NICE Update Bulletin December 2017

Hyperlinks to the relevant NICE web page are included below.

Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number
Technology Appraisals (TAs)	**Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer TA496** **Recommendation** 1.1 Ribociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Ribociclib is recommended only if the company provides it with the discount agreed in the patient access scheme. **The technology** Ribociclib in combination with an aromatase inhibitor is indicated for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy. **Financial factors** This technology is commissioned by NHS England. Ribociclib has a patient access scheme, agreed between the Department of Health and Novartis, which makes it available with a commercial-in-confidence discount to the list price. NICE estimates that 7,500 women with HR-positive, HER2-negative, locally advanced or metastatic breast cancer are eligible for treatment with ribociclib per year. And 900 women will have ribociclib from year 3 onwards once uptake of CDK inhibitor therapy has reached 50%. Of these 50%, 30% of women are assumed to take ribociclib from 2019/20 onwards. **Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer TA495** **Recommendation** 1.1 Palbociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Palbociclib is recommended only if the company provides it with the discount agreed in the patient access scheme. **The technology** Palbociclib is indicated for treating hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor
- in combination with fulvestrant in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist.

Financial factors

This technology is commissioned by NHS England.

Palbociclib has a patient access scheme, agreed between the Department of Health and Pfizer, which makes it available with a commercial-in-confidence discount to the list price.

NICE estimates that 7,500 women with HR-positive, HER2-negative metastatic breast cancer are eligible for treatment with palbociclib each year. And 2,800 women will have palbociclib from year 3 onwards once uptake of CDK inhibitors has reached 50% and 70% of these women take palbociclib.

Naltrexone–bupropion for managing overweight and obesity TA494

Recommendations

1.1 Naltrexone–bupropion is **not recommended** within its marketing authorisation for managing overweight and obesity in adults alongside a reduced-calorie diet and increased physical activity.

1.2 This recommendation is not intended to affect treatment with naltrexone–bupropion that was started in the NHS before this guidance was published. Adults having treatment outside this recommendation 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

Naltrexone–bupropion has a marketing authorisation, as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (aged 18 and over) with an initial BMI of 30 kg/m^2 or more (obese) or from 27 kg/m^2 to 30 kg/m^2 (overweight) in the presence of one or more weight-related co-morbidities (such as type 2 diabetes, dyslipidaemia, or controlled hypertension).

Treatment should be stopped after 16 weeks if the patient has not lost at least 5% of their initial body weight.

Financial factors

Naltrexone–bupropion is not recommended within its marketing authorisation for managing overweight and obesity in adults alongside a reduced-calorie diet and increased physical activity.

NICE has said that the estimate of cost effectiveness for naltrexone–bupropion with lifestyle measures, compared with lifestyle measures alone, is highly uncertain because of uncertainties in the modelling assumptions. Large numbers of people could be eligible for treatment which could potentially be long-term, leading to high overall costs for naltrexone–bupropion. Therefore, in these circumstances more certainty is needed that naltrexone–bupropion will provide value for the NHS.

Cladribine tablets for treating relapsing–remitting multiple sclerosis TA493

Recommendations

1.1 Cladribine tablets are recommended as an option for treating highly active multiple sclerosis in adults, only if the person has:

- rapidly evolving severe relapsing–remitting multiple sclerosis, that is, at least 2 relapses in the previous year and at least 1 T1 gadolinium-enhancing lesion at baseline MRI or

- relapsing–remitting multiple sclerosis that has responded inadequately to treatment with disease-modifying therapy, defined as 1 relapse in the previous year and MRI evidence of disease activity.

1.2 This recommendation is not intended to affect treatment with cladribine tablets that was started in the NHS before this guidance was published. People having treatment outside this recommendation 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

Cladribine tablets are indicated for the treatment of adult patients with highly active relapsing multiple sclerosis as defined by clinical or imaging features.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because the technology is an option alongside current standard treatment options.

Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable TA492

This guidance only includes recommendations for untreated urothelial carcinoma when cisplatin-based chemotherapy is unsuitable. NICE is developing separate guidance for urothelial carcinoma that has progressed after platinum-containing chemotherapy.

Recommendations

1.1 Atezolizumab is recommended **for use within the Cancer Drugs Fund** as an option for untreated locally advanced or metastatic urothelial carcinoma in adults, for whom cisplatin-based chemotherapy is unsuitable, only if the conditions of the managed access agreement for atezolizumab are followed.

1.2 This recommendation is not intended to affect treatment with atezolizumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation 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

Atezolizumab has a marketing authorisation for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy or who are considered cisplatin ineligible.

Financial factors

This technology is commissioned by NHS England.

It is estimated that up to 1,000 people per year with metastatic urothelial carcinoma are eligible for treatment with atezolizumab.

Atezolizumab will be available to the NHS in line with the managed access agreement with NHS England. As part of this, NHS England and Roche have a commercial access agreement that makes atezolizumab available to the NHS at a reduced cost, the terms of which are commercial in confidence.

The resource impact will be covered by the Cancer Drugs Fund budget. The data collection period is expected to end in December 2020, when the final analyses of the IMvigor 130 trial are available. The process for exiting the Cancer Drugs Fund will begin at this point and review of the NICE guidance will start. The aim of the review is to decide whether or not the drug can be recommended for routine use.

Highly specialised technology guidance (HSTs)	None published so far this month.
NICE Guidelines (NGs)	**Autism spectrum disorder in under 19s: recognition, referral and diagnosis CG128 (update)** This guideline covers recognising and diagnosing autism spectrum disorder in children and young people from birth up to 19 years. It also covers referral. It aims to improve the experience of children, young people and those who care for them. **December 2017:** NICE reviewed the evidence and added ADHD as a factor associated with an increased prevalence of autism and changed references from DSM-4 to DSM-5.
NICE Public Health Guidelines	None published so far this month.
NICE Medicines Practice Guidelines	None published so far this month.
Interventional Procedures Guidance (IPGs)	**Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death IPG603** This guidance replaces NICE interventional procedures guidance on insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death (IPG454). **Recommendations** 1.1 Current evidence on the safety and efficacy of subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit. 1.2 Clinicians should enter details about all patients having subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death onto a register by submitting data to the National Audit of Cardiac Rhythm Management database at the UK National Institute for Cardiovascular Outcomes Research (NICOR), and should review local clinical outcomes. 1.3 The procedure should only be done by clinicians with specific training on inserting the device. **The procedure** A subcutaneous implantable cardioverter-defibrillator (ICD) is a device that is placed under the skin of the chest. It detects and treats fast heartbeats called tachyarrhythmias. The device uses electric shocks to help control life-threatening arrhythmias that can cause sudden cardiac death. **Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure IPG602** **Recommendations** 1.1 Current evidence on the safety and efficacy of total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure 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 total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety 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 total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure

1.3 Clinicians should enter details about all patients having total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure onto an appropriate registry and review local clinical outcomes.

1.4 Patient selection should be done by a multidisciplinary team experienced in managing end-stage refractory biventricular heart failure in patients needing a heart transplant, for whom a donor organ is not expected to be available before their own heart fails completely.

1.5 This technically challenging procedure should only be done in centres specialising in heart transplantation. Only cardiothoracic surgeons with specific expertise and training in inserting the device should carry it out.

1.6 NICE encourages further research into total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure, including well matched comparative studies. NICE may update the guidance on publication of further evidence.

The procedure

End-stage biventricular heart failure means that both sides of the heart are no longer strong enough to pump blood around the body. An artificial heart implant involves removing the weakened 2 lower chambers of the heart and 4 valves of the heart and fixing a mechanical device to take over their role. The device is powered by batteries or an external power supply. It can be used for people who are waiting for a heart transplant and are at risk of dying. The aim is to extend life until a donor heart becomes available.

Transcutaneous microwave ablation for severe primary axillary hyperhidrosis IPG601

Recommendations

1.1 Current evidence on the safety and efficacy of transcutaneous microwave ablation for severe primary axillary hyperhidrosis is inadequate 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 microwave ablation for severe primary axillary hyperhidrosis should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In particular, during the consent process patients should be informed about the possibility of nerve damage. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having transcutaneous microwave ablation for severe primary axillary hyperhidrosis.

1.3 NICE encourages further research into transcutaneous microwave ablation for severe primary axillary hyperhidrosis and may update the guidance on

publication of further evidence. Further research should include information on patient selection, objective measures of physiological effect, patient-reported outcome measures and long-term outcomes.

The procedure

Axillary hyperhidrosis is excessive underarm sweating. In this procedure, a hand-held device sends microwaves to the sweat glands in the armpit to damage them. The treatment may need to be repeated about 3 months later. The aim is to destroy the glands and stop the sweating.

Endobronchial valve insertion to reduce lung volume in emphysema IPG600

This guidance replaces NICE interventional procedures guidance on insertion of endobronchial valves for lung volume reduction in emphysema (IPG465).

Recommendations

1.1 Current evidence on the safety and efficacy of endobronchial valve insertion to reduce lung volume in emphysema is adequate in quantity and quality to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a multidisciplinary team experienced in managing emphysema, which should typically include a chest physician, a radiologist, a thoracic surgeon and a respiratory nurse.

1.3 Patients selected for treatment should have had pulmonary rehabilitation.

1.4 The procedure should only be done to occlude volumes of the lung where there is no collateral ventilation, by clinicians with specific training in doing the procedure.

The procedure

Emphysema is a chronic lung disease that causes the walls of the smaller airways in the lungs to break down. This creates abnormally large spaces in the lung so that when a person breathes in, most of the air goes into these spaces, reducing the amount of air that reaches the healthy areas. In this procedure, a thin flexible tube with a camera on the end (bronchoscope) is moved through the nose or mouth into the lungs, and small one-way valves are then placed in some airways leading to the damaged parts of the lungs. The aim is to reduce the air flowing in to the damaged parts, allowing more air to reach the healthy areas.

Transvaginal mesh repair of anterior or posterior vaginal wall prolapse IPG599

This guidance replaces NICE interventional procedures guidance on surgical repair of vaginal wall prolapse using mesh (IPG267).

Recommendations

1.1 Current evidence on the safety of transvaginal mesh repair of anterior or posterior vaginal wall prolapse shows there are serious but well-recognised safety concerns. Evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used **in the context of research**.

1.2 All adverse events involving the medical devices (including the mesh) used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

1.3 Further research should include details of patient selection, long-term outcomes including complications, type of mesh used and method of fixation, and quality of life.

The procedure

Vaginal wall prolapse occurs when the tissue supporting the pelvic organs (the

	womb [uterus], the bladder or the rectum) is weakened by events such as pregnancy, childbirth or hysterectomy. This can lead to one or more of the organs dropping down (prolapsing) into the vagina, which can cause pressure, bulging, heaviness or discomfort and can also affect urinary, bowel or sexual function. In this procedure, a mesh is inserted to replace the weakened tissue. The aim is to move the organs back into their correct positions.
Medical Technologies Guidance	None published so far this month.
Diagnostics Guidance	**Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point of care coagulometers (the CoaguChek XS system) DG14 (update)** **December 2017:** The guidance title and recommendations have been amended because the InRatio2 PT/INR is no longer available. **Recommendations** 1.1 The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if: • the person prefers this form of testing and • the person or their carer is both physically and cognitively able to self-monitor effectively. 1.2 This recommendation has been removed because the InRatio2 PT/INR monitor is no longer available. 1.3 Patients and carers should be trained in the effective use of the CoaguChek XS system and clinicians involved in their care should regularly review their ability to self-monitor. 1.4 Equipment for self-monitoring should be regularly checked using reliable quality control procedures, and by testing patients' equipment against a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme. Ensure accurate patient records are kept and shared appropriately. 1.5 For people who may have difficulty with or who are unable to self-monitor, such as children or people with disabilities, their carers should be considered to help with self-monitoring. **The diagnostic test** The CoaguChek XS system (Roche Diagnostics) comprises a meter and specifically designed test strips that can analyse a blood sample (fresh capillary blood or fresh untreated whole venous blood) and calculate the prothrombin time and the international normalised ratio (INR). These measures indicate the rate at which the blood clots. If the INR is too low, there is a higher risk of blood clots that can lead to a heart attack or a stroke. If the INR is too high, there is a higher risk of bleeding, which in severe cases can be gastrointestinal or intracerebral bleeding.
NICE Quality Standards	**Suspected cancer QS124 (update)** This quality standard covers the investigation and recognition of suspected cancer, and referral to specialist cancer services for adults, young people and children. It describes high-quality care in priority areas for improvement. **December 2017:** the source guidance and definitions for statement 3 were amended to reflect the NICE diagnostics guidance on quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care.

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

Title / link	End date of consultation
Black, Asian and other minority ethnic groups: promoting health and preventing premature mortality	08/01/2018
Eating disorders	08/01/2018
Hearing loss in adults: assessment and management	12/01/2018
Asthma (update)	15/01/2018
Cochlear implants for children and adults with severe to profound deafness	15/01/2018
Atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy [ID1327]	17/01/2018
Serious eye disorders	18/01/2018
Cystic fibrosis	19/01/2019
Developmental follow-up of children and young people born preterm	19/01/2018
Nerve transfer for restoration of upper limb function in tetraplegia	22/01/2018
Robot-assisted kidney transplant	22/01/2018
Prostate Artery Embolisation for Benign Prostatic Hyperplasia	22/01/2018
Micro-invasive subconjunctival insertion of a transcleral gelatin stent for primary open-angle glaucoma	22/01/2018
Multiple sclerosis - interferon beta, glatiramer acetate (review TA32) [ID809]	24/01/2018
Afamelanotide for treating erythropoietic protoporphyria [ID927]	24/01/2018
Decision making and mental capacity	05/02/2018

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