# NICE Update Bulletin April 2017

## (issued Wednesday 26 April 2017)

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)** | **Obeticholic acid for treating primary biliary cholangitis TA443**<br><br>**Recommendations**<br><br>1.1 Obeticholic acid is recommended, within its marketing authorisation, as an option for treating primary biliary cholangitis in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or as monotherapy for people who cannot tolerate ursodeoxycholic acid. Obeticholic acid is recommended only if the company provides it with the discount agreed in the patient access scheme.<br><br>1.2 Assess the response to obeticholic acid after 12 months. Only continue if there is evidence of clinical benefit.<br><br>**The technology**<br><br>Obeticholic acid is a selective and potent agonist for the farnesoid X receptor (FXR), a nuclear receptor expressed at high levels in the liver and intestine. FXR is thought to be an important regulator of bile acid, inflammatory, fibrotic and metabolic pathways. FXR activation lowers intracellular hepatocyte concentrations of bile acids by suppressing de novo synthesis from cholesterol, and by increasing transport of bile acids out of the hepatocytes. These mechanisms limit the overall amount of bile acid circulating in the body while promoting secretion of bile by the liver and reducing hepatic exposure to bile acids.<br><br>**Financial factors**<br><br>This technology is commissioned by NHS England. It is estimated that around 2,700 people with primary biliary cholangitis will be eligible for treatment with obeticholic acid each year in England.<br><br>**Ixekizumab for treating moderate to severe plaque psoriasis TA442**<br><br>**Recommendations**<br><br>1.1 Ixekizumab is recommended as an option for treating plaque psoriasis in adults, only if:<br><br>• the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10<br><br>• the disease has not responded 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, and<br><br>• the company provides the drug with the discount agreed in the patient access scheme.<br><br>1.2 Stop ixekizumab treatment at 12 weeks if the psoriasis has not responded adequately. An adequate response is defined as:<br><br>• a 75% reduction in the PASI score (PASI 75) from when treatment started |

or

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

1.3 When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

1.4 When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

1.5 These recommendations are not intended to affect treatment with ixekizumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

**The technology**

Ixekizumab is an antibody that inhibits IL-17A (interleukin-17A, a pro-inflammatory cytokine).

**Financial factors**

This technology is commissioned by CCGs. NICE estimates that around 17,300 people with plaque psoriasis who are eligible for biological treatments, are eligible for treatment with ixekizumab in England.

**Daclizumab for treating relapsing–remitting multiple sclerosis TA441**

**Recommendations**

1.1 Daclizumab is recommended as an option for treating multiple sclerosis in adults, only if:

- the person has active relapsing–remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing–remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and
- alemtuzumab is contraindicated or otherwise unsuitable and
- the company provides the drug 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 daclizumab 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**

Daclizumab is a human monoclonal antibody that modulates interleukin-2 signalling to reduce central nervous system pathology, and the occurrence of relapses and disability progression.

**Financial factors**

This technology is commissioned by NHS England. It is estimated that 3,700 people with active relapsing–remitting multiple sclerosis previously treated with

disease-modifying therapy or untreated rapidly-evolving severe relapsing–remitting multiple sclerosis are eligible for treatment with daclizumab in England.

**Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine TA440**

**Recommendations**

1.1 Pegylated liposomal irinotecan, in combination with 5-fluorouracil and leucovorin, is **not recommended**, within its marketing authorisation, for treating metastatic adenocarcinoma of the pancreas in adults whose disease has progressed after gemcitabine-based therapy.

1.2 This guidance is not intended to affect the position of patients whose treatment with pegylated liposomal irinotecan 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**

Pegylated liposomal irinotecan consists of the anticancer drug irinotecan contained within tiny fat particles called nanoliposomes. The nanoliposomes accumulate in the tumour and release irinotecan slowly. Irinotecan blocks an enzyme called topoisomerase I, which causes DNA strands to break. This stops the cancer cells dividing and they eventually die.

**Financial factors**

This technology is not recommended by NICE.

The following NICE Guidelines and updates were published at the end of March, after publication of the March bulletin:

**Cetuximab and panitumumab for previously untreated metastatic colorectal cancer TA439**

**Recommendations**

1.1 Cetuximab is recommended, within its marketing authorisation, as an option for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults in combination with:

- 5-fluorouracil, folinic acid and oxaliplatin (FOLFOX) or
- 5-fluorouracil, folinic acid and irinotecan (FOLFIRI).

1.2 Panitumumab is recommended, within its marketing authorisation, as an option for previously untreated RAS wild-type metastatic colorectal cancer in adults in combination with:

- FOLFOX or
- FOLFIRI.

1.3 The drugs are recommended only when the companies provide them with the discounts agreed in their patient access schemes.

**The technologies**

Cetuximab (Erbitux, Merck Serono) is a chimeric monoclonal IgG1 antibody that is specifically directed against epidermal growth factor receptor (EGFR). Panitumumab (Vectibix, Amgen) is a recombinant, fully human IgG2 monoclonal antibody that binds with high affinity and specificity to human EGFR.

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| | **Financial factors**<br>These technologies are commissioned by NHS England.<br><br>**Alectinib for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer TA438 (terminated appraisal)**<br>NICE is **unable to make a recommendation** about the use in the NHS of alectinib for anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer previously treated with crizotinib because no evidence submission was received from Roche.<br><br>**Panitumumab in combination with chemotherapy for the treatment of metastatic colorectal cancer TA240 (terminated appraisal)**<br>NICE is **unable to recommend** panitumumab with 5‑fluorouracil, folinic acid and irinotecan (FOLFIRI) for previously treated metastatic colorectal cancer in adults because no evidence submission was received from the manufacturer or sponsor of the technology.<br>NICE has published guidance on cetuximab and panitumumab for previously untreated metastatic colorectal cancer.<br>Since the publication of TA240, the population covered by the marketing authorisation for panitumumab has changed from 'patients with wild-type KRAS metastatic colorectal cancer' to 'patients with wild-type RAS metastatic colorectal cancer'. |
| **Highly specialised technology guidance (HSTs)** | None published so far this month. |
| **NICE Guidelines (NGs)** | **Sexually transmitted infections: condom distribution schemes NG68**<br>This guideline covers condom distribution schemes. The aim is to reduce the risk of sexually transmitted infections (STIs). In addition, these schemes can provide a good introduction to broader sexual and reproductive health services, especially for younger people, and help prevent unplanned pregnancies.<br>This guideline includes recommendations on:<br>• targeting services<br>• multicomponent condom distribution schemes for young people in health, education, youth and outreach settings<br>• single component schemes<br><br>**Alcohol-use disorders: diagnosis and management of physical complications CG100 (update)**<br>This guideline covers care for adults and young people (aged 10 years and older) with physical health problems that are completely or partly caused by an alcohol-use disorder. It aims to improve the health of people with alcohol-use disorders by providing recommendations on managing acute alcohol withdrawal and treating alcohol-related conditions.<br><br>**April 2017**: NICE reviewed the evidence for corticosteroid treatment for people with severe alcohol-related hepatitis and changed recommendation 1.3.3.1.<br><br>**Irritable bowel syndrome in adults: diagnosis and management CG61 (update)**<br>This guideline covers diagnosing and managing irritable bowel syndrome (IBS) in people aged 18 and over. It details how to accurately diagnose IBS, and aims to |

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| | improve the quality of life for adults with IBS by promoting effective management using dietary and lifestyle advice, pharmacological therapy and referral for psychological interventions.<br><br>**April 2017:** Recommendation 1.1.1.2 was updated in line with more recent guidance on recognition and referral for suspected cancer. Recommendation 1.1.1.3 was removed as it was no longer needed after the changes to recommendation 1.1.1.2.<br><br>The following NICE Guideline was published at the end of March, after publication of the March bulletin:<br><br>**Managing medicines for adults receiving social care in the community NG67**<br><br>This guideline covers medicines support for adults (aged 18 and over) who are receiving social care in the community. It aims to ensure that people who receive social care are supported to take and look after their medicines effectively and safely at home. It gives advice on assessing if people need help with managing their medicines, who should provide medicines support and how health and social care staff should work together.<br><br>This guideline includes recommendations on:<br>• governance arrangements and joint working between health and social care<br>• assessing medicines support needs<br>• supporting people to take their medicines, including covert administration and managing concerns<br>• staff training and competency<br>• sharing medicines information and record keeping<br>• safely ordering and supplying medicines and transporting, storing and disposing of medicines |
| **NICE Medicines Practice Guidelines (MPGs)** | The following NICE Guideline update was published at the end of March, after publication of the March bulletin:<br><br>**Patient Group Directions MPG2 (update)**<br><br>This guideline covers good practice for developing, authorising, using and updating patient group directions. It also offers advice on deciding whether a patient group direction is needed.<br><br>Patient group directions allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This guideline aims to ensure that patient group directions are used in line with legislation, so that patients have safe and speedy access to the medicines they need.<br><br>**March 2017:** Changes were made to update the format of this guideline and a recommendation was removed because it was out of date. Some changes were also made to make recommendation 1.5.4 clearer and to update recommendation 1.1.10. |
| **Interventional Procedures Guidance (IPGs)** | **Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain IPG578**<br><br>**Recommendations**<br><br>1.1 Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. |

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| | 1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.<br><br>1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.<br><br>**<u>The procedure</u>**<br><br>Chronic pain in the lower back triggered from the sacroiliac (SI) joint occurs in 15% to 30% of patients with low back pain. The causes of SI joint pain include degenerative sacroiliitis, osteoarthritis, SI joint disruptions from trauma or pregnancy, problems after lumbar spinal fixation techniques, anatomical abnormalities such as scoliosis, infection, gout, tumour or idiopathic causes.<br><br>Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilise the joint and treat joint pain.<br><br>Minimally invasive surgical fusion of the sacroiliac (SI) joint is done with the patient under general or spinal anaesthesia and in a prone position. Fluoroscopic guidance is used. Using a lateral transarticular approach, the SI joint is accessed laterally through a small incision made in the buttock to reach the ilium. A pin is passed through the ilium across the SI joint into the centre of the sacrum, avoiding the neural foramen. A drill is then used to create a pathway through the ilium to the sacrum. An implant is inserted (with the lateral portion of the implant sitting in the ilium and the medial end in the sacrum), spanning the SI joint. Typically, 3 implants are used.<br><br>Treatment of both SI joints can be done at the same time, or in staged procedures. After surgery, patients are advised to make a gradual return to full weight bearing over several weeks, using a walker for assistance, and then have physiotherapy. |
| **Medical Technologies Guidance** | None published so far this month. |
| **Diagnostics Guidance** | None published so far this month. |
| **NICE Quality Standards** | None published so far this month. |

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

| Title / link | End date of consultation |
|---|---|
| Nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy [ID971] | 04/05/2017 |
| Vitamin D: increasing supplement use among at-risk groups | 05/05/2017 |
| Eye burns (limbal stem cell deficiency) - holoclar [ID899] | 08/05/2017 |
| Physical health of people in prison | 09/05/2017 |
| Radiofrequency treatment of haemorrhoids | 10/05/2017 |
| Liposuction for chronic lymphoedema | 10/05/2017 |
| Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer | 10/05/2017 |
| Cabozantinib for treating renal cell carcinoma [ID931] | 11/05/2017 |
| End of life care for infants, children and young people | 16/05/2017 |
| Multiple myeloma (relapsed, refractory) - ixazomib citrate [ID807] | 19/05/2017 |
| Carers: provision and support for adult carers | 24/05/2017 |
| Parenteral nutrition in neonates: management | 25/05/2017 |
| Intermediate care including reablement | 26/05/2017 |
| Faltering growth - recognition and management of faltering growth in children | 01/06/2017 |

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