NICE Update Bulletin: February 2019

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)	**Dabrafenib with trametinib for treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer TA564 (terminated appraisal)** NICE is unable to make a recommendation about the use in the NHS of dabrafenib with trametinib for treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer because no evidence submission was received from Novartis. NICE will review this decision if the company decides to make a submission. **Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer TA563** **Recommendations** 1.1 Abemaciclib with an aromatase inhibitor is recommended, within its marketing authorisation, as an option for treating locally advanced or metastatic, hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer as first endocrine-based therapy in adults. Abemaciclib is recommended only if the company provides it according to the commercial arrangement. **The technology** Abemaciclib is indicated for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine-based therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. The recommended dose is 150 mg taken orally, twice daily, alongside treatment with an aromatase inhibitor. Treatment should be continued as long as the patient is having clinical benefit or until unacceptable toxicity occurs. Some adverse reactions may need to be managed by temporary dose reductions, dose interruptions, or permanently stopping the treatment. **Financial factors** This technology is commissioned by NHS England. NICE estimates that 8,200 people in England with locally advanced or metastatic, hormone receptor positive, HER2-negative breast cancer are eligible for treatment with abemaciclib. The market share of cyclin-dependent kinase (CDK) inhibitors (abemaciclib, palbociclib and ribociclib) with an aromatase inhibitor will be 60%, which is around 4,900 people, and 2,000 people will start treatment with abemaciclib each year from year 3 onwards

once uptake has reached 40%.

Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma TA562

Recommendations

1.1 Encorafenib with binimetinib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic BRAF V600 mutation-positive melanoma in adults. It is recommended only if the company provides encorafenib and binimetinib according to the commercial arrangements.

The technology

Encorafenib in combination with binimetinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

For encorafenib, the recommended dose is 450 mg (6×75-mg capsules) taken orally, once daily. For binimetinib, the recommended dose is 45 mg (3×15-mg tablets) taken orally, twice daily, 12 hours apart.

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 and the population size is small.

Venetoclax with rituximab for previously treated chronic lymphocytic leukaemia TA561

Recommendations

1.1 Venetoclax with rituximab is recommended, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia in adults who have had at least 1 previous therapy. It is recommended only if the company provides it according to the commercial arrangement.

The technology

Venetoclax plus rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least 1 prior therapy.

Venetoclax should be administered:

- in the titration phase, 20 mg orally once daily for 7 days, increasing by gradual weekly increments over 5 weeks to 400 mg once daily
- in the post-titration phase, 400 mg orally once daily.

Rituximab should be administered after the patient has completed the dose-titration schedule and has had the recommended daily dose of 400 mg venetoclax for 7 days. Rituximab 375 mg/m^2 is given intravenously on day 1 of cycle 1 (a cycle is 28 days), followed by 500 mg/m^2 on day 1 of cycles 2 to 6. Rituximab is stopped after cycle 6.

Venetoclax can be taken for a maximum of 2 years from day 1 of cycle 1 of rituximab, or until disease progression or unacceptable toxicity (see the summary of product characteristics).

	Financial factors This technology is commissioned by NHS England. NICE estimates that 710 people in England with CLL are eligible for treatment with venetoclax with rituximab, and 640 people will start treatment with venetoclax with rituximab and 640 people will continue treatment from prior years from year 2021/22 onwards once uptake has reached 90%. The average treatment durations of venetoclax with rituximab (22 months) and ibrutinib (56 months). **Bevacizumab with carboplatin, gemcitabine and paclitaxel for treating the first recurrence of platinum-sensitive advanced ovarian cancer TA560 (terminated appraisal)** NICE is unable to make a recommendation about the use in the NHS of bevacizumab with carboplatin, gemcitabine and paclitaxel for treating the first recurrence of platinum-sensitive advanced ovarian cancer because no evidence submission was received from Roche. NICE will review this decision if the company decides to make a submission.
Highly specialised technology guidance (HSTs)	None published so far this month.
NICE Guidelines (NGs)	**Antenatal care for uncomplicated pregnancies CG62 (update)** This guideline covers the care that healthy women and their babies should be offered during pregnancy. It aims to ensure that pregnant women are offered regular check-ups, information and support. **February 2019:** NICE withdrew a recommendation on screening for German measles (rubella), as this is no longer offered by the NHS.
Public Health Guidelines	None published so far this month.
Antimicrobial prescribing guidelines	**Cough (acute): antimicrobial prescribing NG120** This guideline sets out an antimicrobial prescribing strategy for acute cough associated with an upper respiratory tract infection or acute bronchitis in adults, young people and children. It aims to limit antibiotic use and reduce antibiotic resistance. This guideline includes recommendations on: • treatment • reassessment • referral and seeking specialist advice • self-care • choice of antibiotic
Social Care Guidelines	None published so far this month.

Interventional Procedures Guidance (IPGs)	**High-intensity focused ultrasound for symptomatic benign thyroid nodules IPG643** **Recommendations** 1.1 The evidence on the safety of high-intensity focused ultrasound for symptomatic benign thyroid nodules raises no major safety concerns, however the current evidence on its 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 high-intensity focused ultrasound for symptomatic benign thyroid nodules should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having high-intensity focused ultrasound for symptomatic benign thyroid nodules. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion). 1.3 Further research should report details of patient selection, nodule size and position, and whether the nodule is cystic. **The condition** Thyroid nodules may be cystic, colloid, hyperplastic, adenomatous or cancerous. Most thyroid nodules are benign and are usually asymptomatic. There may be a single thyroid nodule (solitary nodule) or multiple thyroid nodules (multinodular goitre). Some thyroid nodules produce thyroxine or triiodothyronine and cause thyrotoxicosis. These are called hyperfunctioning or toxic thyroid nodules. Treatment of benign thyroid nodules may be needed if they cause symptoms or cosmetic problems. Conventional treatment includes surgery. Other less invasive approaches than surgery include ethanol ablation, percutaneous laser ablation, radiofrequency ablation and microwave ablation. **The procedure** High-intensity focused ultrasound is a minimally invasive technique that aims to reduce symptoms and improve cosmetic appearance, while preserving thyroid function, and with fewer complications than surgery. High-intensity focused ultrasound for symptomatic benign thyroid nodules is usually done using sedation and systemic analgesia, in an outpatient setting. The patient is placed in the supine position with moderate neck extension. The focused ultrasound device is positioned on the patient's neck to deliver the treatment and allow for simultaneous imaging of the treatment area. The technology uses high-energy sound waves that pass through the tissues, generating local heat and inducing coagulative necrosis, protein denaturation and cellular destruction. A strong acute inflammatory response follows. The treatment duration depends on the nodule size.

Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal IPG642

Recommendations

1.1 The evidence on the safety of Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal shows that there are serious but well-recognised safety concerns. Current evidence on its 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 Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. They should provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Audit, review and publish clinical outcomes of all patients having Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal. This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

1.3 The procedure should only be done by experienced colorectal surgeons with training and mentoring in the specific technique.

1.4 Further research should include details of patient selection, durability and the incidence of complications. Outcomes should be published.

The condition

Various groups of patients may need surgery to remove the colon and sometimes the rectum. They include patients with: ulcerative colitis that is unresponsive to medical treatment or who cannot tolerate the treatment; familial adenomatous polyposis; Crohn's disease; or cancer-related problems. An ileostomy is then needed to allow intestinal contents to exit the body through a stoma on the abdominal wall.

There are different surgical techniques for creating an ileostomy, including: a Brooke ileostomy (this involves creating a standard stoma that empties intestinal contents continuously into an external ileostomy bag); or a Kock continent ileostomy (this involves creating an internal ileal reservoir connected through the abdominal wall, which is drained intermittently by the patient). In patients with good anal sphincter control, a long-term ileostomy may be avoided by creating an ileal pouch reservoir connected directly to the anus (ileal pouch-anal anastomosis).

The procedure

The Barnett Continent Intestinal Reservoir is a type of continent ileostomy and may be considered as an option for some patients.

A pouch incorporating a collar and an isoperistaltic valve is created using the last 60 cm of the ileum. The valve is made by intussuscepting a segment of small bowel and fixing it to the pouch wall with staples.

	This valve functions in the opposite direction to that in a Kock pouch, ensuring the bowel's normal peristaltic action keeps intestinal contents in the pouch rather than expelling them. The collar is formed by wrapping a segment of small bowel around the top of the pouch and valve. It holds the valve in place and provides further continence when the pouch is full and under high pressure. The flat stoma opening is located just above the pubic area and covered with a small adhesive dressing. When there is a sensation of fullness, the patient drains the pouch by inserting a catheter through the stoma and valve into the pouch. This is typically done 2 or 3 times a day, but the patient determines the exact frequency.
Medical Technologies Guidance	None published so far this month.
Diagnostics Guidance	None published so far this month.
NICE Quality Standards	**People's experience using adult social care services QS182** This quality standard covers the experience of adults using social care services. It applies to all settings where people use social care services, including people's own homes, residential care and community settings. Its aim is to help people understand what care they can expect and to improve their experience by supporting them to make decisions about their care. It describes high-quality care in priority areas for improvement. **Air pollution QS181** This quality standard covers road-traffic-related air pollution and its impact on health. It describes high-quality actions in priority areas for improvement. **Serious eye disorders QS180** This quality standard covers the diagnosis and management of cataracts, glaucoma and age-related macular degeneration (AMD) and the prevention of sight loss. It describes high-quality care in priority areas for improvement. **Child abuse and neglect QS179** This quality standard covers recognising, assessing and responding to abuse and neglect of children and young people under 18. It covers physical, sexual and emotional abuse. This quality standard describes high-quality care in priority areas for improvement. **Sexual health QS178** This quality standard covers sexual health, focusing on preventing sexually transmitted infections (STIs). It describes high-quality care in priority areas for improvement.

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

Title / link	End date of consultation
Atezolizumab in combination for treating advanced non-squamous non-small-cell lung cancer [ID1210]	04/03/2019
Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2019 update)	05/03/2019
Pneumonia (hospital-acquired): antimicrobial prescribing	11/03/2019
Pneumonia (community-acquired): antimicrobial prescribing	11/03/2019
Care and support of people growing older with a learning disability	11/03/2019
Endocuff Vision for assisting visualisation during colonoscopy	12/03/2019
Lyme disease	12/03/2019
Hearing loss (adult onset)	12/03/2019
Hypertension in pregnancy: diagnosis and management (Update)	13/03/2019
Investigation and management of heart valve disease in adults	18/03/2019
Service model for people with learning disabilities and behaviour that challenges	18/03/2019
Cardiac contractility modulation device implantation for heart failure	21/03/2019
Reinforcement of permanent stomas with mesh to prevent parastomal hernias	21/03/2019
Transcatheter valve-in-valve implantation for the treatment of aortic bioprosthetic valve dysfunction	21/03/2019
Alcohol: school-based interventions	22/03/2019

Produced by the Clinical Effectiveness Team
County Hall, Topsham Road, Exeter, EX2 4QL
D-CCG.ClinicalEffectiveness@nhs.net

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