NICE Update Bulletin October 2016
issued Wednesday 26th October 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**)

<table>
<tr><th>Type</th><th>Guidance title and reference number</th></tr>
<tr><td>Technology Appraisals (TAs)</td><td>

Elbasvir-grazoprevir for treating chronic hepatitis C TA413

Recommendations

1.1 Elbasvir–grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

Table 1 Elbasvir–grazoprevir for treating chronic hepatitis C in adults

<table>
<tr><th>Genotype</th><th>Treatment and duration</th></tr>
<tr><td rowspan="2">1a</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td>Consider elbasvir–grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml or specific NS5A polymorphisms causing at least a 5-fold reduction in activity of elbasvir.</td></tr>
<tr><td>1b</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td rowspan="2">4</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td>Consider elbasvir-grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml.</td></tr>
</table>

1.2 It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.

The technology

Elbasvir–grazoprevir (Zepatier, Merck Sharp & Dohme) is a fixed-dose combination drug. Elbasvir inhibits hepatitis C virus (HCV) non-structural viral protein NS5A and grazoprevir inhibits HCV NS3/4A protease.

Elbasvir–grazoprevir has a marketing authorisation in the UK for treating chronic hepatitis C in adults.

Financial factors

This technology is commissioned by NHS England. Elbasvir–grazoprevir is a further option for treating genotype 1 or 4 chronic hepatitis C in adults. It is anticipated that elbasvir–grazoprevir will be similarly priced to other treatment options.

Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma TA414

Recommendations

1.1 Cobimetinib in combination with vemurafenib is **not recommended** within its marketing authorisation for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation.

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</table>

1.2 This guidance is not intended to affect the position of patients whose treatment with cobimetinib in combination with vemurafenib 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. It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.

The technology

Cobimetinib in combination with vemurafenib is indicated for the treatment of unresectable or metastatic melanoma in adults with a BRAF V600 mutation. Vemurafenib has a marketing authorisation for use as monotherapy for this indication. Cobimetinib does not have a marketing authorisation for use as monotherapy.

Financial factors

This technology is not recommended by NICE.

Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor TA415

Recommendations

1.1 Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor‑alpha (TNF‑alpha) inhibitor, only if:

- disease activity is severe and
- rituximab is contraindicated or not tolerated and
- the company provides certolizumab pegol with the agreed patient access scheme.

1.2 Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF‑alpha inhibitor, only if:

- disease activity is severe and
- rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated and
- the company provides certolizumab pegol with the agreed patient access scheme.

1.3 Continue treatment only if there is at least a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

1.4 This guidance is not intended to affect the position of patients whose treatment with certolizumab pegol 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

Certolizumab pegol (Cimzia, UCB Pharma) is a recombinant humanised antibody Fab fragment against tumour necrosis factor-alpha (TNF‑alpha) and is conjugated to polyethylene glycol (PEG). TNF‑alpha is a pro-inflammatory mediator that is partly responsible for damage to the joints in rheumatoid arthritis.

Certolizumab pegol in combination with methotrexate (MTX) has a marketing authorisation in the UK for 'the treatment of moderate to severe, active rheumatoid

	arthritis in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate'. Certolizumab pegol can be given as 'monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate'. **Financial factors** This technology is commissioned by CCGs. It is an option alongside current standard treatment options. The Department of Health and the company have agreed a patient access scheme, and the cost of treatment is anticipated to be similar to existing drugs. **Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer TA416** **Recommendations** 1.1 Osimertinib is recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only: • after first-line treatment with an EGFR tyrosine kinase inhibitor and • if the conditions in the managed access agreement for osimertinib are followed. 1.2 This guidance is not intended to affect the position of patients whose treatment with osimertinib 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** Osimertinib (Tagrisso, AstraZeneca) is a small-molecule inhibitor that targets the sensitising and T790M mutant forms of the epidermal growth factor receptor (EGFR)-tyrosine kinase receptor. Osimertinib has a conditional marketing authorisation for 'the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC)'. The marketing authorisation is conditional on the company submitting the clinical study report of the phase III AURA3 study comparing osimertinib with platinum-based doublet chemotherapy (expected June 2017). **Financial factors** This technology is commissioned by NHS England. The resource impact of osimertinib will be covered by the Cancer Drugs Fund budget.
Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Jaundice in newborn babies under 28 days CG98 (update)** This guideline covers diagnosing and treating jaundice, which is caused by increased levels of bilirubin in the blood, in newborn babies (neonates). It aims to help detect or prevent very high levels of bilirubin, which can be harmful if not treated. **October 2016:** recommendation 1.4.9 was amended to clarify when intensified phototherapy should be used in relation to time since birth.
Interventional Procedures Guidance (IPGs)	**Single-incision short sling mesh insertion for stress urinary incontinence in women IPG566** **This guidance replaces NICE IPG262 on single-incision sub-urethral short tape insertion for stress urinary incontinence in women.**

	Recommendations 1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are **special arrangements** in place for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients 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 single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.1). 1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence. 1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery. 1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes. **The procedure** Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options have been tried but incontinence persists. With the patient under local, regional or general anaesthesia, a small incision is made in the vaginal wall, under the urethra. The sling, which is typically 8–14 cm long, is inserted using a delivery needle through the obturator foramen and retracted to deploy the sling into the obturator internus muscle. This is repeated with a second sling on the contralateral side. A special tip anchors the sling in place behind the mid urethra. Sling tension is then controlled using the delivery device until the appropriate tension is achieved. The delivery device is then removed and the incision is closed. The slings are permanent implants. Cystoscopy is used to check that bladder perforation has not occurred during the procedure.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Children's attachment QS133** This quality standard covers the identification, assessment and treatment of attachment difficulties. It focusses on children and young people up to age 18: • on the edge of care (those considered to be at high risk of going into care) • looked after by local authorities in foster homes (including kinship foster care)

	• in special guardianship • adopted from care • in residential settings and other accommodation. **Coeliac disease QS134** This quality standard covers the recognition, assessment and management of coeliac disease in children, young people and adults. **Preterm labour and birth QS135** This quality standard covers care for pregnant women who are considered to be at risk of, or with symptoms and signs of, preterm labour and birth. It does not cover women with a multiple pregnancy.

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

Title / link	End date of consultation
Apremilast for treating active psoriatic arthritis [ID1017] : Appraisal consultation	01/11/2016
Waldenstrom's macroglobulinaemia - ibrutinib [ID884] : Appraisal consultation	02/11/2016
Alcohol: school-based interventions : Draft scope consultation	04/11/2016
Lung cancer (non-small-cell, non-squamous, metastatic, after treatment) - nivolumab [ID900] : Appraisal consultation : 2	04/11/2016
Lung cancer (non-small-cell, squamous, metastatic) - nivolumab (after chemotherapy) [ID811] : Appraisal consultation : 2	04/11/2016
Chronic kidney disease (QS update) : Topic engagement	07/11/2016
Low back pain : Topic engagement	07/11/2016
Fabry disease - migalastat [ID868] : Evaluation consultation	08/11/2016
Diagnostic services : Call for evidence	09/11/2016
Managing medicines for adults receiving social care in the community : Draft guidance consultation	11/11/2016
Molecular testing strategies for Lynch syndrome in people with colorectal cancer : Diagnostics consultation : 1	11/11/2016
Parkinson's disease (update) : Draft guidance consultation	15/11/2016
Psoriatic arthritis - certolizumab pegol and secukinumab (after DMARDs) [ID579] : Appraisal consultation	15/11/2016
Mental health of adults in contact with the criminal justice system : Draft guidance consultation	18/11/2016
Trabecular stent bypass microsurgery for open-angle glaucoma : Interventional procedure consultation	21/11/2016
Irreversible electroporation for treating pancreatic cancer : Interventional procedure consultation	21/11/2016
Lateral interbody fusion in the lumbar spine for low back pain : Interventional procedure consultation	21/11/2016
ENDURALIFE-powered CRT-D devices for treating heart failure : Draft guidance	23/11/2016

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