NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: October 2020

Hyperlinks to the relevant NICE web page are included below.

NICE rapid COVID-19 guidelines

COVID-19 rapid guideline: cystic fibrosis NG170 (update)

The purpose of this guideline is to maximise the safety of patients with cystic fibrosis and make the best use of NHS resources, while protecting staff from infection.

October 2020: NICE withdrew their recommendations on reducing or deprioritising cystic fibrosis registry data entry, limiting transplant services and deferring transition to adult services because these emergency measures are no longer needed.

COVID-19 rapid guideline: antibiotics for pneumonia in adults in hospital NG173 (update)

The purpose of this guideline is to ensure the best antibiotic management of suspected or confirmed bacterial pneumonia in adults in hospital during the COVID-19 pandemic. This includes people presenting to hospital with moderate to severe community-acquired pneumonia and people who develop pneumonia while in hospital. It will enable services to make the best use of NHS resources.

October 2020: NICE amended the cefuroxime dosage for adults in line with the summaries of product characteristics.

COVID-19 rapid guideline: managing symptoms (including at the end of life) in the community NG163 (update)

The purpose of this guideline is to provide recommendations for managing COVID-19 symptoms for patients in the community, including at the end of life. It also includes recommendations about managing medicines for these patients, and protecting staff from infection.

October 2020: NICE amended recommendations on taking into account a patient's existing medicines to link to MHRA advice on warfarin and other anticoagulants – monitoring of patients during the COVID-19 pandemic, which includes reports of supratherapeutic anticoagulation with warfarin.

Technology Appraisals (TAs)

Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy TA655

This guidance updates and replaces NICE technology appraisal guidance 483 on nivolumab for previously treated squamous non-small-cell lung cancer, which was available through the Cancer Drugs Fund.

Recommendations

Nivolumab is **recommended** as an option for treating locally advanced or metastatic squamous non-small-cell lung cancer (NSCLC) in adults after chemotherapy, only if:

- it is stopped at 2 years of uninterrupted treatment, or earlier if their disease progresses and
- they have not had a PD-1 or PD-L1 inhibitor before.

It is recommended only if the company provides nivolumab according to the commercial arrangement.

This recommendation is not intended to affect treatment with nivolumab that was started in the Cancer Drugs Fund before final guidance was published. For those people, nivolumab will be funded by the company until they and their NHS clinician consider it appropriate to stop.

The technology

Nivolumab has a marketing authorisation in the UK for the treatment of locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults.

The treatment pathway for locally advanced or metastatic squamous NSCLC starts with a PD-1 or PD-L1 inhibitor or chemotherapy. Nivolumab would be used after chemotherapy. In line with clinical practice, nivolumab is a treatment option for people who have not had a PD-1 or PD-L1 inhibitor.

Evidence was collected in the Cancer Drugs Fund for people with advanced or metastatic squamous NSCLC having up to 2 years of nivolumab treatment in the NHS. The key clinical trial shows that people who have nivolumab live longer than those who have docetaxel, which is the most appropriate comparator. There is uncertainty about how long people should have nivolumab for, but evidence suggests that there is continued benefit when treatment is stopped at 2 years.

Nivolumab meets NICE's criteria to be considered a life-extending treatment at the end of life. The cost-effectiveness estimates for nivolumab compared with docetaxel are likely to be within what NICE considers to be an acceptable use of NHS resources. Therefore, it is now recommended in the NHS after chemotherapy for people who have not had a PD-1 or PD-L1 inhibitor before, if it is stopped at 2 years.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources.

Immunotherapies are available for untreated disease and most people with locally advanced or metastatic squamous NSCLC will receive a PD-1 or PD-L1 inhibitor at first line. Nivolumab is not recommended for use after a previous PD-1 or PD-L1 inhibitor, therefore the number of people eligible for nivolumab is expected to be small (around 30 people starting treatment per year).

Additionally, the treatment is already in use in the Cancer Drugs Fund and there is not anticipated to be a significant increase in the number of patients starting treatment when it moves into routine commissioning.

Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer TA654

This guidance updates and replaces NICE technology appraisal guidance 621 on osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer.

Recommendations

Osimertinib is **recommended**, within its marketing authorisation, as an option for untreated locally advanced or metastatic epidermal growth factor receptor (EGFR) mutation-positive non-small-cell lung cancer (NSCLC) in adults. It is recommended only if the company provides osimertinib according to the commercial arrangement.

The technology

Osimertinib is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.

Locally advanced or metastatic EGFR mutation-positive NSCLC is usually first treated with afatinib, erlotinib or gefitinib.

Evidence from a randomised controlled trial suggests that people who take osimertinib live longer than people who take erlotinib or gefitinib. They also live longer before their disease gets worse. There is some uncertainty about the comparison of osimertinib with afatinib, which may be more effective than erlotinib and gefitinib, because there is no direct evidence comparing them. But, because of a new commercial arrangement, the cost-effectiveness estimates for osimertinib are within what NICE considers an acceptable use of NHS resources.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that 1,440 people in England with untreated EGFR mutation-positive NSCLC are eligible for treatment with osimertinib each year. People with untreated disease receive treatment for an average of 21 months. Uptake is estimated to reach 80% of the eligible population in 2023/24. Around 2,300 people will be treated with osimertinib from year 2024/25 onwards (includes people continuing treatment from a previous year).

Osimertinib for treating EGFR T790M mutation-positive advanced non-small-cell lung cancer TA653

This guidance updates and replaces NICE technology appraisal guidance 416 on osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung, which was available through the Cancer Drugs Fund.

Recommendations

Osimertinib is **recommended** as an option for treating epidermal growth factor receptor (EGFR) T790M mutation-positive locally advanced or metastatic non-small-cell lung cancer (NSCLC) in adults, only if:

- their disease has progressed after first-line treatment with an EGFR tyrosine kinase inhibitor and
- the company provides osimertinib according to the commercial arrangement.

This recommendation is not intended to affect treatment with osimertinib 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

Osimertinib has a marketing authorisation for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC).

EGFR T790M mutation-positive locally advanced or metastatic NSCLC that has progressed after treatment with an EGFR tyrosine kinase inhibitor is usually treated with platinum doublet chemotherapy (PDC).

Evidence from clinical trials suggests that people who take osimertinib live longer than those who have PDC, although there is some uncertainty about the results. Osimertinib meets NICE's criteria to be considered a life-extending treatment at the end of life. Although the cost-effectiveness estimates for osimertinib are uncertain, they are likely to be within what NICE considers to be an acceptable use of NHS resources.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because targeted treatment options (now including osimertinib) are recommended earlier in the treatment pathway for EGFR positive tumours. It is therefore anticipated that many people who have the T790M mutation would have already received osimertinib as a first-line treatment and would not receive it again if their disease progresses. As a result the population size is likely to be small.

Alpelisib with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer TA652 (terminated appraisal)

NICE is **unable to make a recommendation** on alpelisib with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer because Novartis did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Highly specialised technology guidance (HSTs)

Volanesorsen for treating familial chylomicronaemia syndrome HST13

Recommendations

Volanesorsen is **recommended**, within its marketing authorisation, as an option for treating familial chylomicronaemia syndrome in adults with genetically confirmed familial chylomicronaemia syndrome who are at high risk of pancreatitis, and when response to diet and triglyceride-lowering therapy has been inadequate. It is recommended only if the company provides volanesorsen according to the commercial arrangement.

The technology

Familial chylomicronaemia syndrome (FCS) is a rare and potentially life-threatening condition that has a significant effect on the quality of life of people with the condition, and their families and carers. People with the condition have severe abdominal pain, unpredictable and recurrent acute pancreatitis and fatigue, and need to have a restricted low-fat diet. Current treatment options are limited.

Volanesorsen is an antisense oligonucleotide drug that aims to reduce the production of apolipoprotein C-III (APOC-III), a key regulator of lipoprotein metabolism and plasma triglyceride levels. It is administered by subcutaneous injection.

Financial factors

This technology is commissioned by NHS England.

The prevalence of FCS is estimated to be 1 to 2 per million people, which equates to about 55 to 110 people in England.

Clinical trial evidence shows short-term benefits with volanesorsen, including reduced triglyceride levels. It is uncertain whether this is maintained in the longer term, particularly at the licensed dose, which was not used in clinical trials.

There are also other uncertainties, especially around volanesorsen's effect on acute pancreatitis and the utility values used in the economic model. Despite these, volanesorsen is likely to provide important clinical and psychological benefits for people with familial chylomicronaemia syndrome, and value for money within the context of a highly specialised service.

NICE Guidelines (NGs)

Rheumatoid arthritis in adults: management NG100 (update)

This guideline covers diagnosing and managing rheumatoid arthritis. It aims to improve quality of life by ensuring that people with rheumatoid arthritis have the right treatment to slow the progression of their condition and control their symptoms. People should also have rapid access to specialist care if their condition suddenly worsens.

October 2020: NICE amended the 'treat to target' recommendations to clarify that multiple disease-modifying anti-rheumatic drugs can be offered one after the other to achieve treatment targets.

Public Health Guidelines

Behaviour change: digital and mobile health interventions NG183

This guideline covers interventions that use a digital or mobile platform to help people eat more healthily, become more active, stop smoking, reduce their alcohol intake or practise safer sex. The interventions include those delivered by text message, apps, wearable devices or the internet. The guideline only includes those that are delivered by the technology itself and not by healthcare professionals using technology to deliver interventions.

This guideline includes recommendations on:

- developing digital and mobile health interventions
- commissioning digital and mobile health interventions
- using digital and mobile health interventions
- interventions for diet and physical activity
- interventions for smoking
- interventions for alcohol use
- interventions for unsafe sexual behaviour

Antimicrobial prescribing guidelines

None published this month.

Social Care guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Balloon cryoablation for squamous dysplasia of the oesophagus IPG683

Recommendations

Evidence on the safety and efficacy of balloon cryoablation for squamous dysplasia of the oesophagus is inadequate in quantity and quality. Therefore, this procedure should only be used in the **context of research**. This could be in the form of randomised controlled trials or published registry data.

Patient selection should be done by clinicians experienced in managing squamous dysplasia of the oesophagus.

Further research should report patient selection, longer-term follow up and complications, including oesophageal stricture.

The condition

Squamous cells in the oesophagus may become dysplastic (squamous dysplasia). In some people, this condition may become malignant.

Current management includes lifestyle change, acid-suppressing medicines, endoscopic mucosal resection, endoscopic submucosal dissection, ablative therapies and surgery. Ablative therapies include radiofrequency ablation, photodynamic therapy, argon plasma coagulation, laser ablation, multipolar electrocoagulation and cryotherapy.

The procedure

This procedure is usually done using sedation. A balloon catheter is inserted through an endoscope, aligned with the dysplastic tissue in the oesophagus, and inflated. Nitrous oxide is then sprayed through a radial diffuser head within the balloon aimed at the target tissue. The tissue is destroyed by the extreme cold. The nitrous oxide gas remains fully contained within the balloon and exits through the proximal end of the catheter.

The ablation sequence is repeated until all the abnormal cells have been destroyed. Multiple ablations can be done without removing the balloon. The procedure typically takes 15 to 20 minutes to complete.

Balloon cryoablation for Barrett’s oesophagus IPG682

Recommendations

Evidence on the safety and efficacy of balloon cryoablation for Barrett's oesophagus is inadequate in quantity and quality. Therefore, this procedure should only be used in the **context of research**. This could be in the form of randomised controlled trials or published registry data.

Patient selection should be done by clinicians experienced in managing Barrett's oesophagus.

Further research should report patient selection, longer-term follow up and complications, including oesophageal stricture.

The condition

Barrett's oesophagus happens when the normal stratified squamous epithelium in the oesophagus transforms into simple columnar epithelium. In some people, this condition may become malignant.

Current management includes lifestyle change, acid-suppressing medicines, endoscopic mucosal resection, endoscopic submucosal dissection, ablative therapies and surgery. Ablative therapies include radiofrequency ablation, photodynamic therapy, argon plasma coagulation, laser ablation, multipolar electrocoagulation and cryotherapy.

The procedure

This procedure is usually done using sedation. A balloon catheter is inserted through an endoscope, aligned with the dysplastic tissue in the oesophagus, and inflated. Nitrous oxide is then sprayed through a radial diffuser head within the balloon aimed at the target tissue. The tissue is destroyed by the extreme cold. The nitrous oxide gas remains fully contained within the balloon and exits through the proximal end of the catheter.

The ablation sequence is repeated until all the abnormal cells have been destroyed. Multiple ablations can be done without removing the balloon. The procedure typically takes 15 to 20 minutes to complete.

Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis IPG681

Recommendations

Evidence on the safety of pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis shows that this procedure can cause serious but well-recognised side effects. Evidence on its efficacy is inadequate in quality. Therefore, this procedure should only be used in the **context of research**.

Further research should be in the form of randomised controlled trials comparing pressurised intraperitoneal aerosol chemotherapy with standard care. Studies should report details of patient selection including type of tumour, the chemotherapy drugs used, survival and quality-of-life outcomes.

The condition

Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer associated with short survival and poor quality of life. It may lead to bowel obstruction, fluid build-up in the peritoneal cavity and pain.

There is no curative treatment. Current standard treatment uses systemic chemotherapy or surgery for short-term palliation of complications such as bowel obstruction.

The procedure

Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis is a laparoscopic procedure that is usually done using general anaesthesia. The aim is to distribute the drug uniformly to all surfaces of the abdomen and pelvis.

Trocars are inserted and the abdomen insufflated with carbon dioxide. Peritoneal biopsies or local partial peritonectomy may be done at this time. The chemotherapy is delivered using an aerosol device containing normothermic chemotherapy solution. The chemotherapy is kept in the insufflated peritoneum for about 30 minutes. The procedure is usually repeated several weeks later. One standard course of treatment comprises 3 procedures, usually given 6 weeks apart, although the timing can vary.

Medical Technologies Guidance (MTGs)

SEM Scanner 200 for preventing pressure ulcers MTG51

This guidance replaces the NICE medtech innovation briefing on SEM Scanner 200 for preventing pressure ulcers (MIB182).

Recommendations

SEM Scanner 200, with visual skin assessment, shows promise for preventing pressure ulcers. However, there is **not enough good-quality evidence to support** the case for routine adoption in the NHS.

A randomised controlled trial is recommended to address uncertainties about the clinical benefits of using the scanner compared with standard risk assessment. This should assess:

- using the scanner plus visual skin assessment compared with visual skin assessment alone for identifying pressure ulcer risk
- whether changes in clinical decision making from using the scanner reduce pressure ulcer incidence
- the clinical benefits and resource impact of using the scanner in different care settings
- the clinical benefits for different skin tones
- how well the scanner works across populations with a range of comorbidities
- patient-related outcome measures.

The technology

Inflammation occurs when tissue is damaged. Increased moisture under the skin is thought to reflect inflammation and may mean an increased risk of pressure ulcer formation. SEM Scanner 200 is a device that measures differences in moisture under the skin of the heels and the area around the base of the spine (sacrum). Using SEM Scanner 200 could mean that measures to prevent pressure ulcers can be taken before visible or tactile signs of tissue damage develop.

Financial factors

NICE has said that SEM Scanner 200 is used with standard care in studies looking at its effect on pressure ulcer incidence. This makes it difficult to distinguish between the effect of SEM Scanner 200 alone and that of increased awareness of preventing pressure ulcers. Also, standard care is poorly described in the studies. More evidence is needed on how using SEM Scanner 200 affects clinical decision making and whether this benefits patients.

Diagnostics Guidance (DGs)

Testing strategies for Lynch syndrome in people with endometrial cancer DG42

Recommendations

Offer testing for Lynch syndrome to people who are diagnosed with endometrial cancer. Use immunohistochemistry (IHC) to identify tumours with mismatch repair (MMR) deficiency:

- If IHC is abnormal with loss of MLH1, or loss of both MLH1 and PMS2 protein expression, do MLH1 promoter hypermethylation testing of tumour DNA. If MLH1 promoter hypermethylation is not detected, offer germline genetic testing to confirm Lynch syndrome.
- If IHC is abnormal with loss of MSH2, MSH6 or isolated PMS2 protein expression, offer germline genetic testing to confirm Lynch syndrome.

Healthcare professionals should inform people about the possible implications of test results for both themselves and their relatives, and give support and information. Discussion of genetic testing and obtaining consent should be done by a healthcare professional with appropriate training.

Laboratories doing IHC for MMR proteins, MLH1 promoter hypermethylation testing or germline genetic testing should take part in a recognised external quality assurance programme.

The tests

Lynch syndrome is an inherited genetic condition associated with an increased risk of several cancers, particularly endometrial and colorectal cancer. It is caused by mutations in, or near, the DNA sequence of mismatch repair (MMR) genes. If a person has Lynch syndrome, these mutations are in every cell of their body and can be identified by genetic testing of non-tumour tissue.

If Lynch syndrome is diagnosed, treatment and surveillance can be offered to reduce the risk of having another Lynch syndrome-associated cancer (in particular colorectal cancer) or identify it earlier. Genetic testing for Lynch syndrome can also be offered to relatives with the aim of preventing Lynch syndrome-associated cancer developing or detecting it at an early stage.

Several types of tests can be done in different orders and combinations to see if endometrial cancer is likely to have been caused by Lynch syndrome. Economic modelling has shown that IHC testing then MLH1 promoter testing is likely to be the most cost-effective approach. If both these tests show that a person may have Lynch syndrome, genetic testing of a person's non-tumour DNA should be done to confirm.

Financial factors

Services for genetic testing for Lynch syndrome are commissioned by NHS England and immunohistochemistry services are commissioned by CCGs.

NICE estimates that 169 people in Devon with endometrial cancer are eligible for testing for Lynch syndrome.

From year 5 onwards, once uptake has reached 95%, 161 people with endometrial cancer will have testing for, and 7 will be diagnosed with Lynch syndrome. 25 family members will have testing for, and 11 will be diagnosed with Lynch syndrome.

NICE Quality Standards

Heavy menstrual bleeding QS47 (update)

This quality standard covers assessing and managing heavy menstrual bleeding (menorrhagia), including suspected or confirmed fibroids and adenomyosis. It describes high-quality care in priority areas for improvement.

October 2020: NICE updated this quality standard in response to an annual review, which identified changes in the areas for improvement for this topic.

Current NICE consultations

Title / link	End date of consultation
Atrial fibrillation: management	04/11/2020
Autism spectrum disorder in under 19s: recognition, referral and diagnosis (2019)	06/11/2020
Autism spectrum disorder in adults: diagnosis and management	06/11/2020
Autism spectrum disorder in under 19s: support and management	06/11/2020
Alpha Stim AID (MT477)	06/11/2020
Supporting adult carers	09/11/2020
Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours [ID1626]	17/11/2020
Head injury: assessment and early management	18/11/2020
Caesarean section (update)	26/11/2020
Postnatal care	27/11/2020
Subarachnoid haemorrhage due to ruptured aneurysms	11/12/2020