence on the efficacy and safety of insertion of a double catheter balloon for

	induction of labour in women without previous caesarean section is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. **The procedure** Insertion of a double balloon catheter for induction of labour at term in pregnant women aims to facilitate induction through causing dilation of the cervix when the cervix is unfavourable for induction. The double balloon is claimed to stimulate local prostaglandin release, which leads to cervical ripening, through the 2 balloons squeezing the cervix. **Joint distraction for knee osteoarthritis without alignment correction IPG529** **Recommendations** 1.1 Current evidence on the safety and efficacy of joint distraction for knee osteoarthritis without alignment correction 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 knee osteoarthritis without alignment correction should include comparative studies against existing forms of management. Studies should record patient selection, joint space measurements in the medium to long term, functional outcomes, quality of life and complications. They should also report the nature and timing of any further surgery on the knee. NICE may update the guidance on publication of further evidence. **The procedure** Joint distraction for knee osteoarthritis without alignment correction aims to offload and modify the mechanical environment in osteoarthritic joints to allow cartilage regrowth. Intra-articular surgery (such as debridement) may be done before distraction to stimulate cartilage healing.
Medical Technologies Guidance	**The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites MTG25** **Recommendations** 1.1 The case for adopting the 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites is supported by the evidence. This technology allows observation, and provides antiseptic coverage, of the catheter insertion site. It reduces catheter-related bloodstream infections and local site infections compared with semipermeable transparent (standard) dressings. It can be used with existing care bundles. 1.2 The 3M Tegaderm CHG IV securement dressing should be considered for use in critically ill adults who need a central venous or arterial catheter in intensive care or high dependency units. 1.3 The estimated cost saving from using a 3M Tegaderm CHG IV securement dressing (Tegaderm CHG) instead of a standard transparent semipermeable dressing is £73 per patient. This estimate is based on a baseline catheter-related bloodstream infection rate of 1.48 per 1000 catheter days. Tegaderm CHG is estimated to be cost neutral when the baseline catheter-related bloodstream infection rate is 0.24 per 1000 catheter days, and cost incurring when the baseline rate falls below that figure. Estimates of the population for Tegaderm CHG based on adult intensive care episodes needing a central venous or arterial catheter vary from around 88,000 to 226,000 depending on whether episodes longer than 48 hours, or all episodes, are used. Based on these estimates, if the use of Tegaderm CHG became standard practice, it has the potential to save the NHS in England between £4.2 million and £10.8 million each year, assuming the baseline catheter-related bloodstream infection rate is 1.48 per 1000 catheter days. **The technology** The 3M Tegaderm CHG IV securement dressing (Tegaderm CHG) is a sterile transparent semipermeable polyurethane adhesive dressing with an integrated gel pad containing a 2% concentration by weight of chlorhexidine gluconate (CHG). Tegaderm CHG is used to secure percutaneous devices and to cover and protect central

	venous and arterial catheter insertion sites. It aims to provide an effective barrier against external contamination. The dressing and the integrated gel pad are transparent to allow observation of the catheter insertion site. **Financial Factors** It is estimated that the annual cost saving from implementing this technology for the population of England will be between £4.2 million and £10.8 million per year, when uptake has reached the level assumed in the costing assumptions. The savings (guidance) are based upon a baseline catheter related bloodstream infections (CRBSI) rate of 1.48 per 1000 catheter days. The level of saving is dependent on current rates of CRBSI. Savings will be greater where current rates of CRBSI are higher.
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Smoking: harm reduction QS92** This quality standard covers ways of reducing harm from smoking. In particular, this includes people who are highly dependent on nicotine and who may not be able (or want) to stop smoking in one step, who may want to stop smoking without giving up nicotine, who may want to reduce the amount they smoke without stopping, or who want to abstain temporarily from smoking. **Atrial fibrillation: treatment and management QS93** This quality standard covers identification, treatment and management of atrial fibrillation (including paroxysmal, persistent and permanent atrial fibrillation, and atrial flutter) in adults (18 years and older). It will cover adults with both valvular and non-valvular atrial fibrillation unless specified otherwise at statement level. **Obesity: prevention and lifestyle weight management in children and young people QS94** This quality standard covers a range of approaches at a population level to prevent children and young people aged under 18 years from becoming overweight or obese. It includes interventions for lifestyle weight management. These statements are particularly relevant to local authorities, NHS organisations, schools and providers of lifestyle weight management programmes. **Bipolar disorder in adults QS95** This quality standard covers recognition, assessment and management of bipolar disorder (including bipolar I, bipolar II, mixed affective and rapid cycling disorder) in adults (18 years and older) in primary and secondary care **Dyspepsia and gastro-oesophageal reflux disease in adults: investigation and management QS96** This quality standard covers the investigation and management of dyspepsia and gastro-oesophageal reflux disease (GORD) symptoms in adults 18 and older. It includes the investigation of dyspepsia and GORD symptoms as a risk factor for oesophagogastric cancer but it does not include the diagnosis and management of oesophagogastric cancer because this will be covered by a separate quality standard.
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
Joint distraction for ankle osteoarthritis: consultation	26/06/2015	23/07/2015
Sacral nerve stimulation for chronic non-obstructive urinary retention: consultation	26/06/2015	23/07/2015
Transcranial magnetic stimulation for severe depression: consultation	26/06/2015	23/07/2015
Type 2 diabetes: guideline consultation 2	26/06/2015	24/07/2015
Dementia (update): the scope	08/07/2015	05/08/2015
Multiple sclerosis: quality standard consultation	08/07/2015	05/08/2015
Electrical stimulation of the lower oesophageal sphincter for treating gastro-oesophageal reflux disease: consultation	10/07/2015	06/08/2015
Endovascular aneurysm sealing for abdominal aortic aneurysm: consultation	10/07/2015	06/08/2015
Gallstone disease: quality standard consultation	09/07/2015	06/08/2015
Implantation of a corneal graft-keratoprosthesis combination for severe corneal opacity in wet blinking eyes: consultation	10/07/2015	06/08/2015
Insertion of a sub-retinal implant for retinitis pigmentosa: consultation	10/07/2015	06/08/2015
Sunlight exposure - risks and benefits: guideline consultation 2	09/07/2015	06/08/2015
Transition between inpatient hospital settings and community or care home settings for adults with social care needs: draft guideline consultation	25/06/2015	06/08/2015
Faltering growth - recognition and management of faltering growth in children: the scope	13/07/2015	10/08/2015
Service model for people with learning disabilities and challenging behaviour: consultation on the draft scope	15/07/2015	12/08/2015
Air pollution - outdoor air quality and health: the scope	16/07/2015	13/08/2015
Harmful sexual behaviour among children and young people: call for evidence 2	13/07/2015	14/08/2015

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