# NICE Update Bulletin March 2016 issued Wednesday 23rd March 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 |
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| **Technology Appraisals (TAs)** | **Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis TA386**<br><br>**Recommendations**<br><br>1.1 Ruxolitinib is recommended as an option for treating disease-related splenomegaly or symptoms in adults with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, only:<br><br>• in people with intermediate-2 or high-risk disease, and<br><br>• if the company provides ruxolitinib with the discount agreed in the patient access scheme.<br><br>1.2 People whose treatment with ruxolitinib 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.<br><br>**The technology**<br><br>Ruxolitinib (Jakavi) is a protein kinase inhibitor that targets Janus-associated kinase (JAK) signalling. Ruxolitinib has a UK marketing authorisation for 'the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis'. It is administered orally. The recommended starting dose is 15 mg twice daily for patients with a platelet count between 100,000/$mm^3$ and 200,000/$mm^3$, and 20 mg twice daily for patients with a platelet count of more than 200,000/$mm^3$. The maximum recommended starting dose for patients with platelet counts between 50,000/$mm^3$ and 100,000/$mm^3$ is 5 mg twice daily.<br><br>**Financial factors**<br><br>The cost of ruxolitinib is £3,360 for a 56-tablet pack of 10 mg, 15 mg or 20 mg tablets, or £1,680 for a 56-tablet pack of 5 mg tablets (British national formulary [BNF], December 2015). This amounts to an annual cost of about £43,680 per patient (assuming a 15 mg or 20 mg dose, taken twice daily, for 52 weeks). However the company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount (the level of which is commercial in confidence) to the list price of ruxolitinib applied at the point of purchase or invoice.<br><br>This technology is commissioned by NHS England.<br><br>**Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer) TA23 (updated)**<br><br>**March 2016:** The wording of recommendation 1.1 has been updated in line with NICE's wording conventions. Recommendations 1.2 and 1.3 for temozolomide for the first-line chemotherapy treatment of malignant glioma when primary therapy (surgery and/or radiotherapy) has failed have been withdrawn and are updated by recommendation 1.1 of NICE's technology appraisal guidance on carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma (TA121).<br><br>**Recommendations**<br><br>1.1 Temozolomide is recommended as an option for treating malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy only if the person has a Karnofsky performance status score |

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| | greater than or equal to 70 and a life expectancy of 12 weeks or more.<br><br>When using the Karnofsky performance status score, clinicians should be aware of the need to secure equality of access to treatment for people with disabilities. Clinicians should bear in mind that people with disabilities may have difficulties with activities of daily living that are unrelated to their prognosis for malignant glioma. For such people clinicians should make appropriate judgements about performance status, taking into account the person's usual functional capacity and need for assistance with activities of daily living.<br><br>1.2 This recommendation has been updated by recommendation 1.1 in the NICE technology appraisal guidance on carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma.<br><br>1.3 This recommendation has been updated by recommendation 1.1 in the NICE technology appraisal guidance on carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma.<br><br>1.4 People whose treatment with temozolomide 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.<br><br>**The technology**<br><br>Temozolomide (Temodal) is an alkylating agent derived from dacarbazine and first synthesised in 1984. It is indicated for the treatment of patients with malignant glioma showing recurrence or progression after standard therapy. |
| **Highly specialised technology guidance (HSTs)** | **None published so far this month** |
| **NICE Guidelines (NGs)** | **Community engagement: improving health and wellbeing and reducing health inequalities NG44**<br><br>This guideline covers community engagement approaches to reduce health inequalities, ensure health and wellbeing initiatives are effective and help local authorities and health bodies meet their statutory obligations. It updates and replaces NICE guideline PH9 (published February 2008).<br><br>**This guideline includes recommendations on:**<br><br>• overarching principles of good practice – what makes engagement more effective?<br>• developing collaborations and partnerships approaches to encourage and support alliances between community members and statutory, community and voluntary organisations to meet local needs and priorities<br>• involving people in peer and lay roles – how to identify and recruit people to represent local needs and priorities<br>• making community engagement an integral part of health and wellbeing initiatives<br>• making it as easy as possible for people to get involved<br><br>**Financial factors**<br><br>The NICE resource impact report states that it is not anticipated that the guideline will have a significant resource impact because any cost is likely to be offset by savings and benefits to the public sector as a whole. The recommendation that it is considered may have the greatest resource impact and needs to be considered locally is:<br><br>• plan to ensure the resources needed for community engagement are available. |

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| | **Antenatal care for uncomplicated pregnancies CG62 (updated)**<br><br>**March 2016:** Recommendations 1.9.1.1–1.9.1.3 were deleted as the guideline they were taken from has since been updated. For guidance on assessing risk of gestational diabetes, see the section on risk assessment in the NICE guideline on diabetes in pregnancy (NG3).<br><br>This guidance has been partially updated by the NICE guidelines on vitamin D: increasing supplement use among at-risk groups (PH56) and antenatal and postnatal mental health (CG192).<br><br>Recommendation 1.3.2.4 was updated in November 2014 to take into account vitamin D: increasing supplement use among at-risk groups NICE guideline (PH56).<br><br>**The advice in the NICE guideline covers:**<br><br>• the routine care that all healthy women can expect to receive during their pregnancy.<br><br>It does not specifically look at:<br><br>• women who are pregnant with more than one baby, women with certain medical conditions or women who develop a health problem during their pregnancy. |
| **Interventional Procedures Guidance (IPGs)** | **Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia IPG550**<br><br>**Recommendations**<br><br>1.1 Current evidence on the safety and efficacy of endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia is inadequate in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.<br><br>1.2 Clinicians wishing to do endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia should:<br><br>• Inform the clinical governance leads in their NHS trusts.<br><br>• 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.<br><br>• Audit and review clinical outcomes of all patients having endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia (see section 7.2).<br><br>1.3 Patient selection for endoscopic carbon dioxide laser cricopharyngeal myotomy should be done by a multidisciplinary team that specialises in managing oropharyngeal dysphagia.<br><br>1.4 Further research on endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia could include the publication of collaborative audit data. Reports should separate outcomes for different groups of patients; in particular for patients with primary neuromuscular dysfunction alone, those with associated phargyngeal diverticula and those with dysphagia caused by radiotherapy. Outcome measures should include dysphagia scores, quality of life, long-term outcomes and the need for further treatment. All complications should be reported. NICE may update this guidance on publication of further evidence.<br><br>**The procedure**<br><br>Endoscopic carbon dioxide laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia divides the cricopharyngeal muscle via an endoscope using a carbon dioxide laser, as an alternative to open surgery. |

## Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis IPG551

### Recommendations

1.1 Current evidence on the safety of corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis raises no major safety concerns. The evidence on efficacy is limited; there is some evidence of improving sinus patency in the short term, but there is inadequate evidence on patient-reported outcomes and quality of life. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to insert a corticosteroid eluting bioabsorbable stent or spacer during endoscopic sinus surgery to treat chronic rhinosinusitis should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's 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 a corticosteroid eluting stent or spacer inserted during endoscopic sinus surgery to treat chronic rhinosinusitis (see section 6.1).

1.3 NICE encourages further research on corticosteroid eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery and, specifically, controlled studies designed for between patient (rather than within patient) comparisons. Outcomes should include symptom scores, quality of life and the need for retreatment in the long term. All complications should be reported. NICE may update this guidance on publication of further evidence.

### The procedure

Inserting a corticosteroid-eluting bioabsorbable stent or spacer for paranasal sinus disease aims to deliver topical corticosteroid after surgery and to maintain patency of the newly created drainage system. It is usually done with the patient under general anaesthesia, during functional endoscopic sinus surgery, which may include balloon sinuplasty. At the end of the surgery, the corticosteroid-eluting stent is inserted into the relevant ostium under endoscopic guidance. The stent dissolves over a variable period of time.

## Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine IPG552

### Recommendations

1.1 Current evidence on the safety of transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine raises no major concerns. The evidence on efficacy 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 do transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's 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 transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (see section 7.2).

1.3 NICE encourages further research on transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine. Studies should describe whether the procedure is used for treatment or prevention, and whether it is used for

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| | cluster headache or migraine. Clinicians should clearly document details of patient selection and the treatment regimen. Outcome measures should include changes in the number and severity of cluster headache or migraine episodes, medication use, quality of life in the short and long term, side effects, acceptability, and device durability. NICE may update this guidance on publication of further evidence.<br><br>**The procedure**<br><br>Transcutaneous vagus nerve stimulation uses low-voltage electrical currents to stimulate the cervical branch of the vagus nerve. The aim is to relieve pain and reduce the frequency of attacks for both cluster headaches and migraine.<br><br>Therapy is administered by the patient, using a handheld device the size of a mobile phone. The patient places the device on the side of the neck, over the cervical branch of the vagus nerve, positioning its 2 smooth metal stimulation surfaces in front of the sternocleidomastoid muscle, over the carotid artery. The patient slowly increases the stimulation strength until small muscle contractions are felt under the skin; stimulation is then applied for approximately 90 seconds. The device can be used to treat acute attacks, and as prophylaxis between attacks. |
| **Medical Technologies Guidance** | **Spectra Optia for automatic red blood cell exchange in patients with sickle cell disease MTG28**<br><br>**Recommendations**<br><br>1.1 The case for adopting Spectra Optia for automated red blood cell exchange in patients with sickle cell disease is supported by the evidence. Spectra Optia is faster to use and needs to be done less often than manual red blood cell exchange.<br><br>1.2 Spectra Optia should be considered for automated red blood cell exchange in patients with sickle cell disease who need regular transfusion.<br><br>1.3 NICE recommends collaborative data collection to generate further clinical evidence on some outcomes of treatment with Spectra Optia. In particular, there is a need for long-term data on how automated and manual exchange affect iron overload status and the subsequent need for chelation therapy.<br><br>1.4 Based on current evidence and expert advice on the anticipated benefits of the technology when used in patients with iron overload, cost modelling shows that in most cases using Spectra Optia is cost saving compared with manual red blood cell exchange or top-up transfusion. The savings depend on the iron overload status of the patient and are more likely to be achieved if devices already owned by the NHS can be used to treat sickle cell disease. The estimated cost saving for adopting Spectra Optia is £18,100 per patient per year, which has the potential to save the NHS in England £12.9 million each year.<br><br>This technology is commissioned by NHS England. |
| **Diagnostics Guidance** | **None published so far this month** |
| **NICE Quality Standards** | **Preventing excess winter deaths and illness associated with cold homes QS117**<br><br>This quality standard covers preventing excess winter deaths and health problems associated with cold homes. It includes people of all ages, and takes into account that some people are particularly vulnerable to the effects of the cold, such as people with cardiovascular or mental health conditions, young children and older people. |
| **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 |
|---|---|---|
| Leukaemia (chronic lymphocytic) - ibrutinib [ID749] : Appraisal consultation | 02/03/2016 | 23/03/2016 |
| Coeliac disease : Quality Standard consultation | 25/02/2016 | 24/03/2016 |
| Motor neurone disease : Quality Standard consultation | 25/02/2016 | 24/03/2016 |
| Skin cancer : Quality Standard consultation | 25/02/2016 | 24/03/2016 |
| People's experience in adult social care services: improving the experience of care for people using adult social care services : Call for evidence | 02/03/2016 | 30/03/2016 |
| Workplace health: support for employees with disabilities and long term conditions : Call for evidence | 03/03/2016 | 01/04/2016 |
| Harmful sexual behaviour among children and young people : Draft guidance consultation | 24/02/2016 | 06/04/2016 |
| Community engagement: improving health and wellbeing : Topic engagement | 21/03/2016 | 06/04/2016 |
| Transition from children's to adults' services : Topic engagement | 21/03/2016 | 06/04/2016 |
| Early years - promoting health and wellbeing : Quality Standard consultation | 14/03/2016 | 11/04/2016 |
| Diabetes in adults QS (update) : Quality Standard consultation | 11/03/2016 | 12/04/2016 |
| Melanoma (metastatic) - talimogene laherparepvec [ID508] : Appraisal consultation : 508 | 16/03/2016 | 13/04/2016 |
| Lyme disease : Draft scope consultation | 17/03/2016 | 14/04/2016 |
| Cystic fibrosis (F508del mutation) - lumacaftor (with ivacaftor) [ID786] : Appraisal consultation:1 | 16/03/2016 | 15/04/2016 |
| Mental health problems in people with learning disabilities : Draft guidance consultation | 07/03/2016 | 20/04/2016 |
| Mental health problems with learning disability : Topic engagement | 07/03/2016 | 20/04/2016 |
| Contraceptive services : Quality Standard consultation | 22/03/2016 | 20/04/2016 |
| Transition between inpatient mental health settings and community and care home settings : Draft guidance consultation | 16/03/2016 | 27/04/2016 |

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