NICE Update Bulletin August 2016
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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)	**Trifluride-tipiracil for previously treated metastatic colorectal cancer TA405** **Recommendations** 1.1 Trifluridine–tipiracil is recommended, within its marketing authorisation, as an option for treating metastatic colorectal cancer, that is: • in adults who have had previous treatment with available therapies including fluoropyrimidine-, oxaliplatin- or irinotecan-based chemotherapies, anti-vascular endothelial growth factor (VEGF) agents and anti-epidermal growth factor receptor (EGFR) agents, or when these therapies are not suitable, and • only when the company provides trifluridine–tipiracil with the discount agreed in the patient access scheme. **The technology** Trifluridine–tipiracil combines 2 drugs: a nucleoside analogue (trifluridine) and a thymidine phosphorylase inhibitor (tipiracil). Trifluridine is taken into the DNA of tumour cells and inhibits tumour growth. Tipiracil slows the breakdown of trifluridine to prolong this action. It has a marketing authorisation for 'The treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF [anti-vascular endothelial growth factor] agents, and anti-EGFR [anti-epidermal growth factor receptor] agents.' **Financial factors** This technology is commissioned by NHS England. NHS Expenditure is anticipated to increase because trifluridine–tipiracil is available only when people have no further treatment options available except best supportive care. The average treatment duration is estimated to be 3.1 months. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of trifluridine–tipiracil, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. **Degarelix for treating advanced hormone-dependent prostate cancer TA404** **Recommendations** 1.1 Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016. 1.2 This guidance is not intended to affect the position of patients whose treatment with degarelix 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** Degarelix (Firmagon, Ferring Pharmaceuticals) is a selective gonadotrophin-releasing hormone antagonist that reduces the release of gonadotrophins by the pituitary, which in turn reduces the secretion of testosterone by the testes.

Gonadotrophin-releasing hormone is also known as luteinising hormone-releasing hormone. Because gonadotrophin-releasing hormone antagonists do not produce a rise in hormone levels at the start of treatment, there is no initial testosterone surge or tumour stimulation, and therefore no potential for symptomatic flares. Degarelix has a marketing authorisation in the UK for the 'treatment of adult male patients with advanced hormone-dependent prostate cancer'. It is administered as a subcutaneous injection.

Financial factors

This technology is commissioned by CCGs.

No resource impact is anticipated from this technology appraisal. Degarelix is another treatment option for advanced hormone-dependent prostate cancer in people with spinal metastases. Because of the small number of people who may have treatment, it is considered that clinical practice will not change substantially as a result of this guidance.

A benefit of degarelix is that there is no testosterone flare at the start of treatment. This avoids the cost of using an anti-androgen treatment to prevent flares.

Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer TA403

Recommendations

1.1 Ramucirumab, in combination with docetaxel, is **not recommended** within its marketing authorisation for treating locally advanced or metastatic non-small-cell lung cancer in adults whose disease has progressed after platinum-based chemotherapy.

1.2 This guidance is not intended to affect the position of patients whose treatment with ramucirumab 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

Ramucirumab is a fully human immunoglobulin G1 monoclonal antibody. It blocks the vascular endothelial growth factor receptor-2, which plays an important role in the formation of new blood vessels in tumours. Its marketing authorisation is Ramucirumab in combination with docetaxel for treating locally advanced or metastatic non-small-cell lung cancer in adults with disease progression after platinum-based chemotherapy.

Financial factors

This technology is commissioned by NHS England.

Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin TA402

Recommendations

1.1 Pemetrexed is recommended as an option for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer in adults when:

- their disease has not progressed immediately after 4 cycles of pemetrexed and cisplatin induction therapy
- their Eastern Cooperative Oncology Group (ECOG) performance status is 0 or 1 at the start of maintenance treatment and
- the company provides the drug according to the terms of the commercial access agreement as agreed with NHS England.

1.2 When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate.

1.3 This guidance is not intended to affect the position of patients whose treatment with pemetrexed 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

Pemetrexed is a multi-targeted anticancer antifolate agent that disrupts crucial folate-dependent metabolic processes essential for cell replication. Pemetrexed has a marketing authorisation as 'monotherapy for the maintenance treatment of locally advanced or metastatic non-small-cell lung cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy'.

Financial factors

This technology is commissioned by NHS England.

Pemetrexed will be available to the NHS through a commercial access agreement between the company and NHS England, which makes it available with a discount. The average treatment duration is 8 cycles. Pemetrexed has been available under the Cancer Drugs Fund (CDF) since April 2013. It is anticipated that there will be no significant change in overall NHS spending because the guidance results in funding for pemetrexed moving from the CDF into routine commissioning.

Bosutinib for previously treated chronic myeloid leukaemia TA401

Recommendations

1.1 Bosutinib is recommended as an option, within its marketing authorisation, for chronic, accelerated and blast phase Philadelphia chromosome positive chronic myeloid leukaemia in adults, when:

- they have previously had 1 or more tyrosine kinase inhibitor and
- imatinib, nilotinib and dasatinib are not appropriate and
- the company provides bosutinib with the discount agreed in the patient access scheme (as revised in 2016).

The technology

Bosutinib is a second-generation tyrosine kinase inhibitor that inhibits Abl-kinases, including Bcr-Abl kinase. It also inhibits the Src family kinases, which have been implicated in driving chronic myeloid leukaemia (CML) progression. It has a UK marketing authorisation for 'the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options'.

Financial factors

This technology is commissioned by NHS England.

As bosutinib has been available to people in England through the cancer drugs fund it is known that around 80 people per year have been treated with the drug and it is estimated that this will increase to around 100 people per year as a result of the guidance.

Cabazitaxel for hormone-relapsed metastatic prostate cacner treated with docetaxel TA391 (update)

August 2016: This guidance has been re-issued after a change to the commercial arrangements in August 2016. This change does not affect cost effectiveness.

Recommendations

1.1 Cabazitaxel in combination with prednisone or prednisolone is recommended as an option for treating metastatic hormone-relapsed prostate cancer in people whose

	disease has progressed during or after docetaxel chemotherapy, only if: • the person has an eastern cooperative oncology group (ECOG) performance status of 0 or 1 • the person has had 225 mg/m2 or more of docetaxel • treatment with cabazitaxel is stopped when the disease progresses or after a maximum of 10 cycles (whichever happens first). • In addition, cabazitaxel is recommended only if: • the company provides cabazitaxel with the discount in the patient access scheme agreed with the Department of Health, and • NHS trusts purchase cabazitaxel in accordance with the commercial access agreement between the company and NHS England, either: o in pre-prepared intravenous infusion bags, or o in vials, at a reduced price that includes a further discount reflecting the average cost of waste per patient (see section 2.3 for details). 1.2 When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate. 1.3 This guidance is not intended to affect the position of patients whose treatment with cabazitaxel was started within the NHS before this guidance was published and whose treatment with cabazitaxel is not recommended in this NICE guidance. 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** Cabazitaxel is an antineoplastic drug in a class of drugs known as taxanes, which includes paclitaxel and docetaxel. Taxanes disrupt the microtubular network essential for mitotic and interphase cellular functions, therefore inhibiting cell division and causing cell death. Cabazitaxel has a UK marketing authorisation for use 'in combination with prednisone or prednisolone for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen'. It is administered by intravenous infusion. **Financial factors** This technology is commissioned by NHS England. Cabazitaxel has been available under the Cancer Drugs Fund (CDF) since April 2013. It is anticipated that there will be no significant change in overall NHS spending because the guidance results in funding for cabazitaxel moving from the CDF into routine commissioning.
Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Heavy menstrual bleeding: assessment and management CG44 (update)** This guideline includes recommendations on history, examination and investigations; education and information; choice of treatments; pharmaceutical treatments and surgical treatments for heavy menstrual bleeding. **August 2016:** NICE looked at new evidence on drug treatments for women with large fibroids and made new recommendations.

	Fertility problems: assessment and treatment CG156 (update) This guideline covers diagnosing and treating fertility problems. It aims to reduce variation in practice and improve the way fertility problems are investigated and managed. **August 2016:** the evidence for recommendation 1.9.1.3 on intrauterine insemination was reviewed and it was concluded that the evidence reviewed did not justify a change to the recommendation. **Autism spectrum disorder in adults: diagnosis and management CG142 (update)** This clinical guideline offers evidence-based advice on the diagnosis and management of autism in adults. **August 2016:** two research recommendations were removed from this guideline. **Palliative care for adults: strong opioids for pain relief CG140 (update)** This guideline covers safe and effective prescribing of strong opioids for pain relief in adults with advanced and progressive disease. It aims to clarify the clinical pathway for prescribing and help to improve pain management and patient safety. Care during the last 2 to 3 days of life is covered by care of dying adults in the last days of life. **August 2016:** recommendation 1.1.12 was deleted and a link added to NICE's guideline on controlled drugs: safe use and management, which has newer advice on the topic. Two out of date research recommendations have also been deleted.
Interventional Procedures Guidance (IPGs)	**Extracorporeal carbon dioxide removal for acute respiratory failure IPG564** **Recommendations** 1.1 Current evidence on the safety of extracorporeal carbon dioxide removal (ECCO2R) for acute respiratory failure shows several serious but well-recognised complications. Evidence on its efficacy is limited in quality and quantity. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to do ECCO2R should: • Inform the clinical governance leads in their trusts. • Ensure that patients (if possible) and their families or carers understand the uncertainty about the procedure's efficacy and the risk of complications 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 ECCO2R 1.3 Only patients with potentially reversible acute respiratory failure or those being considered for lung transplantation should be selected for this procedure. ECCO2R should only be used by specialist intensive care teams trained in its use. 1.4 NICE encourages clinicians to enter patients into ongoing trials such as the protective ventilation with veno-venous lung assist in respiratory failure (REST) trial, and to collaborate in data collection initiatives such as the Extracorporeal Life Support Organization register. Data collected should include information on patient selection criteria, thresholds for intervention, the type of ECCO2R technique being used and clinical outcomes. NICE may update the guidance on publication of further evidence. **The procedure** Extracorporeal carbon dioxide removal (ECCO2R) aims to reduce the level of CO2 in the blood, and reduce the risk of lung injury with mechanical ventilation. In ECCO2R, small tubes are inserted into large veins or arteries. The tubes are then connected to a special device that helps to remove CO2 from the blood. ECCO2R may be used for several weeks.

Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Early years: promoting health and wellbeing in under 5s QS128** This quality standard covers services to support the health, social and emotional wellbeing of children under 5. This includes: home visiting, childcare, early intervention services in children's social care, and early education. The standard includes vulnerable children who may need additional support. It does not cover clinical treatment or the role of child protection services. **Obesity: clinical assessment and management QS127** This quality standard covers the clinical assessment and management of obesity in children, young people and adults. This includes those with established comorbidities and those with risk factors for other medical conditions. It does not cover public health strategies to prevent people becoming overweight or obese, or the delivery of lifestyle weight management interventions. These are covered by obesity in children and young people: prevention and lifestyle weight management programmes (NICE QS94) and obesity in adults: prevention and lifestyle weight management programmes (NICE QS 111). **Diabetes in adults QS6 (update)** This quality standard covers preventing type 2 diabetes in adults (18 years and older), structured education programmes, care and treatment, and preventing and managing foot problems in adults with diabetes. It does not cover diabetes in pregnancy or diabetes in children and young people. **August 2016:** This quality standard has been updated. It was identified for update after the annual review of quality standards in 2014. The review identified that there had been changes in the areas for improvement for diabetes in adults.

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

Title / link	End date of consultation
Ectopic pregnancy and miscarriage: Surveillance consultation	30/08/2016
Lymphoma (Hodgkin's, CD30-positive) - brentuximab vedotin [ID722] : Appraisal consultation	01/09/2016
Heavy menstrual bleeding (update): Draft scope consultation	02/09/2016
Liver disease: Topic engagement	02/09/2016
Mental health problems with learning disability: Quality Standard consultation	02/09/2016
Menopause: Quality Standard consultation	02/09/2016
Infection: Surveillance consultation	05/09/2016
Headaches: Surveillance consultation	05/09/2016
Cardiovascular events (reducing, high risk) - ticagrelor [ID813] : Appraisal consultation	05/09/2016
Intrapartum care (standing committee update) : Draft guidance consultation	06/09/2016
Renal replacement therapy : Draft scope consultation	07/09/2016
Drug misuse prevention: Draft guidance consultation	07/09/2016
Anaphylaxis: assessment and referral after emergency treatment : Surveillance consultation	09/09/2016
Lymphoma (mantle cell, relapsed, refractory) - ibrutinib [ID753] : Appraisal consultation	09/09/2016
Breast cancer (HER2 negative, oestrogen receptor positive, metastatic) – everolimus (with aromatase inhibitor) (review of TA295) [ID1011] - CDF rapid reconsideration process : Appraisal consultation : 1	09/09/2016
Integrated multiplex PCR tests for identifying gastrointestinal pathogens in people with suspected gastroenteritis (the xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay) : Diagnostics consultation : 1	09/09/2016
Hepatocellular carcinoma (advanced and metastatic) - sorafenib (first line) (review of TA189) [ID1012] - CDF rapid reconsideration process : Appraisal consultation : 1	12/09/2016
End of life care for adults in the last year of life: service delivery: Call for evidence	12/09/2016
Healthy workplaces: improving employee mental and physical health and wellbeing: Quality Standard consultation	13/09/2016
Sexually transmitted infections: condom distribution schemes: Draft guidance consultation	16/09/2016
Cerebral palsy: Draft guidance consultation	20/09/2016

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