NHS Devon

NICE Update Bulletin: September 2023

This bulletin includes details of the following new and updated NICE guidance – click on the titles below for further details:

1. **Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency TA914**
2. **Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy TA913**
3. **Semaglutide for managing overweight and obesity TA875 (UPDATE)**
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Technology Appraisals (TAs)

Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency TA914

Recommendations

Pembrolizumab is **recommended** as an option for treating tumours with high microsatellite instability (MSI) or mismatch repair (MMR) deficiency in adults with:

- advanced or recurrent endometrial cancer that has progressed during or after a platinum-based therapy, who cannot have curative surgery or radiotherapy
- unresectable or metastatic gastric, small intestine or biliary cancer that has progressed during or after 1 therapy
- colorectal cancer after fluoropyrimidine combination therapy, only if they cannot have nivolumab with ipilimumab.

It is only recommended if:

- pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if the cancer progresses, and
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with pembrolizumab 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

Solid tumours are abnormal localised masses of tissue. They can be cancerous (malignant) or not cancerous (benign) and are classified according to the type of cells that form them.

The two major types of cancerous solid tumours are:

1. Sarcomas- developed from cells of muscles, bone or fat tissue
2. Carcinomas- carcinomas start from the epithelial cells in the skin or tissues that line or cover internal organs

Advanced solid tumours can be locally advanced (tumour that has spread to surrounding tissues or lymph nodes but has not yet spread to other parts of the body) or metastatic (tumour that has spread to other parts of the body).

Mismatch repair (MMR) is a process where cells of the body recognise and repair nucleotide mismatches or insertion of excess DNA during replication of the DNA as cells divide. Deficiencies in MMR (dMMR) are associated with genomic instability and the accumulation of simple repetitive DNA sequences, which are known as microsatellites (MSI). The accumulation of numerous MSI is classified as an MSI high (MSI-H) phenotype and if these MSI affect regions of the genome associated with apoptosis (programmed cell death) and cell growth, it can result in the development of tumours.

Nivolumab with ipilimumab (TA716) and pembrolizumab (TA709) are treatment options that target colorectal cancers with MSI-H and dMMR. Dostarlimab (TA779) is a treatment option that is available through the Cancer Drugs Fund for treating advanced or recurrent endometrial cancer with MSI-H and dMMR in adults who have had platinum-based chemotherapy. There are currently no treatment options available which broadly target a range of MSI-H and dMMR classified solid tumours. Current treatments for different solid tumour cancers generally include surgery, chemotherapy, radiotherapy, hormone therapy, immunotherapy, small molecule inhibitor treatments, or a combination of these treatments.

Financial Factors

This technology is commissioned by NHS England.

Pembrolizumab has not been compared directly with chemotherapy in clinical trials. When compared indirectly, the results suggest that people having pembrolizumab live for longer and have longer before their cancer gets worse than people having chemotherapy, although these results are uncertain.

When considering the condition's severity, its effect on quality and length of life, and the uncertainty in the clinical evidence, the most likely cost-effectiveness estimates for pembrolizumab in all the types of cancer are within the range that NICE considers an acceptable use of NHS resources, therefore, it is recommended.

The company has a commercial arrangement. This makes pembrolizumab available to the NHS with a discount.

Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy TA913

Recommendations

Mavacamten is **recommended** as an option for treating symptomatic obstructive hypertrophic cardiomyopathy in adults who have a New York Heart Association class of 2 to 3. It is recommended only if:

- it is an add-on to individually optimised standard care that includes beta-blockers, non-dihydropyridine calcium-channel blockers or disopyramide, unless these are contraindicated **and**
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with mavacamten 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

Hypertrophic cardiomyopathy (HCM) is a genetic condition that is most often caused by a change or fault in one or more genes and is characterised by the thickening of the muscular wall of the heart. Thickening of the septum (the dividing wall between the left and the right side of the heart), resulting in reduced or restricted blood flow is classified as obstructive HCM. Most people with HCM may initially have few or no symptoms. However, the disease is progressive and symptoms may develop or worsen at any age. Common symptoms of HCM include shortness of breath, chest pain, palpitations, light headedness, and fainting. People with obstructive HCM can develop serious complications such as atrial fibrillation, heart failure, malignant ventricular arrhythmias and sudden cardiac death.

HCM is the most common genetic cardiovascular disease. However, most people with HCM have few, if any, symptoms. The disease most commonly presents in the second or third decade of life but may present at any age. HCM is the most common cause of sudden unexpected death in childhood and in young athletes.

There is no curative treatment for HCM. Treatment approaches vary depending on symptoms and risk of sudden disease. People with HCM often need to make lifestyle changes, such as limiting their activity, to adjust for their disease. European Society of Cardiology (ESC) Guidelines on HCM recommend that people with symptomatic disease, predominately with left ventricular outflow tract obstruction, receive beta-blockers to reduce symptoms and obstruction. If betablockers are ineffective or contraindicated, non-dihydropyridine calcium channel blockers are suitable alternatives. Disopyramide, alone or in combination with either beta-blockers or non-dihydropyridine calcium channel blockers, can also be considered. If severe symptoms persist despite maximally tolerated medical therapy, people may be offered surgical myectomy or non-surgical reduction of the myocardial septum (IPG40). For people with obstructive HCM who

progress to heart failure, the only ESC guideline recommended treatment options are those recommended to manage left ventricular outflow obstruction.

Mavacamten is a small molecule that binds selectively to cardiac myosin ATPase which changes the heart muscle's ability to contract. It is administered orally.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence suggests that mavacamten plus standard care is more effective than standard care alone and that it may avoid or delay the need for invasive surgery.

The most likely cost-effectiveness estimate for mavacamten is within the range that NICE considers an acceptable use of NHS resources. So mavacamten is recommended.

NICE estimate that in Devon, 138 people are eligible for treatment.

The company has a commercial arrangement. This makes mavacamten available to the NHS with a discount.

Semaglutide for managing overweight and obesity TA875 (UPDATE)

Recommendations

Semaglutide is **recommended** as an option for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity in adults, only if:

- it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and
- they have at least 1 weight-related comorbidity and:
- a body mass index (BMI) of at least 35.0 kg/m^2, or
- a BMI of 30.0 kg/m^2 to 34.9 kg/m^2 and meet the criteria for referral to specialist weight management services in NICE's guideline on obesity: identification, assessment and management (CG189).
- **the company provides semaglutide according to the commercial arrangement [new September 2023]**

Use lower BMI thresholds (usually reduced by 2.5 kg/m^2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds.

Consider stopping semaglutide if less than 5% of the initial weight has been lost after 6 months of treatment.

These recommendations are not intended to affect treatment with semaglutide 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

Overweight and obesity is a chronic condition characterised by increased body fat. People living with overweight or obesity are at an increased risk of developing cardiovascular disease, type 2 diabetes, atherosclerosis, hypertension and dyslipidaemia. Other conditions associated with obesity are non-alcoholic fatty liver disease, non-diabetic hyperglycaemia, subfertility, osteoarthritis, dyslipidaemia, obstructive sleep apnoea and idiopathic intracranial hypertension. The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. Overweight is typically defined by a BMI of 25 kg/m^2 to <30 kg/m^2 and obesity by a BMI of 30 kg/m^2 or more. Some ethnic groups may be at increased risk of some ill health conditions at lower BMI than people of European family origin.

CG189 states multicomponent interventions are the treatment of choice. Weight management programmes include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. Pharmacological treatments are usually considered only after dietary, exercise and behavioural approaches have been started and evaluated.

If dietary and lifestyle advice, behaviour modification and drug treatments are unsuccessful, the CG189 recommends bariatric surgery for people meeting certain criteria.

TA664 recommends liraglutide as an option for managing overweight and obesity alongside a reduced-calorie diet and increased activity in adults if they have a BMI of at least 35 kg/m^2.

Semaglutide binds to and activates the glucagonlike peptide-1 (GLP-1) receptor in order to increase insulin levels and suppress glucagon secretion. This action leads to the slowing of glucose absorption and lower post-meal blood glucose levels. It is administered by subcutaneous injection.

Financial Factors

This technology is commissioned by ICBs.

For people who have at least 1 weight-related comorbidity and a BMI of at least 35 kg/m^2 or a BMI of 30 kg/m^2 to 34.9 kg/m^2 and also meet the NICE criteria for referral to a specialist weight management service, the cost-effectiveness estimates for semaglutide are likely to be within what

is normally considered a cost-effective use of NHS resources. For these groups, semaglutide is recommended alongside lifestyle interventions in an appropriate multidisciplinary setting.

NICE estimate that in Devon, 93,441 people will be eligible for treatment and that 620 people will choose treatment with semaglutide in year and that 469 people will continue with semaglutide in year 2. To note, NICE estimate that 91,909 people will choose diet and exercise.

The company has a commercial arrangement. This makes semaglutide available to the NHS with a discount.

Highly Specialised Technology Guidance (HSTs)

Birch bark extract for treating epidermolysis bullosa HST28

Recommendations

Birch bark extract is **recommended**, within its marketing authorisation, as an option for treating partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa in people aged 6 months and over. It is only recommended if the company provides it according to the commercial arrangement.

The Technology

Epidermolysis bullosa (EB) is a general term used to describe a group of rare inherited skin disorders that cause the skin to become very fragile. Any trauma or friction can cause the skin to blister and tear easily. There are different types of EB and the condition is classified according to where on the body the blistering takes place and which layer of skin is affected.

As well as external blisters, EB can manifest internally affecting areas such as the eye, mouth or stomach. Other complications associated with EB can include the development of aggressive skin cancers, dental problems, or nutritional compromise. EB is usually diagnosed in babies and children and is thought to affect 1 in 17,000 births in the UK.

There is currently no cure for EB. Treatments help ease and control symptoms. It aims to avoid skin damage, improve quality of life and reduce the risk of developing complications such as infection and malnutrition. Given the complex needs of children with EB, treatment is usually carried out by a multidisciplinary team.

Birch bark extract consists of an active ingredient of dry, refined extract from birch bark. Oleogel-S10 contains 10% of birch bark extract in 90% of sunflower oil. It is applied topically.

Financial Factors

This technology is commissioned by NHS England.

In a clinical trial, birch bark extract led to quicker wound healing than a control gel. The results also suggest that it may lead to a reduced amount of affected skin.

The results of the trial were used to estimate the numbers of people with different disease severities in the economic model. But some people did not finish the trial and a higher proportion of people with severe epidermolysis bullosa dropped out than those with less severe epidermolysis bullosa. This means there was uncertainty around cost-effectiveness estimates.

Taking into account the evidence and the uncertainties, the most likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources, therefore, birch bark extract is recommended.

The company has a commercial arrangement. This makes birch bark extract available to the NHS with a discount.

NICE Guidelines (NGs)

Intrapartum care NG235

This guidance updates and replaces CG190 (published December 2014).

This guideline covers the care of women and their babies during labour and immediately after birth. It focuses on women who give birth between 37 and 42 weeks of pregnancy (‘term’). The guideline helps women to make informed choices about where to have their baby and about their care in labour. It also aims to reduce variation in aspects of care.

Spinal metastases and metastatic spinal cord compression NG234

This guideline updates and replaces CG75 (published November 2008).

This guideline covers recognition, referral, investigation and management of spinal metastases and metastatic spinal cord compression (MSCC). It is also relevant for direct malignant infiltration of the spine and associated cord compression. It aims to improve early diagnosis and treatment to prevent neurological injury and improve prognosis.

Caesarean birth NG192 (UPDATE)

This guideline covers when to offer and discuss caesarean birth, procedural aspects of the operation, and care after caesarean birth. It aims to improve the consistency and quality of care for women and pregnant people who are thinking about having a caesarean birth or have had a caesarean birth in the past and are now pregnant again.

September 2023: NICE updated the recommendations on the use of neuraxial opioids for postoperative pain relief and monitoring for women and pregnant people who have had neuraxial opioids.

Acute kidney injury: prevention, detection and management NG148 (UPDATE)

This guideline covers preventing, detecting and managing acute kidney injury in children, young people and adults. It aims to improve assessment and detection by non-specialists and specifies when people should be referred to specialist services. This will improve early recognition and treatment and reduce the risk of complications in people with acute kidney injury.

September 2023: NICE amended recommendations on offering iodine-based contrast media to adults to clarify that, for non-emergency imaging, an estimated glomerular filtration rate (eGFR) measurement is only needed if the person is at increased risk of kidney injury.

Cirrhosis in over 16s: assessment and management NG50 (UPDATE)

This guideline covers assessing and managing suspected or confirmed cirrhosis in people who are 16 years or older. It aims to improve how cirrhosis is identified and diagnosed, and gives advice on the monitoring, prevention and early management of complications.

September 2023: NICE reviewed the evidence and made new or updated recommendations on safe prescribing and use of carvedilol and propranolol in people with cirrhosis, detecting and preventing bleeding from medium or large varices, preventing spontaneous bacterial peritonitis, and primary prevention of decompensation.

NICE Rapid COVID-19 Guidelines

COVID-19 rapid guideline: haematopoietic stem cell transplantation NG164 (UPDATE)

The purpose of this guideline is to maximise the safety of patients who need haemopoietic stem cell transplantation and make the best use of NHS resources, while protecting staff from infection.

September 2023: NICE have removed and amended recommendations throughout the guideline to reflect changes to current best practice and service organisation, which have been adapted over time throughout the pandemic.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment IPG772

Recommendations

Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment may be used if **standard arrangements** are in place for clinical governance, consent and audit.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Clinicians should enter details about everyone having removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment onto a suitable register, such as the UKSTORE register.

Patient selection should be done by a multidisciplinary team experienced in the procedure, ideally using nationally agreed criteria.

The Condition

Some treatments for cancer or other medical conditions can damage the ovaries (gonadotoxic treatment). This can lead to early menopause and infertility.

There are a number of pharmacologic and surgical strategies that aim to reduce the risk of infertility after gonadotoxic treatment, including ovarian transposition, ovarian suppression and fertility-sparing surgery.

For people who are going to have treatments that may damage their ovaries, cryopreservation of oocytes or embryos before the treatment begins are options for preserving fertility. These both involve ovarian stimulation, which may lead to a delay in treatment. Embryo cryopreservation also requires sperm from a partner or donor.

The Procedure

Before starting gonadotoxic treatments, ovarian tissue is removed surgically through laparoscopy, mini-laparotomy, or laparotomy. Usually, at least half of one ovary is removed and the other ovary is left in place to act as a site for future orthotopic autotransplantation. After histological examination of a portion to exclude malignancy, most of the excised ovarian tissue is frozen for future autotransplantation.

When indicated, the frozen cortical ovarian tissue is thawed and transplanted back to the same person. It can be placed into pelvic sites such as the remaining ovary, ovarian fossa, or broad ligament through laparoscopy or mini-laparotomy. Alternatively, it can be placed into extra-pelvic sites such as the subcutaneous space of the abdominal wall or forearm. In this case, the follicle and oocyte develop outside the usual environment, so subsequent ovarian stimulation, egg collection and in vitro fertilisation are needed to achieve pregnancy. Another technique involves the vascular grafting and anastomosis of a frozen–thawed whole ovary through mini-laparotomy or laparotomy.

Future pregnancies may require assisted reproduction technologies, although the procedure can offer the possibility of natural conception.

Ovarian stimulation is not needed before removal of ovarian tissue for autotransplantation and gonadotoxic treatment can start immediately afterwards. It may be the only fertility preservation option suitable before puberty or for people with oestrogen-sensitive malignancies.

Cryotherapy for chronic rhinitis IPG771

Recommendations

Cryotherapy for chronic rhinitis should be used **only in research**.

Further research should report details of patient selection, duration of the effect (including whether repeat procedures are needed), and long-term outcomes.

The Condition

Rhinitis is inflammation and swelling of the mucous membrane inside the nose. Chronic nasal inflammation lasts over a long period of time, usually longer than 12 weeks. Common symptoms include sneezing, itchiness and a stuffy or runny nose. There are 3 main types of rhinitis: allergic rhinitis, infectious rhinitis and non-allergic, non-infectious rhinitis.

Treating rhinitis depends on the specific cause or diagnosis. Treatment options include:

- non-pharmacological treatments (such as avoiding triggers and using environmental controls)
- pharmacological treatments (such as steroid nasal sprays and oral antihistamines)

- surgery (such as posterior nasal neurectomy).

The Procedure

This procedure is done under local anaesthesia. A probe is inserted into the nasal cavity and its balloon tip is placed endoscopically in the posterior middle meatus. Once the tip is in contact with the targeted tissue over the branches of the posterior nasal nerve, nitrous oxide cryogen is released through the tip from the canister. This freezes the targeted mucosal tissue, with the aim of ablating the posterior nasal nerve. Cryogen is delivered for 30 to 60 seconds and the contralateral side is treated the same way if needed.

Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia IPG770

This guidance updates and replaces IPG629 (published September 2018)

Recommendations

Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH) may be used if **standard arrangements** are in place for clinical governance, consent and audit.

For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).

The Condition

Benign prostatic hyperplasia (BPH) is a common condition that affects older people with a prostate. Stromal and epithelial cells increase in number, causing the prostate to get bigger. It often happens in the periurethral region of the prostate, with large discrete nodules compressing the urethra. Symptoms include hesitancy during urination, interrupted or decreased urine stream (volume and flow rate), nocturia, incomplete voiding and urinary retention.

Mild symptoms are usually managed conservatively. Drugs may also be offered, such as alpha-adrenoceptor blockers and 5-alpha-reductase inhibitors. If other treatments have not worked, surgical options include transurethral resection of the prostate (TURP), transurethral vaporisation, holmium laser enucleation, insertion of prostatic urethral lift implants, prostatic artery embolisation or prostatectomy (see NICE's guideline on lower urinary tract symptoms in men CG97). Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.

The Procedure

Transurethral water-jet ablation for lower urinary tract symptoms caused by BPH uses a specialised system that combines image guidance and robotics for the targeted removal of prostate tissue.

The procedure is usually done under general or spinal anaesthesia. Transrectal ultrasound is used throughout the procedure. A handpiece with an integrated cystoscope and ablation probe is inserted through the urethra and into the bladder. When it is correctly positioned, planning software is used to create a personalised treatment plan. A high-speed jet of saline is then delivered to the prostate at various flow rates, to give targeted and controlled tissue removal, according to the treatment plan. The ablated tissue is aspirated through ports in the handpiece and can be used for histological analysis. After the procedure, a 3-way Foley catheter is placed through the penis into the urethra and the bladder is continuously irrigated. The catheter is removed before discharge from hospital, usually on the day after the procedure.

A possible advantage of the procedure is the potential to preserve sexual function. The procedure does not use heat to ablate the prostate tissue, which removes the risk of complications from thermal injury.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

Health Technology Evaluations (HTE)

Artificial intelligence-derived software to analyse chest X-rays for suspected lung cancer in primary care referrals: early value assessment HTE12

Recommendations

More research is needed on the following artificial intelligence (AI)-derived software to analyse chest X-rays alongside clinician review for suspected lung cancer in adults referred from primary care:

- AI-Rad Companion Chest X-ray
- Annalise CXR
- Auto Lung Nodule Detection
- ChestLink
- ChestView
- Chest X-ray
- ClearRead Xray
- InferRead DR Chest
- Lunit INSIGHT CXR
- Milvue Suite
- qXR
- Red dot
- SenseCare-Chest DR PRO
- VUNO Med-Chest X-Ray

Access to the technology should be through company, research or non-core NHS funding.

Centres already using AI-derived software to review chest X-rays in adults referred from primary care may continue to do so but only under an appropriate evaluation framework and only alongside clinician review.

More research

More research is needed on the following key outcomes:

- the impact of the software on clinical decision making and the number of people referred to have a chest CT scan
- how using the software affects healthcare costs and resource use
- the impact on review and reporting time, and time to CT referral and diagnosis
- the diagnostic accuracy of AI-derived software alongside clinician review in detecting nodules or other abnormal lung features that suggest lung cancer
- the diagnostic accuracy of using AI-derived software alongside clinician review for identifying normal X-rays with high confidence and the impact of this on work prioritisation and patient flow
- the technical failure and rejection rates of the software
- whether the software works in cases when it is hard to get high-quality images, for example, scoliosis and morbid obesity
- whether the software works in groups that could particularly benefit, including people with multiple conditions, people from high-risk family backgrounds, and younger women who do not smoke
- patient perceptions of using AI-derived software.

The Technology

Lung cancer is one of the most common types of cancer in the UK. It causes symptoms such as persistent cough, coughing up blood, and feeling short of breath. People in the early stages of the disease may not have symptoms and so lung cancer is often diagnosed late. The NHS Long Term Plan sets out the NHS's ambition to diagnose 75% of all cancers at stages 1 or 2 by 2028.

Detecting abnormal lung features such as lung nodules, pleural effusion, collapsed lung or lung segments, destruction or erosion of bony structures such as the ribs, as well as masses or lymph nodes within the mediastinum could help find lung cancer early. Lung abnormalities can be seen on a chest X-ray. The chest X-ray may be done because of signs and symptoms that suggest lung cancer. Lung abnormalities that suggest cancer can also be detected incidentally on chest X-rays done for reasons unrelated to lung cancer, such as trauma, heart problems, or investigation and monitoring of other lung conditions.

Software with artificial intelligence (AI)-derived algorithms can be used to automatically detect lung abnormalities on chest X-ray images. This could help a radiologist or reporting radiographer with review and interpretation of chest X-ray images and support clinical decisions about the need for a CT scan or further investigations.

All software technologies in clinical settings use fixed algorithms. They cannot adapt in real time using data from the clinical practice setting in which they are used. In the NHS, AI-based technologies are only used alongside healthcare professionals. The healthcare professional who reviews the chest X-ray using the software makes the final reporting decision.

Financial Factors

This technology is commissioned by ICBs.

The Department of Health and Social Care (DHSC) and NHS England have launched several initiatives that will support the generation of more evidence for the use of AI technologies. This includes the AI Diagnostic Fund. One area of focus of the fund is AI to support radiologists to read chest X-rays. DHSC, the National Institute for Health and Care Research (NIHR) and NHS England are collaborating to support the winning trusts to do 'in-service evaluations'. These evaluations, alongside plans for national collation of data and metrics from the deployments across multiple imaging networks, aim to answer the evidence gaps set out in the guidance and evidence generation plan.

Artificial intelligence technologies to aid contouring for radiotherapy treatment planning: early value assessment HTE11

Recommendations

Nine artificial intelligence (AI) technologies **can be used** in the NHS while more evidence is generated to aid contouring for radiotherapy treatment planning in people having external beam radiotherapy. AI technologies must be used with healthcare professional review of contours.

The following technologies can only be used once they have Digital Technology Assessment Criteria (DTAC) approval:

- AI-Rad Companion Organs RT
- ART-Plan
- DLCExpert
- INTContour
- Limbus Contour
- MIM Contour ProtégéAI
- MRCAT Prostate plus Auto-contouring
- MVision Segmentation Service
- RayStation

The technology developers or companies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

At the end of the evidence generation period (3 years, or sooner if sufficient evidence is available), the technology developers or companies should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technologies can be routinely adopted in the NHS.

Evidence generation

More evidence needs to be generated on the following key outcomes:

- clinical acceptability of contours and amount of edits needed
- impact of AI autocontouring on radiation dose to organs at risk (OAR) and the tumour
- time saving including time for healthcare professional review and edits
- resource use defined by healthcare professional grade and time
- contouring errors and adverse events associated with AI autocontouring.

The Technology

Contouring is an important part of the radiotherapy treatment planning process. It involves outlining the target volumes and organs at risk (OAR) to guide radiotherapy so that treatment is effective and radiation toxicity is minimised. Artificial intelligence (AI) technologies aim to improve contouring efficiency by automatically contouring the OAR and sometimes the target volumes before radiotherapy. The technologies have been trained to process images from CT, cone-beam CT or MRI scans to produce an initial contour. Images and contours are then reviewed by trained healthcare professionals and modified as needed before use.

Manual contouring is the most common contouring method in standard care. Manual contouring of target regions is usually done by clinical oncologists. Contouring of OAR may also be done by clinical technologists, dosimetrists or therapeutic radiographers.

NICE has assessed AI technologies to aid contouring for radiotherapy treatment planning. Nine technologies have regulatory approval for use in the NHS:

- AI-Rad Companion Organs RT is a standalone software that contours over 60 OAR structures on CT scans including the abdomen, head and neck, pelvis and thorax.
- ART-Plan is a standalone software that contours over 150 structures including OAR and lymph nodes in the abdomen, brain, head and neck, thorax and pelvis on CT images and the abdomen, brain and male pelvis on MRI scans.

- DLCExpert is deployed on Mirada Medical's Workflow Box platform. It contours over 160 structures on CT and MRI images, including the abdomen, breast, head and neck, prostate and thorax.

- INTContour is a standalone software that contours over 60 target and OAR structures from the abdomen, head and neck, male pelvis and thorax.

- Limbus Contour is a standalone software that contours over 200 OAR and target volumes including lymph nodes, the abdomen, breast, central nervous system, head and neck, lungs, pelvis and prostate on CT images, and the central nervous system, gynaecological and brachy structures on MRI scans.

- MIM Contour ProtégéAI is a standalone software that contours the head and neck, thorax, lungs and liver, prostate and abdomen structures from CT images and the prostate from MRI scans.

- MRCAT Prostate plus Auto-contouring is a clinical application integrated in the Philips MR-RT systems for MRI in radiation therapy. It provides automatic contours of the prostate and associated OAR.

- MVision Segmentation Service is a standalone software that contours over 160 structures including OAR and target volumes in the abdomen and thorax, brain, breast, head and neck, and pelvis.

- RayStation is a radiotherapy external beam and brachytherapy planning system with AI autocontouring functionality. It contours over 70 structures on CT images including the breast and lymph nodes, head and neck, male pelvis, thorax and abdomen.

Financial Factors

This technology is commissioned by NHS England.

Depending on current local practice, areas which may require additional resources and result in additional costs include:

- the AI contouring technology, including specific hardware/software and upgrades to support the technology.

- time required for training to support.

Implementing the guideline may:

- help healthcare professionals to produce contours more quickly.

- decrease the time needed for healthcare professionals to review and edit structures.

- improve consistency of contouring between people, standardise processes and improve adherence to national and international guidelines.

KardiaMobile 6L for measuring cardiac QT interval in adults having antipsychotic medication HTE10

Recommendations

KardiaMobile 6L **can be used** in psychiatric services as an option to measure cardiac QT interval for adults having or about to have antipsychotic medication while more evidence is generated only if:

- A repeat QT interval measurement using a 12-lead electrocardiogram (ECG) device is offered to:
    - women with a corrected QT interval (QTc) longer than 470 milliseconds
    - men, trans people having hormone treatment and intersex people who have QTc longer than 440 milliseconds
    - people who have a follow-up ECG with more than a 50-millisecond increase in QTc.

  For trans people not having hormone treatment, use the QTc threshold for their sex registered at birth.
- Training for healthcare professionals on recording an ECG and measuring and interpreting QT interval is provided.
- People are offered information about why this testing is done and why testing may be repeated using a 12-lead device after it has been measured using KardiaMobile 6L.

The technology developers must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

At the end of the evidence generation period (3 years), the technology developers should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technologies can be routinely adopted in the NHS.

Evidence generation

More evidence needs to be generated on:

- the accuracy of KardiaMobile 6L to measure QT interval in adults having or about to have antipsychotic medications
- how the test result affects clinical decision making

- how long the testing takes, who interprets the results and how often the test is repeated using a 12-lead device
- patient preferences
- how long it takes before antipsychotic medication is started
- how many adults who need an ECG to measure QT interval have one
- how common prolonged QT is in adults having antipsychotic medication.

The Technology

People taking antipsychotic medication may need to have tests for cardiac abnormalities before starting treatment and at regular intervals during treatment. NICE guidelines on bipolar disorder (CG185) and psychosis and schizophrenia in adults (CG178) have recommendations on using antipsychotic medication. Detecting cardiac abnormalities such as prolonged QT interval can inform choice of therapy, dosing, whether to stop therapy and potentially avoid severe cardiac events.

QT interval is usually measured using a 12-lead ECG device to record the ECG. This needs the person to partially undress and use conductive stickers or gel on the skin to create contact with the electrodes. This can cause reluctance and distress. An ECG is recorded in primary or secondary care centres.

KardiaMobile 6L is a 6-lead, handheld, ECG device and allows for ECG recording with less need for undressing and without using conductive stickers or gel. KardiaMobile 6L ECG can be recorded during a routine home visit by a community health professional. This may reduce stress and anxiety. KardiaMobile 6L is not intended for use in children.

Financial Factors

This technology is commissioned by NHS England.

Depending on current local practice, areas that may require additional resources and result in additional costs include:

- Costs for healthcare professionals who need access to KardiaMobile devices in the community and clinic settings. Each device will need a licence for which there is an annual fee.
- Time for interpretation of the result from KardiaMobile 6L, which involves manual calculations and may involve psychologist or cardiologist time.
- Additional capacity demand for community nurses to provide QT assessment in the community with KardiaMobile 6L, for people receiving antipsychotic medication, where 12-lead ECG assessment was previously carried out in a clinical setting. Any additional

capacity impact may be partly offset where the assessment is moving from a 12-lead ECG and a cardiac technician's time is reduced per procedure.

Implementing the guideline may:

- reduce the number of outpatient and GP appointments for 12-lead ECGs, where KardiaMobile 6L is used as triage before a 12-lead ECG
- enable people to access antipsychotic medication in a timelier manner with a clearer understanding of the QT risk for the individual.

Guided self-help digital cognitive behavioural therapy for children and young people with mild to moderate symptoms of anxiety or low mood: early value assessment HTE3 (UPDATE)

September 2023: NICE has developed tools and resources, in association with relevant stakeholders, to help organisations put this guidance into practice, including an evidence generation plan. The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

NICE Quality Standards

Spinal metastases and metastatic spinal cord compression QS56 (UPDATE)

This quality standard covers diagnosis and management of spinal metastases and metastatic spinal cord compression. It describes high-quality care in priority areas for improvement.

September 2023: Changes were made to align this quality standard with the updated NICE guideline on spinal metastases and metastatic spinal cord compression (NG234). NICE have also updated the name of this quality standard.

Chronic obstructive pulmonary disease in adults QS10 (UPDATE)

This quality standard covers assessing, diagnosing and managing chronic obstructive pulmonary disease (COPD). It describes high-quality care in priority areas for improvement.

September 2023: NICE have made changes to this quality standard following the annual review of quality standards. Links, definitions, data sources and source guidance sections have also been updated throughout.

Current NICE Consultations

Title/link	End date of consultation
Acute respiratory infection in over 16s: initial assessment and management, including using virtual wards	02/10/2023
GID-MT575 GaitSmart rehabilitation exercise programme for gait and mobility issues	03/10/2023
Cardiovascular disease: risk assessment and reduction, including lipid modification - Escalation of Therapy	05/10/2023
Jaundice in newborn babies under 28 days	06/10/2023
Meningitis (bacterial) and meningococcal disease : recognition, diagnosis and management	12/10/2023
Trastuzumab deruxtecan for treating HER2-low metastatic or unresectable breast cancer after chemotherapy [ID3935]	17/10/2023
Artificial intelligence (AI) software to help clinical decision making in stroke	19/10/2023
Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer	26/10/2023
Endoscopic sleeve gastroplasty for obesity	26/10/2023
Transition from children's to adults' services - update	26/10/2023
Ovarian cancer: identifying and managing familial and genetic risk	27/10/2023