NICE Update Bulletin February 2015 for guidance issued Wednesday 25th February 2015

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)	**Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262) TA329** **Background** Ulcerative colitis is a chronic condition where inflammation develops in the large intestine. Symptoms include bloody diarrhoea, abdominal pain, weight loss, fatigue, anaemia and an urgent need to defaecate. These vary according to the extent and severity of the inflammation. Symptoms can flare up and then disappear for months or even years, but approximately 50% of people with ulcerative colitis will relapse at least once a year. **Recommendations** 1.1 Infliximab, adalimumab and golimumab are recommended, within their marketing authorisations, as options for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme. 1.2 The choice of treatment between infliximab, adalimumab or golimumab should be made on an individual basis after discussion between the responsible clinician and the patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). 1.3 Infliximab is recommended, within its marketing authorisation, as an option for treating severely active ulcerative colitis in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. 1.4 Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: • They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. • They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again. **The technology** Adalimumab, golimumab and infliximab are monoclonal antibodies that inhibit the pro-inflammatory cytokine, TNF-alpha. All 3 have the same marketing authorisation in the UK for the 'treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who are intolerant to or have

medical contraindications for such therapies'.

Financial factors

There is variation in current clinical practice across the country and a lack of data on treatment outcomes. It is anticipated that there will be increased drug costs for clinical commissioning groups. There may be savings from delaying or avoiding surgery, and reduced hospital admissions because of improved disease management.

The acquisition cost for an induction cycle of treatment varies between £2,289 and £5,035 depending on the choice of drug and the maintenance cycle cost varies between £4,910 and £5,455 compared with £50–£850 for conventional drug treatments. Approximately 198 adult patients would be eligible for treatment with TNF–alpha inhibitors under this guidance in the NEW Devon CCG area under standard assumptions.

Sofosbuvir for treating chronic hepatitis C TA330

Background

The hepatitis C virus (HCV) causes inflammation of the liver and affects the liver's ability to function. HCV is a blood-borne virus, meaning that it is spread by exposure to contaminated blood. Contaminated needles used for injecting drugs are currently the most common route of transmission.

Chronic hepatitis is categorised according to the extent of liver damage, as mild, moderate, or severe (where severe refers to cirrhosis). About 30% of people infected with HCV will develop cirrhosis; the time for progression to cirrhosis varies, but takes 40 years on average.

Recommendations

1.1 Sofosbuvir is recommended as an option for treating chronic hepatitis C in adults depending on the patient genotype and treatment history.

1.2 People currently receiving treatment initiated within the NHS with sofosbuvir that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

The technology

Sofosbuvir is a uridine nucleotide analogue that inhibits hepatitis C virus (HCV) polymerase, preventing viral replication.

Financial factors

NHS England commissions this technology. The estimated cost of implementing the guidance is £106 million for the population of England. This cost includes savings from onward transmissions avoided of £10 million and resources released from reduced treatment periods (£10 million). The population eligible for treatment is approximately 28,600 people per year in England.

The cost of a 12 week course of treatment is £34,982 and a 24 week course is £69,965 (both excluding VAT), not including the cost for ribavirin and peginterferon alfa. Costs may vary in different settings because of negotiated procurement discounts.

Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C TA331

Background

The true prevalence of HCV infection is difficult to establish and likely to be underestimated because many people do not have symptoms. There are 6 major genotypes and several subtypes of HCV; the prevalence of each varies geographically. People can be infected with more than 1 genotype. The most recent national estimates (2012) suggest that around 215,000 people are chronically infected with HCV in the UK and that approximately 90% of these people are infected with genotype 1 or genotype 3. However, more than half of people with chronic hepatitis C are unaware of their infection.

Recommendations

This guidance gives recommendations for simeprevir in combination with peginterferon alfa and ribavirin. Simeprevir also has a marketing authorisation for use in combination with sofosbuvir. Recommendations for simeprevir in combination with sofosbuvir will be

developed in separate guidance.

1.1 Simeprevir, in combination with peginterferon alfa and ribavirin, is recommended within its marketing authorisation as an option for treating genotype 1 and 4 chronic hepatitis C in adults.

The technology

Simeprevir is a protease inhibitor. It inhibits the NS3/4A enzyme that is essential for HCV replication and therefore prevents viral replication. Simeprevir is administered orally.

Financial factors

NHS England commissions this technology.

The estimated cost of implementing the guidance is £4 million for the population of England. This cost includes savings from onward transmissions avoided of £3 million and resources released from reduced treatment periods £3 million. The population eligible for treatment is approximately 13,200 people per year in England.

Sipuleucel-T for treating asymptomatic or minimally symptomatic metastatic hormone-relapsed prostate cancer TA332

Background

Prostate cancer is a disease in which tumours develop in the prostate, a gland in the male reproductive system. Its cause is thought to be multi-factorial, involving both environmental and genetic factors. The incidence of prostate cancer increases with age and is higher in men of African-Caribbean family origin.

Around 55–65% of people with prostate cancer develop metastatic disease (that is, the cancer spreads to other parts of the body). Metastatic prostate cancer initially responds to hormonal therapy in over 90% of people but eventually become resistant to it. This clinical condition is described as hormone-relapsed prostate cancer.

Recommendations

1.1 Sipuleucel **is not recommended** within its marketing authorisation for treating adults who have asymptomatic or minimally symptomatic metastatic non visceral hormone relapsed prostate cancer for which chemotherapy is not yet clinically indicated.

The technology

Sipuleucel-T is an autologous cellular immunotherapy that stimulates the patient's own immune cells to identify and attack prostate cancer cells. The treatment involves collecting white blood cells from the patient, combining the cells with a protein to make sipuleucel-T, and then infusing the cells back into the patient.

Financial factors

Sipuleucel T is not recommended within its marketing authorisation as a result, no significant resource impact is anticipated.

Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment TA333

Background

Renal cell carcinoma (RCC) is a type of kidney cancer that usually originates in the lining of the tubules of the kidney and contains many blood vessels. American Joint Committee on Cancer (AJCC) tumour node metastases (TNM) system is used to grade RCC into stages I to IV. Advanced RCC, in which the tumour is either locally advanced and/or has spread to regional lymph nodes, is generally defined as stage III or IV. Metastatic RCC, in which the tumour has spread beyond the regional lymph nodes to other parts of the body, is also defined as stage IV.

Recommendations

1.1 Axitinib is recommended as an option for treating adults with advanced renal cell carcinoma after failure of treatment with a first-line tyrosine kinase inhibitor or a cytokine, only if the company provides axitinib with the discount agreed in the patient access scheme.

1.2 At the time of publication (February 2015), axitinib has a UK marketing

	authorisation only for use after failure with first-line sunitinib or a cytokine. If it is considered for use after any other first-line treatments, the prescriber should obtain and document informed consent and follow the relevant guidance published by the General Medical Council. 1.3 Because the remit referred to NICE by the Department of Health for this technology appraisal only includes adults who have been previously treated with sunitinib, the use of axitinib after treatment with other tyrosine kinase inhibitors is not subject to statutory funding. **The technology** Axitinib is an oral multi-targeted tyrosine kinase inhibitor with anti-tumour activity. Axitinib selectively inhibits vascular endothelial growth factor receptors 1, 2 and 3, platelet-derived growth factor receptor, and c-kit, which may inhibit angiogenesis in tumours. **Financial factors** NHS England commissions this technology as part of specialised cancer services. There are currently no second-line drugs approved by NICE for treating advanced renal cell carcinoma after failure of first-line treatments. The estimated cost of implementing the guidance is £12 million for the population of England. This cost is before taking into account the discount available in the patient access scheme. The population eligible for treatment is approximately 1,500 people per year in England. **Regorafenib for metastatic colorectal cancer after treatment for metastatic disease (terminated appraisal) TA334** **Recommendations** NICE is unable to make a recommendation about the use in the NHS of regorafenib for metastatic colorectal cancer after treatment for metastatic disease because no evidence submission was received from Bayer for the technology
Highly specialized technology guidance (HSTs)	**None published so far this month**

Note: From January 2015 NICE has decided to use a single set of methods and processes to develop all NICE guidelines, whether they are clinical, public health, social care, safe staffing or medicines practice.

Technology appraisals, interventional procedures, medical technologies and diagnostics guidance; and quality standards and advice products, are unaffected by this change.

NICE Guidelines (NGs)	**Bladder cancer: diagnosis and management of bladder cancer NG2** **Background information** Bladder cancer is the seventh most common cancer in the UK. It is 3–4 times more common in men than in women. In the UK in 2011, it was the fourth most common cancer in men and the thirteenth most common in women. The majority of cases occur in people aged over 60. The main risk factor for bladder cancer is increasing age, but smoking and exposure to some industrial chemicals also increase risk. **Key priorities for implementation** • Information and support for people with bladder cancer • Diagnosing and staging bladder cancer • Treating non-muscle-invasive bladder cancer

- Follow-up after treatment for non-muscle-invasive bladder cancer
- Treating muscle-invasive bladder cancer

The recommendations in full cover

1.1 Information and support for people with bladder cancer

1.2 Diagnosing and staging bladder cancer

1.3 Treating non-muscle-invasive bladder cancer

1.4 Follow-up after treatment for non-muscle-invasive bladder cancer

1.5 Treating muscle-invasive bladder cancer

1.6 Follow-up after treatment for muscle-invasive bladder cancer

1.7 Managing locally advanced or metastatic muscle-invasive bladder cancer

1.8 Specialist palliative care for people with incurable bladder cancer

Financial factors

Using the standard assumptions the estimated annual impact of implementing these recommendations in England produce a saving of £6.1 million. Although this cost impact is not significant at a national level, costs could vary widely depending on which secondary diagnostic technique is adopted.

Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period NG3

Background information

Approximately 700,000 women give birth in England and Wales each year, and up to 5% of these women have either pre-existing diabetes or gestational diabetes. Of women who have diabetes during pregnancy, it is estimated that approximately 87.5% have gestational diabetes 7.5% have type 1 diabetes and the remaining 5% have type 2 diabetes. The incidence of gestational diabetes is also increasing as a result of higher rates of obesity in the general population and more pregnancies in older women. Diabetes in pregnancy is associated with risks to the woman and to the developing fetus

Key priorities for implementation

- Preconception planning and care
- Gestational diabetes
- Antenatal care for women with diabetes
- Intrapartum care
- Postnatal care

The recommendations in full cover

1.1 Preconception planning and care

1.2 Gestational diabetes

1.3 Antenatal care for women with diabetes

1.4 Intrapartum care

1.5 Neonatal care

1.6 Postnatal care

Financial factors

Expert clinical opinion suggests current practice is highly variable and the guideline might have resource implications at a local level. Because the cost impact of the recommendations may vary, organisations are encouraged to evaluate their own practice against the recommendations in the NICE guideline and assess costs and savings locally.

Potential areas for additional costs locally are:

	• the cost of prescribing a greater number of blood glucose monitoring strips • the cost of additional ultrasounds and hospital appointments • the cost of additional HbA1c tests. If gestational diabetes is not managed properly or is not detected, it could cause a range of serious complications. Avoiding such complications could lead to potential savings and benefits, including: • reduction in complications during pregnancy and labour and their related costs • improved care for the mother and baby. **Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care CG61** **Background information** Irritable bowel syndrome (IBS) is a chronic, relapsing and often life-long disorder. It is characterised by the presence of abdominal pain or discomfort, which may be associated with defaecation and/or accompanied by a change in bowel habit. Symptoms may include disordered defaecation (constipation or diarrhoea or both) and abdominal distension, usually referred to as bloating. Symptoms sometimes overlap with other gastrointestinal disorders such as non-ulcer dyspepsia or coeliac disease. IBS most often affects people between the ages of 20 and 30 years and is twice as common in women as in men. Prevalence in the general population is estimated to be between 10% and 20%. **Key priorities for implementation** • Initial assessment • Diagnostic tests • Dietary and lifestyle advice • Pharmacological therapy **The recommendations cover** 1.1 Diagnosis of IBS 1.2 Clinical management of IBS **Financial factors** The recommendation on linaclotide (a guanylate cyclase-C receptor agonist) may have a potential resource impact. People with IBS should only be prescribed linaclotide if optimal or maximum tolerated doses of previous laxatives from different classes have not helped **and** they have had constipation for at least 12 months Linaclotide costs are approximately £488 per annum per person. The impact of implementing this recommendation in the guidance will depend on current clinical practice.
Interventional Procedures Guidance (IPGs)	**Flexible endoscopic treatment of a pharyngeal pouch IPG213** **Recommendations** 1.1 Current evidence on the efficacy and safety of flexible endoscopic treatment of a pharyngeal pouch is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Flexible endoscopic treatment of a pharyngeal pouch should only be done by experienced interventional endoscopists with training in the procedure. **The procedure** Flexible endoscopic treatment of a pharyngeal pouch is done with the patient under sedation or general anaesthesia. Initially, a diagnostic endoscopy is done, identifying the normal oesophageal lumen and allowing a nasogastric tube to be inserted.

Medical Technologies Guidance	**TheTURis system for transurethral resection of the prostate MTG23** **Background** An enlarged prostate gland is common in older men and can cause problems in passing urine. If lifestyle changes or medication do not help, surgery to remove prostate tissue may be offered. TURis is a surgical system that uses electric current to remove prostate tissue. NICE has said that the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate' (or monopolar TURP). **Recommendations** 1.1 The case for adopting the transurethral resection in saline (TURis) system for resection of the prostate is supported by the evidence. Using bipolar diathermy with TURis instead of a monopolar system avoids the risk of transurethral resection syndrome and reduces the need for blood transfusion. It may also reduce the length of hospital stay and hospital readmissions. 1.2 Using the transurethral resection in saline (TURis) system instead of monopolar transurethral resection of the prostate (TURP) results in an estimated saving of £71 per patient for hospitals that already use an Olympus monopolar system and an estimated additional cost of £20 per patient for other hospitals. However, there is some evidence of a reduction in readmissions with the TURis system compared with monopolar TURP. If this evidence is included, using the TURis system results in an estimated saving of £375 per patient for hospitals that already use an Olympus monopolar system and an estimated saving of £285 per patient for other hospitals.
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Psychosis and schizophrenia in adults QS80** This quality standard covers the treatment and management of psychosis and schizophrenia (including related psychotic disorders such as schizoaffective disorder, schizophreniform disorder and delusional disorder) in adults (18 years and older) with onset before the age of 60 years in primary, secondary and community care. It will not cover adults with transient psychotic symptoms. **Inflammatory bowel disease QS81** This quality standard covers the diagnosis and management of inflammatory bowel disease (Crohn's disease and ulcerative colitis) in adults, children and young people. For more information see the topic overview.
Commissioning Guides	**None published so far this month**
Public health briefings for local government	**Older people in care homes LGB25** This briefing summarises NICE's key recommendations for local authorities and partner organisations on the health and care of older people in care homes. It also highlights relevant quality standards. It is particularly relevant to health and wellbeing boards, scrutiny panels, councillors and adult social care commissioners. **Tackling the causes of premature mortality (early death) LGB26** This briefing summarises NICE's recommendations for local authorities and partner organisations on tackling the more direct causes of premature mortality. It is particularly relevant to health and wellbeing boards and others with a responsibility for, or interest in, delivering the Department of Health's Public Health Outcomes Framework for England 2013 to 2016 and the government's call for action Living well for longer: a call to action to reduce avoidable premature mortality.

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
CG120 Psychosis with coexisting substance misuse - Assessment and management in adults and young people: surveillance review proposal	13/02/2015	27/02/2015
Eating disorders (update): scope consultation	02/02/2015	02/03/2015
Lower urinary tract symptoms (update SC): addendum consultation	03/02/2015	03/03/2015
Diabetes in children and young people: guideline consultation	10/12/2014	04/03/2015
Diabetic foot problems: guideline consultation	07/01/2015	04/03/2015
Type 2 Diabetes: guideline consultation	07/01/2015	04/03/2015
Type 1 Diabetes (update): guideline consultation	10/12/2015	04/03/2015
Smoking - harm reduction: quality standard consultation	05/02/2015	05/03/2015
Rifaximin for preventing episodes of overt hepatic encephalopathy: final appraisal determination	19/02/2015	05/03/2015
CG107 Hypertension in pregnancy: surveillance review proposal	24/02/2015	09/03/2015
Asthma - diagnosis and monitoring: guideline consultation	28/01/2015	11/03/2015
Macular oedema (diabetic) - aflibercept [ID717]: appraisal consultation	20/02/2015	12/03/2015
Macular oedema (diabetic) - dexamethasone intravitreal implant [ID653]: appraisal consultation	20/02/2015	12/03/2015
Melanoma: guideline consultation	30/01/2015	13/03/2015
Atrial fibrillation: quality standard consultation	13/02/2015	13/03/2015
Antimicrobial Stewardship: guideline consultation	18/02/2015	17/03/2015
Organ rejection (liver transplantation, prevention) - everolimus: appraisal consultation	25/02/2015	18/03/2015
Cyanoacrylate embolisation of refluxing great saphenous veins for varicose veins: consultation	20/02/2015	19/03/2015
Living-donor liver transplantation: consultation	20/02/2015	19/03/2015
Transcutaneous cranial electrical stimulation for insomnia, depression or anxiety: consultation	20/02/2015	19/03/2015
Venous Thromboembolism - Reducing the risk: addendum consultation	24/02/2015	24/03/2015
Cataracts: scope consultation	25/02/2015	25/03/2015

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