NICE Update Bulletin September 2016
issued Wednesday 28th September 2016

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)	**Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer TA406** **Recommendations** 1.1 Crizotinib is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer in adults. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme. **The technology** Crizotinib (Xalkori, Pfizer) is an inhibitor of the anaplastic lymphoma kinase (ALK) tyrosine kinase receptor and its variants. Crizotinib has a marketing authorisation in the UK which includes 'the first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC)'. **Financial factors** This technology is commissioned by NHS England. The list price of crizotinib has a discount that is commercial in confidence under the patient access scheme. **Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors TA407** **Recommendations** 1.1 Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme. 1.2 Assess the response to secukinumab after 16 weeks of treatment and only continue if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. 1.3 When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate. **The technology** Secukinumab (Cosentyx, Novartis). It is a monoclonal antihuman antibody of the IgG1/kappa isotype that targets interleukin-17A. Secukinumab has a marketing authorisation in the UK for the treatment of active ankylosing spondylitis 'in adults who have responded inadequately to conventional therapy'. **Financial factors** This technology is commissioned by CCGs. The technology is cost saving before application of the confidential discount agreed in the patient access scheme.

Pegaspargase for treating acute lymphoblastic leukaemia TA408

Recommendations

1.1 Pegaspargase, as part of antineoplastic combination therapy, is recommended as an option for treating acute lymphoblastic leukaemia in children, young people and adults only when they have untreated newly diagnosed disease.

1.2 This guidance is not intended to affect the position of patients whose treatment with pegaspargase was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by the clinician and the child or young person, or the child or young person's parents or carers.

The technology

Pegaspargase (Oncaspar, Baxalta [now part of Shire Pharmaceuticals]) is a polyethylene glycol conjugate of Escherichia coli (E. coli)‑derived L‑asparaginase.

L‑asparaginase is a bacterial enzyme that depletes circulating asparagine, an essential amino acid on which leukaemic cells, incapable of synthesising asparagine, depend. This leads to cell death.

Pegaspargase received its marketing authorisation in January 2016. It is indicated as 'a component of antineoplastic combination therapy in acute lymphoblastic leukaemia in paediatric patients from birth to 18 years, and adult patients'.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have an impact on resources because practice is not anticipated to change substantially as a result of this guidance.

Pegaspargase is the current standard of care for people with untreated newly diagnosed acute lymphoblastic leukaemia in England, and has been included in NHS England baseline commissioning from April 2013 onwards.

This technology only recently obtained a marketing authorisation for this condition.

Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion TA409

Recommendations

1.1 Aflibercept is recommended as an option within its marketing authorisation for treating visual impairment in adults caused by macular oedema after branch retinal vein occlusion, only if the company provides aflibercept with the discount agreed in the patient access scheme.

The technology

Aflibercept solution for injection (Eylea, Bayer) administered by intravitreal injection. It is a soluble vascular endothelial growth factor (VEGF) receptor fusion protein.

Aflibercept has a marketing authorisation in the UK for treating 'visual impairment due to macular oedema secondary to retinal vein occlusion (branch or central)'.

NICE has already issued guidance for aflibercept when treating visual impairment due to macular oedema secondary to central retinal vein occlusion.

Financial factors

This technology is commissioned by CCGs. The list price of aflibercept has a discount that is commercial in confidence under the patient access scheme.

Aflibercept is considered to be more effective than laser photocoagulation.

Talimogene laherparepvec for treating unresectable metastatic melanoma TA410

Recommendations

1.1 Talimogene laherparepvec is recommended, in adults, as an option for treating unresectable, regionally or distantly metastatic (Stage IIIB, IIIC or IVM1a) melanoma that has not spread to bone, brain, lung or other internal organs, only if:

- treatment with systemically administered immunotherapies is not suitable and
- the company provides talimogene laherparepvec with the discount agreed in the patient access scheme.

1.2 This guidance is not intended to affect the position of patients whose treatment with talimogene laherparepvec was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

The technology

Talimogene laherparepvec (Imlygic, Amgen) is derived from the herpes simplex virus type-1. It is a modified form of the virus that kills cancer cells. It is injected directly into cutaneous, subcutaneous and nodal lesions that are visible on the skin, palpable, or detectable with ultrasound guidance.

The company states that talimogene laherparepvec has 2 complementary mechanisms of action: replication that causes cell rupture/lysis and death (intracellular or direct effect) and post-lysis release of tumour-derived antigens and granulocyte macrophage colony-stimulating factor (GM-CSF), stimulating a systemic immune response from antigen-presenting cells upon distant tumour sites (extracellular or indirect effect).

Talimogene laherparepvec has a marketing authorisation in the UK for the treatment of adults with 'unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease'.

Financial factors

This technology is commissioned by NHS England.

NICE has said that no resource impact is anticipated because the population size is small (estimated to be less than 100 people nationally).

Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer TA411

Recommendations

1.1 Necitumumab, in combination with gemcitabine and cisplatin, is not recommended within its marketing authorisation for adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been treated with chemotherapy.

1.2 This guidance is not intended to affect the position of patients whose treatment with necitumumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

The technology

Necitumumab (Portrazza, Eli Lilly) is a fully human monoclonal antibody, which inhibits the epidermal growth factor receptor (EGFR).

Necitumumab has a marketing authorisation in the UK, in combination with gemcitabine and cisplatin chemotherapy, for treating locally advanced or metastatic EGFR-expressing squamous non-small-cell lung cancer (NSCLC), in adults who have not had chemotherapy for this condition.

	Financial factors This technology is commissioned by NHS England. No resource implications are anticipated as this technology is not recommended. **Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases TA412** **This guidance is a Cancer Drugs Fund reconsideration of radium‑223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (TA376).** **Recommendations** 1.1 Radium‑223 dichloride is recommended as an option for treating hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases in adults, only if: • they have already had docetaxel or • docetaxel is contraindicated or is not suitable for them. The drug is only recommended if the company provides radium‑223 dichloride with the discount agreed in the patient access scheme. 1.2 This guidance is not intended to affect the position of patients whose treatment with radium‑223 dichloride was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. **The technology** Radium‑223 dichloride (Xofigo, Bayer) is a radiopharmaceutical agent designed to deliver alpha radiation to bone metastases without affecting normal bone marrow. The marketing authorisation for radium‑223 dichloride (hereafter referred to as radium‑223) is 'for the treatment of adults with castration‑resistant prostate cancer, symptomatic bone metastases and no known visceral metastases'. **Financial factors** This technology is commissioned by NHS England.
Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Multimorbidity: clinical assessment and management NG56** This guideline covers optimising care for adults with multimorbidity (multiple long-term conditions) by reducing treatment burden (polypharmacy and multiple appointments) and unplanned care. It aims to improve quality of life by promoting shared decisions based on what is important to each person in terms of treatments, health priorities, lifestyle and goals. The guideline sets out which people are most likely to benefit from an approach to care that takes account of multimorbidity, how they can be identified and what the care involves. This guideline includes recommendations on: • taking account of multimorbidity in tailoring an approach to care • how to identify people who may benefit • how to assess frailty • principles of an approach to care that takes account of multimorbidity • delivering the approach to care

Harmful sexual behaviour among children and young people NG55

This guideline covers children and young people who display harmful sexual behaviour, including those on remand or serving community or custodial sentences. It aims to ensure these problems don't escalate and possibly lead to them being charged with a sexual offence. It also aims to ensure no-one is unnecessarily referred to specialist services.

'Young people' refers mainly to those aged 10 to 18 but also includes people up to 25 with special educational needs or a disability.

This guideline includes recommendations on:

- multi-agency approach and universal services
- early help assessment
- risk assessment for children and young people referred to harmful sexual behaviour services
- engaging with families and carers before an intervention begins
- developing and managing a care plan for children and young people displaying harmful sexual behaviour
- developing interventions for children and young people displaying harmful sexual behaviour
- supporting a return to the community for 'accommodated' children and young people

Mental health problems in people with learning disabilities: prevention, assessment and management NG54

This guideline covers preventing, assessing and managing mental health problems in people with learning disabilities in all settings (including health, social care, education, and forensic and criminal justice). It aims to improve assessment and support for mental health conditions, and help people with learning disabilities and their families and carers to be involved in their care.

This guideline includes recommendations on:

- organising and delivering care
- involving people in their care
- prevention, including social, physical environment and occupational interventions
- annual GP health checks
- assessment
- psychological interventions, and how to adapt these for people with learning disabilities
- prescribing, monitoring and reviewing pharmacological interventions

Dementia: supporting people with dementia and their carers in health and social care CG42 (update)

This guideline covers preventing, diagnosing, assessing and managing dementia in health and social care, and includes recommendations on Alzheimer's disease. It aims to improve care for people with dementia by promoting accurate diagnosis and the most effective interventions, and improving the organisation of services.

September 2016: recommendation 1.3.3.2 was updated and replaced by recommendations 1.2.9, 1.6.3, 1.6.4, 1.7.5 and 1.8.17 in the NICE guideline on mental health problems in people with learning disabilities, and recommendations 1.5.1.2 and 1.6.2.7 were replaced by recommendation 1.8.16 in the NICE guideline on mental health problems in people with learning disabilities.

	Cardiovascular disease: risk assessment and reduction, including lipid modification CG181 (update) This guideline covers the assessment and care of adults who are at risk of or who have cardiovascular disease (CVD), such as heart disease and stroke. It aims to help healthcare professionals identify people who are at risk of cardiovascular problems including people with type 1 or type 2 diabetes, or chronic kidney disease. It describes the lifestyle changes people can make and how statins can be used to reduce their risk. **September 2016:** recommendation 1.3.28 was amended to clarify what was meant by high-intensity statin treatment, and that the recommendation applies to both primary and secondary prevention. The term 'high-intensity statin' was also added to the 'Terms used in this guideline' section and linked to throughout. The following updated NICE Guidelines were published at the end of August, after publication of the August bulletin: **Transition between inpatient mental health settings and community or care home settings NG53** This guideline covers the period before, during and after a person is admitted to, and discharged from, a mental health hospital. It aims to help people who use mental health services, and their families and carers, to have a better experience of transition by improving the way it's planned and carried out. **Stable angina: management CG126 (update)** This guideline offers evidence-based advice on the care and treatment of adults diagnosed with stable angina. Stable angina is usually caused by coronary heart disease, a condition in which blood vessels in the heart become narrowed by a build-up of fat. This reduces the supply of blood and oxygen to the heart. The most common symptom of stable angina is pain or a feeling of discomfort or tightness in the chest, which can often spread to the jaw, back, shoulders and arms. **August 2016:** The footnote to recommendations 1.4.11 and 1.4.12 were amended to cover the new advice from the Medicines and Healthcare products Regulatory Agency (MHRA) about safety concerns related to ivabradine (June 2014 and December 2014) and nicorandil (January 2016). **Acute upper gastrointestinal bleeding in over 16s: management CG141 (update)** This guideline covers how upper gastrointestinal bleeding can be effectively managed in adults and young people aged 16 years and older. It aims to identify which diagnostic and therapeutic steps are useful so hospitals can develop a structure in which clinical teams can deliver an optimum service for people who develop this condition. **August 2016:** NICE reviewed the evidence and found nothing new that affects the recommendations in this guideline. They added a footnote to recommendation 1.7.1 covering the licensing limitations of H2-receptor antagonists and proton pump inhibitors for primary prevention of upper gastrointestinal bleeding in acutely ill patients.
Interventional Procedures Guidance (IPGs)	**Miniature lens system implantation for advanced age-related macular degeneration IPG565** **Recommendations** 1.1 Evidence on the efficacy of miniature lens system implantation for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Data on short-term safety are available for limited numbers of patients. There is currently insufficient long-term evidence on both efficacy and safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to do miniature lens system implantation for advanced AMD should take the following actions:

	• Inform the clinical governance leads in their trusts. • Ensure that patients understand the need to adapt to having a lens system implanted into 1 eye, the risk of early complications, and the uncertainties about long-term efficacy and safety. Clinicians should provide patients with clear information in an appropriate format. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having miniature lens system implantation for advanced AMD. 1.3 Patient selection should include detailed assessment to predict the patient's ability to cope with the changes in vision after the operation. Extensive visual rehabilitation after the procedure may be required. 1.4 This procedure should only be done by experienced cataract surgeons with appropriate training in the implantation of miniature lens systems. 1.5 NICE encourages further research and publication on which patients may benefit and on safety and efficacy outcomes, particularly longer-term results. NICE may update the guidance on publication of further evidence. **The procedure** This procedure involves implanting an artificial lens system into one eye only (not both eyes). The aim is to improve vision by magnifying the image in that eye or by moving the image to an undamaged part of the eye. Under local anaesthetic the natural lens is removed through a small cut at the front of the eye where the cornea (the clear film at the front of the eye) meets the sclera (the white part of the eye), and the miniature lens system is put in. Miniature lens systems can have a single miniature telescope (to magnify the image), or 2 separate artificial lenses (to align the image). After the procedure, people need training and therapy to learn how to see using the implant.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Contraception QS129** This quality standard covers advice about all methods of contraception for women, including emergency contraception. It applies to young people (under 25) and adults. This includes all women of childbearing potential, and young people under 16 who are competent to consent to contraceptive treatment under the Department of Health's Reference guide to consent for examination or treatment. It does not cover sexual health or reducing sexually transmitted infections. **Skin cancer QS130** This quality standard covers the prevention, assessment, diagnosis and management of skin cancer (malignant melanoma and non-melanoma) in children, young people and adults. **Intravenous fluid therapy in children and young people in hospital QS131** This quality standard covers the management of intravenous (IV) fluids in term neonates (babies born at term or born prematurely with a corrected age of term or more), children and young people under 16 years. It covers IV fluids used for a range of conditions and in different hospital settings. It does not cover term neonates, children and young people with condition-specific IV fluid needs, because they are under the care of specialists due to their specific needs. NICE quality standard 66 for intravenous fluid therapy in adults in hospital covers young people and adults aged 16 and over.

	Social care for older people with multiple long-term conditions QS132 This quality standard covers the planning and delivery of coordinated, person-centred social care and support for older people with multiple long-term conditions. The quality standard is focused on people aged over 65 as this is the largest group of people affected by multiple long-term conditions. It includes older people living in their own homes, in specialist settings or in care homes, and those who receive support with funding for their social care and those who do not.

Current NICE consultations with links and end dates for stakeholders to contribute

Title / link	End date of consultation
Vaccine uptake in under 19's : Quality Standard consultation	29/09/2016
Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence : Surveillance consultation	04/10/2016
HumiGard for preventing inadvertent perioperative hypothermia : Draft guidance	04/10/2016
Inadvertent perioperative hypothermia (standing committee B update) : Addendum consultation	05/10/2016
Oral health promotion in care homes and hospitals : Topic engagement	05/10/2016
Lymphoma (follicular, rituximab-refractory) - obinutuzumab (with bendamustine) [ID841] : Appraisal consultation	05/10/2016
Violence and aggression : Topic engagement	06/10/2016
Multimorbidity : Topic engagement	06/10/2016
Hypophosphatasia (paediatric-onset) - asfotase alfa [ID758] : Evaluation consultation	13/10/2016
Head and neck cancer : Quality Standard consultation	14/10/2016
Hepatitis C (chronic) - sofosbuvir and velpatasvir [ID921] : Appraisal consultation	14/10/2016
Smoking cessation interventions and services : Call for evidence	24/10/2016
Spondyloarthritis : Draft guidance consultation	25/10/2016
Diagnostic services : Call for evidence	26/10/2016

Produced by
Rebecca Heayn (Clinical Effectiveness Governance Manager),
NEW Devon CCG Clinical Effectiveness and Medicines Optimisation Team
County Hall, Topsham Road, Exeter, EX2 4QL

For distribution Northern, Eastern and Western Devon CCG & South Devon and Torbay CCG