NHS Devon

NICE Update Bulletin: March 2026

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

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2. **Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils TA1142**
3. **Nivolumab with chemotherapy for untreated unresectable or metastatic urothelial cancer (terminated appraisal) TA1141**
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Technology Appraisals (TAs)

Fezolinetant for treating moderate to severe vasomotor symptoms associated with menopause TA1143

Recommendation

Fezolinetant **can be used** as an option to treat moderate to severe vasomotor symptoms associated with menopause when hormone replacement therapy is unsuitable.

This recommendation is not intended to affect treatment with fezolinetant 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

The menopause occurs when menstruation stops and the end of natural reproductive life is reached. Usually, it is defined as having occurred when there has been no naturally occurring period for 12 consecutive months. It is a natural part of ageing. Changes associated with menopause occur when the ovaries stop maturing eggs and secreting oestrogen and progesterone. The experience of symptoms varies (length and severity) but most people will have some vasomotor symptoms associated with the decrease in oestrogen. Vasomotor symptoms include hot flushes and night sweats caused by constriction and dilatation of blood vessels in the skin that can lead to a sudden increase in blood flow to allow heat loss. Vasomotor symptoms can have a significant impact on a person's life and have been linked to problems with sleep, quality of life and low moods and anxiety that occur with menopause. Perimenopause starts when symptoms of menopause appear and continues until 1 year after the last period.

Menopause usually occurs between age 45 and 55 with an average age of 51 years. The prevalence of problematic vasomotor symptoms that need treatment is estimated to be 25%, and the prevalence decreases with age to 15% at age 55 to 59, 6% at age 60-69 and only 3% at over 702. However, medical intervention is often not sought so the true prevalence of vasomotor symptoms may be much higher, with studies showing that up to 80% may experience vasomotor symptoms as part of the menopause.

Hormone replacement therapy (HRT) is the main treatment option for vasomotor symptoms in menopause. NICE recommends oestrogen and progestogen for those with a uterus; or oestrogen alone for those without a uterus (**NG23**). **NG101** notes that HRT should be stopped if breast cancer is diagnosed and should not be offered routinely when there is a history of breast cancer unless in exceptional circumstances. HRT may be considered unsuitable for other people such as those who have other hormone-dependent cancers, who have had significant side effects from HRT, or who prefer not to have hormonal treatment.

Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

The comparator treatments for the eligible population are paroxetine, venlafaxine and oxybutynin which are all administered orally, or no treatment.

Financial Factors

This technology is commissioned by ICBs.

The payment mechanism for the technology is determined by the responsible commissioner and depends on whether the technology is classified as high cost.

The key drivers of resource impact are that:

- the annual drug cost of fezolinetant is higher than comparator treatment options
- all treatment options are administered orally
- liver monitoring is needed before treatment with fezolinetant. An estimated 3 liver function tests per year are assumed and this can be amended in the resource impact template to reflect local practice
- in more complex cases, fezolinetant may require prescription or support from secondary care for additional liver monitoring.

NICE estimate that in year 3, 8,089 people in Devon will be eligible for treatment, with 809 having fezolinetant each year.

Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils TA1142

Recommendation

Dupilumab **can be used** as an add-on maintenance treatment option for uncontrolled chronic obstructive pulmonary disease (COPD) with raised blood eosinophils in adults if:

- they are having:
    - triple therapy including an inhaled corticosteroid, a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or
    - double therapy including a LABA and a LAMA if inhaled corticosteroids are not appropriate, and
- the company provides dupilumab according to the commercial arrangement.

Uncontrolled COPD is defined as 1 or more severe exacerbations or 2 or more moderate exacerbations in the previous 12 months. Raised blood eosinophils is defined as having a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).

Assess response to dupilumab at 12 months. Stop dupilumab if, compared with the 12 months before starting it, the number of severe exacerbations:

- is higher, or
- is the same, and the number of moderate exacerbations is higher.

These recommendations are not intended to affect treatment with dupilumab 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 healthcare professional consider it appropriate to stop.

The Technology

Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that can cause breathing difficulties. It includes chronic bronchitis, emphysema, chronic obstructive airways disease and chronic airflow limitation. It is characterised by persistent airways obstruction, causing symptoms including persistent and often progressive breathlessness, a chronic productive cough and limited exercise capacity. The impairment of lung function is usually progressive and is not fully reversible. COPD is often caused by smoking although it can be caused by long-term exposure to harmful fumes or dust and can also affect people who have never smoked. NICE guideline **NG115** defines COPD as a post bronchodilator ratio of forced expiratory volume in 1 second (FEV_1) to forced vital capacity (FVC) of less than 0.7. Moderate COPD is defined as FEV_1 between 50% and 79% predicted normal and severe COPD as FEV_1 30% and 49% predicted normal. Type 2 inflammation is associated with higher rates of exacerbations and lower quality of life, it can be identified through raised blood eosinophils and fractional exhaled nitric oxide (FeNO).

There is an estimated 1.2 million people with a COPD diagnosis. The prevalence of COPD is increasing, the number of those newly diagnosed increased by 27% in the last 10 years to approximately 2,000 per 100,000. COPD is more common in men and people over the age of 40, it becomes more common with increasing age and is generally higher among smokers.

Treatment for COPD aims to slow its progression, control the symptoms and reduce exacerbations. For people with stable chronic obstructive pulmonary disease who are breathless and have limited exercise capacity, NICE guideline **NG115** recommends initial therapy with short-acting beta2 agonist (SABA) or short-acting muscarinic antagonists (SAMA). For people who have symptoms that adversely impact quality of life or have 1 severe or 2 moderate exacerbations, dual therapy with long-acting beta2 agonists (LABA) and long-acting muscarinic antagonists (LAMA) or inhaled corticosteroids (ICS) is recommended before trial of all these treatments (triple inhaled therapy). NICE guideline **NG115** also recommends smoking cessation, pulmonary rehabilitation, pneumococcal and influenza vaccinations, personalised self-management plan and optimising treatment for co-morbidities as part of the management of stable chronic obstructive pulmonary disease.

Dupilumab is indicated in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate.

The treatments for the eligible population are triple or dual therapy or dupilumab with triple or dual therapy.

Triple or dual therapy is a combination of self-administered treatments that are inhaled; dupilumab is a self-administered subcutaneous injection.

Financial Factors

This technology is commissioned by ICBs.

The list price of dupilumab is £1,264.89 for a 2-pack of 300 mg per 2 ml pre-filled pens or pre-filled syringes.

The company has a commercial arrangement. This makes dupilumab available to the NHS at a discount. The size of the discount is commercial in confidence.

The payment mechanism for the technology is determined by the responsible commissioner and depends on whether the technology is classified as high cost.

The key drivers of resource impact are:

- dupilumab is a new drug given in addition to existing treatments
- training of people with chronic obstructive pulmonary disease (COPD) on how to administer the treatment
- home visits to administer the treatment
- the eligible population for dupilumab is large
- reduction in exacerbations.

NICE estimate that in year 3, 823 people in Devon will be eligible for treatment, 428 people having dupilumab each year.

Nivolumab with chemotherapy for untreated unresectable or metastatic urothelial cancer (terminated appraisal) TA1141

NICE is **unable to make a recommendation** on nivolumab for untreated unresectable or metastatic urothelial cancer. This is because the company did not provide an evidence submission.

Ruxolitinib cream for treating non-segmental vitiligo in people 12 years and over TA1140

Recommendation

Ruxolitinib cream **can be used** as an option to treat non-segmental vitiligo with facial involvement in people 12 years and over. Ruxolitinib cream can only be used if:

- topical first-line treatments have not worked or are not suitable, and
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with ruxolitinib cream 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 healthcare professional consider it appropriate to stop. For children or young people, this decision should be made jointly by the healthcare professional, the child or young person, and their parents or carers.

The Technology

Vitiligo is a chronic auto-immune condition in which areas of the skin lose its normal colour (pigment) and become very pale, white or light pink. Depigmentation (loss of colour) occurs when melanocytes, the cells that make the pigment, melanin become inactive. The causes are unclear but may be related to disorders of the immune system, family history or trigger events such as skin trauma, severe sunburn or stress. The extent and speed that vitiligo affects the skin are unpredictable and can range from small single patches to a total loss of colour. Vitiligo commonly affects the face, neck, hands and skin creases. It can be classified as segmental (unilateral or localised) in which only one area of the body is affected or non-segmental where symmetrical patches can appear on both sides of the body. Non-segmental vitiligo may be categorised as:

- focal (small, isolated, depigmented patch without an obvious segmental distribution pattern)
- acrofacial (depigmented patches on the hands, feet and or face, especially around orifices)
- mucosal (depigmented patches on the mouth and/or genital mucosa)
- follicular (depigmented body hairs)
- generalised (usually symmetrical, depigmented patches randomly occurring over the entire body)
- universal (complete or nearly complete skin depigmentation)
- mixed (both segmental and non-segmental forms co-exist), or
- unclassified (isolated mucosal involvement and persistent focal vitiligo)

Vitiligo may cause psychological distress and is associated with other auto-immune conditions such as Grave's disease.

Vitiligo affects males and females, and all ethnicities equally. It may be more noticeable in people with darker skin tones and its noticeability may also vary by the proportion and location of the skin affected. It can start at any age, but in more than half of the people with vitiligo, it appears before 20 years of age. In the UK, it is estimated that 1 in 100 people have vitiligo, of which 85% to 90% have the non-segmental type. Based on 2020 figures, it is estimated that approximately 570,000 people in England and Wales have non-segmental vitiligo.

Ruxolitinib cream is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

The comparator treatments for the eligible population are no active treatments or phototherapy. Where ruxolitinib cream is used but fails to be effective then it may move phototherapy further down the pathway. Phototherapy is resource intensive, requiring many treatments over a 12-month period. A person can potentially have another course of phototherapy in their lifetime.

Financial Factors

This technology is commissioned by ICBs.

The company has a commercial arrangement. This makes ruxolitinib cream available to the NHS with a discount. The size of the discount is commercial in confidence.

The payment mechanism for the technology is determined by the responsible commissioner and depends on whether the technology is classified as high cost.

The key drivers of resource impact are that:

- Ruxolitinib cream may increase the number of people having treatment for non-segmental vitiligo, which may have service implications. Because it is anticipated that ruxolitinib cream will be prescribed, supplied and monitored in secondary care, it may increase demands in dermatology clinics.
- Ruxolitinib cream is expected to lead to a decrease in the number of people having phototherapy.

NICE estimate that in year 3, 1,853 people in Devon will be eligible for treatment, with 371 having ruxolitinib each year.

Epcoritamab for treating relapsed or refractory follicular lymphoma after 2 or more lines of systemic treatment TA1139

Recommendation

Epcoritamab **can be used** as an option to treat relapsed or refractory follicular lymphoma in adults after 2 or more lines of systemic treatment, only if:

- epcoritamab is stopped after 3 years of treatment or earlier if the lymphoma progresses, and

- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with epcoritamab 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 healthcare professional consider it appropriate to stop.

The Technology

Lymphomas are cancers of the lymphatic system, which is a part of the immune system. Lymphomas are divided into Hodgkin and non-Hodgkin lymphomas. Non-Hodgkin lymphomas (NHL) are a diverse group of conditions categorised according to the cell type affected (B-cell or T-cell), as well as the clinical features and rate of progression of disease.

Follicular lymphoma is a type of indolent, low-grade lymphoma, meaning they are slow growing, which affects B-lymphocytes. It is the most common type of low-grade lymphoma. People with this condition typically present with painless lumps (enlarged lymph nodes) in the neck, armpit or groin although there may be additional symptoms such as night sweats and recurrent fevers in some people. But some people do not have symptoms so the disease may have advanced by the time it is diagnosed.

Follicular lymphomas are commonly staged from I (best prognosis) to IV (worse prognosis) and the staging depends on how many groups of lymph nodes are affected, where they are in the body, the size of the areas of lymphoma and whether other organs outside of the lymphatic system such as the bone marrow or liver are affected.

In England in 2022 there were 2,404 diagnoses of follicular lymphoma. The 5-year survival rate for those diagnosed with follicular lymphoma is around 90% but is likely to be lower for people with additional risk factors or whose disease has relapsed or is refractory after several lines of treatment. Duration of response to chemoimmunotherapy and survival decreases with each subsequent relapse of follicular lymphoma.

Epcoritamab is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Comparator treatments for the eligible population include various combinations of chemotherapy and rituximab-based treatment. The resource impact template includes rituximab with endamustine, lenalidomide with rituximab, and obinutuzumab with bendamustine, all of which are administered intravenously. It also includes chlorambucil chemotherapy, which is administered orally. Epcoritamab is administered subcutaneously.

Financial Factors

This technology is commissioned by NHS England.

The list price of epcoritamab is £547.33 for 1 vial of 4 mg/0.8 ml concentrate for solution for injection and £6,568.00 for 1 vial of 48 mg/0.8 ml solution for injection.

The company has a commercial arrangement. This makes epcoritamab available to the NHS with a discount. The size of the discount is commercial in confidence.

The payment mechanism for epcoritamab is determined by the responsible commissioner and depends on whether it is classified as high cost.

The key drivers of resource impact are:

- the average treatment duration of epcoritamab and comparators
- that epcoritamab is administered subcutaneously but most comparators are administered intravenously.

NICE estimate that in year 3, 7 people in Devon will be eligible for treatment, with 5 having epcoritamab each year.

Durvalumab with gemcitabine and cisplatin for neoadjuvant treatment then alone for adjuvant treatment of muscle-invasive bladder cancer TA1138

Recommendation

Durvalumab can be used, within its marketing authorisation, as an option with gemcitabine and cisplatin for neoadjuvant treatment, and then alone for adjuvant treatment, of muscle-invasive bladder cancer in adults. Durvalumab can only be used if the company provides it according to the commercial arrangement.

The Technology

Bladder cancer is where a growth of abnormal tissue, known as a tumour, develops in the bladder lining. Muscle-invasive bladder cancer is when cancerous cells spread beyond the lining into the surrounding bladder muscle. Common symptoms of bladder cancer include blood in the urine, passing urine often, pain or burning sensation when passing urine, fatigue, pain in lower back or abdomen and unexplained weight loss.

In 2022, 18,060 new bladder cancer cases were diagnosed in England. At diagnosis, 30% of bladder cancers are muscle-invasive bladder cancer. The majority of cases are in those aged over 75 but bladder cancer can affect young people too. Bladder cancer is more common among men than women (3 males for every 1 female), but women are more likely to be diagnosed at a later stage. Smoking is the biggest cause of preventable bladder cancer.

Durvalumab with gemcitabine and cisplatin as neoadjuvant treatment then alone as adjuvant treatment after radical cystectomy is indicated for the treatment of adults with resectable muscle-invasive bladder cancer.

The comparator is neoadjuvant treatment with gemcitabine and cisplatin followed by radical cystectomy and no treatment, or adjuvant nivolumab for a small subgroup of eligible people with high-risk of recurrence after surgery and whose tumours express PD-L1 at a level of 1% or more.

Financial Factors

This technology is commissioned by NHS England.

The list price of durvalumab is £592.00 per 2.4-ml vial and £2,466.00 per 10-ml vial. The list price of cisplatin is £5.36 per 10-ml vial. The list price of gemcitabine varies by pack size and dose.

The company has a commercial arrangement. This makes durvalumab available to the NHS with a discount. The size of the discount is commercial in confidence.

The payment mechanism for the technology is determined by the responsible commissioner and depends on whether the technology is classified as high cost.

The key drivers of the resource impact are:

- The recommendation will increase the number of people with bladder cancer having adjuvant treatment.
- Treatment with neoadjuvant durvalumab with gemcitabine and cisplatin may result in a small increased chance of the person having a radical cystectomy.
- Adjuvant durvalumab has fewer administrations than nivolumab. Durvalumab is administered via intravenous infusion. Nivolumab can be administered intravenously or subcutaneously. If durvalumab displaces intravenous nivolumab then this will result in fewer intravenous infusions, but if durvalumab displaces subcutaneous nivolumab, then more intravenous infusions will take place.
- An additional 4 outpatient review appointments will be required for those who have adjuvant durvalumab as per advice from NHS England.
- PD-L1 testing may decrease because this is only a requirement for treatment with nivolumab.
- Adverse events are not assumed to have additional resource impact from current practice because of the clinical similarity between the treatment options.

NICE estimate that in year 3, 12 people in Devon will be eligible for treatment.

Highly Specialised Technology Guidance (HSTs)

Pegzilarginase for treating arginase-1 deficiency in people 2 years and over HST35

Recommendation

Pegzilarginase **can be used**, within its marketing authorisation, as an option to treat arginase-1 deficiency (also called hyperargininaemia) in people 2 years and over. Pegzilarginase can only be used if the company provides it according to the commercial arrangement.

The Technology

Arginase-1 deficiency (ARG1-D) is a urea cycle disorder in which the body is unable to process arginine, an amino acid used to build protein. It is a metabolic condition caused by mutations in the ARG1 gene, inherited from both parents. A lack of the enzyme arginase in the liver and red blood cells leads to excess nitrogen stored in the form of ammonia (hyperammonaemia) in the blood and arginine (hyperargininemia) in the blood and cerebrospinal fluid.

ARG1 deficiency is a severe condition, presenting in early childhood and symptoms include developmental delay, stiffness, vomiting and seizures. Disease progression is characterised by severe spasticity, inability to walk, complete loss of bowel and bladder control and severe intellectual disability.

It is estimated that ARG1 deficiency occurs in about 1 in 300,000 to 1,000,000 births. However, newborn screening for ARG1 deficiency is not routinely screened for at birth and arginine levels may be within the normal range in the first days of life. It is estimated that the UK population prevalence of ARG1 deficiency is 0.58 cases per million.

Treatment is focused on lowering arginine levels and preventing the build-up of ammonia in the blood. Management includes frequent blood tests to check arginine levels, restricting dietary protein and using oral nitrogen-scavenging medicines such as sodium benzoate and/or sodium phenylbutyrate/phenylacetate for chronic or recurrent hyperammonaemia. Amino acid formulas, multivitamins and calcium supplements may be used.

Pegzilarginase is indicated for the treatment of arginase-1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older.

Financial Factors

The list price for pegzilarginase is £4,690.00 per 2-mg vial (excluding VAT, company submission). The company has a commercial arrangement which makes pegzilarginase available to the NHS with a discount. The size of the discount is commercial in confidence.

NICE Guidelines (NGs)

Fertility problems: assessment and treatment NG257

This guideline covers diagnosing and treating health-related fertility problems. It aims to reduce variation in practice and improve how fertility problems are investigated and managed.

This guideline updates and replaces NICE guideline CG156 (February 2013).

Kidney cancer: diagnosis and management NG256

This guideline covers diagnosing and managing renal cell carcinoma in people aged 18 and over. It aims to improve care by helping healthcare professionals offer people the right treatments and support, taking into account the person's individual preferences.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

HealthTech guidance (HTGs)

Percutaneous insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock HTG775

Recommendations

Percutaneous insertion of a catheter-based left ventricular microaxial flow pump can be used in the NHS during the evidence generation period as an option to manage cardiogenic shock. There must be enhanced informed consent and auditing of outcomes.

The Condition

Acute heart failure is a complex clinical syndrome of signs and symptoms that happen when the efficiency of the heart as a pump is impaired. It can lead to reduced blood flow to the body and increased filling pressures in the heart. Cardiogenic shock is the most severe form of acute heart failure, potentially leading to organ failure and death. It has multiple causes, including heart attack,

chronic heart failure, sudden heart valve failure, cardiac arrhythmias, inflammation of the heart muscle, blood clots in the lungs, drug overdoses and poisoning. It can also happen after open heart surgery (postcardiotomy cardiogenic shock).

The Procedure

Catheter-based left ventricular microaxial flow pumps are temporary mechanical circulatory support devices. Percutaneous insertion is typically done through the femoral artery, under general anaesthetic or sedation with local anaesthesia. The microaxial flow pump catheter is advanced into the ascending aorta, across the aortic valve and into the left ventricle, guided by fluoroscopic or echocardiographic imaging. Once it is in position, the catheter-based pump delivers blood from the inlet area, which sits inside the left ventricle, through a cannula to the outlet opening in the ascending aorta. A wired console controls the pump speed and monitors its function and position. Different blood flow rates can be achieved, depending on the power of the pump that has been implanted.

The aim is to reduce ventricular work and provide the circulatory support needed to allow the heart time to recover from an acute injury. It can also be used as a bridge to longer-term treatments, such as a heart transplant or implantation of a durable left ventricular assist device.

Some pumps can be surgically inserted using a graft cut-down technique through the axillary or subclavian artery, or through a direct aortic approach using a sternotomy or thoracotomy. This is covered by NICE's HealthTech guidance on surgical insertion of a catheter-based microaxial flow pump for cardiogenic shock.

The procedure can also be used as support during high-risk percutaneous coronary intervention. This is covered by NICE's HealthTech guidance on percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions.

Surgical insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock HTG774

Recommendations

Surgical insertion of a catheter-based left ventricular microaxial flow pump can be used in the NHS during the evidence generation period as an option to manage cardiogenic shock. There must be enhanced informed consent and auditing of outcomes.

The Condition

Acute heart failure is a complex clinical syndrome of signs and symptoms that happen when the efficiency of the heart as a pump is impaired. It can lead to reduced blood flow to the body and increased filling pressures in the heart. Cardiogenic shock is the most severe form of acute heart failure, potentially leading to organ failure and death. It has multiple causes, including:

- heart attack
- chronic heart failure

- sudden heart valve failure
- cardiac arrhythmias, inflammation of the heart muscle
- blood clots in the lungs
- drug overdoses and poisoning.

It can also happen after open heart surgery (postcardiotomy cardiogenic shock).

The Procedure

Catheter-based left ventricular microaxial flow pumps are temporary mechanical circulatory support devices. Surgical insertion is usually done under general anaesthetic. The microaxial flow pump catheter is inserted using a surgically implanted end-to-side graft onto the axillary artery through an infraclavicular incision. The catheter is advanced into the ascending aorta, across the aortic valve and into the left ventricle, guided by fluoroscopic or echocardiographic imaging. Alternatively, the pump can be surgically inserted directly into the aorta, through a sternotomy or thoracotomy. Once it is in position, the pump delivers blood from the inlet area, which sits inside the left ventricle, through a cannula to the outlet opening in the ascending aorta. A wired console controls the pump speed, and monitors its function and position. The procedure is intended to be used for a period of days to a few weeks.

The aim is to reduce ventricular work and provide the circulatory support needed to allow the heart time to recover from an acute injury. It can also be used as a bridge to longer-term treatments, such as a heart transplant or implantation of a durable left ventricular assist device.

Smaller pumps can be inserted percutaneously. This is covered by NICE's HealthTech guidance on percutaneous insertion of a catheter-based microaxial flow pump for cardiogenic shock.

Artificial intelligence (AI) technologies to help detect or characterise colorectal polyps HTG773

Recommendations

For people who do not have diagnosed IBD or Lynch Syndrome

Can be used during the evidence generation period to help detect colorectal polyps

Six artificial intelligence (AI) technologies can be used in the NHS during the evidence generation period as options to help detect colorectal polyps during colonoscopy, for people who do not have diagnosed inflammatory bowel disease (IBD) or Lynch syndrome. The technologies are:

- CADDIE
- CAD EYE
- ENDO-AID
- EndoScreener

- GI Genius
- MAGENTIQ-COLO.

These technologies can only be used:

- if the evidence outlined in the evidence generation plan for AI technologies to help detect or characterise colorectal polyps is being generated
- as long as they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

The companies must confirm that agreements are in place to generate the evidence. NICE will contact the companies annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

At the end of the evidence generation period (4 years), the companies should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed to help detect colorectal polyps

More research is needed on 4 AI technologies used to help detect colorectal polyps during colonoscopy. The technologies are:

- Argus
- Discovery
- ENDOANGEL
- Endoscopic Multimedia Information System (EMIS).

More research is needed to help characterise colorectal polyps

More research is needed on 4 AI technologies used to help characterise colorectal polyps. The technologies are:

- Argus
- Discovery
- ENDOANGEL
- Endoscopic Multimedia Information System (EMIS).

For people with diagnosed IBD or Lynch syndrome

More research is needed on 10 AI technologies to help detect or characterise colorectal polyps for people with diagnosed IBD or Lynch syndrome. The technologies are:

- Argus (for detecting)
- CAD EYE (for detecting and characterising)

- CADDIE (for detecting and characterising)
- Discovery (for detecting)
- EMIS (for detecting)
- ENDO-AID (for detecting)
- ENDOANGEL (for detecting)
- EndoScreener (for detecting)
- GI Genius (for detecting and characterising)
- MAGENTIQ-COLO (for detecting and characterising).

The Technologies

Polyps are small growths in the bowel. It is important to detect and identify these because some may develop into bowel (colorectal) cancer if left untreated. Colonoscopy is a procedure that allows healthcare professionals to look inside the bowel using a thin, flexible tube with a camera to check for problems such as polyps or early signs of cancer. Colonoscopy is usually done as an outpatient procedure, with the option of sedation or pain relief.

Artificial intelligence (AI) technologies support polyp detection during colonoscopy by highlighting areas of concern for the endoscopist in a process known as computer-aided detection (CADe). Some AI technologies also offer computer-aided diagnosis (CADx), which helps assess polyp features to guide decisions about removal. Ten AI technologies to assist colonoscopy in the detection of polyps were identified as relevant to the NHS (table 1). All 10 technologies featured CADe and 4 also featured CADx

Financial Factors

Gastroenterology and colorectal surgery services are commissioned by ICBs.

The key drivers of resource impact are:

- The costs of procuring AI technologies and associated subscription and maintenance costs.
- Improvement in detection rates are not expected to be significant; however, a possible increase in the rate of detection of adenomatous polyps may lead to an increase in treatment and management following colonoscopy.
- Possible increased detection may reduce the need for more intensive healthcare resources later, such as for emergency presentations or more advanced stages of cancer.
- Increased procedure time during implementation while staff learn to use the technologies.

The comparator treatment for the eligible population is colonoscopy without AI technologies. There may be an initial increase in procedure length, but a significant increase is not anticipated when using AI technologies.

Off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation HTG772

Recommendations

When open-heart surgery and other mitral valve procedures are unsuitable

Off-pump minimal access mitral valve repair by artificial chordae insertion can be used in the NHS during the evidence generation period, as an option to treat mitral regurgitation caused by mitral valve leaflet prolapse in adults when open-heart surgery and other mitral valve repair procedures are considered unsuitable by the multidisciplinary team. There must be enhanced informed consent and auditing of outcomes.

When open-heart surgery or other mitral valve procedures are suitable

More research is needed on off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation caused by mitral valve leaflet prolapse in adults when open-heart surgery or other mitral valve repair procedures are considered suitable by the multidisciplinary team, before it can be used in the NHS.

This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

The Condition

The mitral valve allows blood to flow from the left atrium to the left ventricle. Mitral regurgitation happens when the valve does not close properly, allowing blood to flow back into the atrium from the ventricle during systole (when the heart contracts). The heart must work harder, resulting in an enlarged left ventricle. If untreated, this can lead to problems such as heart failure. Mitral regurgitation can be degenerative (primary or structural) or functional (secondary). Degenerative mitral regurgitation is caused by 'wear and tear' to the chordae and leaflets in the valve. In functional mitral regurgitation the chordae and leaflets are structurally normal but there is geometrical distortion of the subvalvular apparatus. This is caused by idiopathic cardiomyopathy or weakening of the cardiac walls because of coronary artery disease (ischaemic mitral regurgitation).

The Procedure

This minimal access procedure for mitral regurgitation is done under general anaesthesia on a beating heart with no need for cardiopulmonary bypass (off-pump). Using transoesophageal echocardiography imaging, a left-sided anterior thoracotomy is used to access the left ventricle. The device delivery system is passed through the wall of the left ventricle with a purse-string suture and into the left side of the heart to the target mitral valve leaflet. Once it is correctly positioned, artificial chordae are passed through the target mitral valve using a needle and anchored to the leaflet. Typically, 3 or 4 chordae are placed along the free edge of the mitral valve leaflet to re-suspend the prolapsed segment. The delivery system is removed, and the purse-

string suture is tightened. The tension on the chordae is adjusted until there is improvement or elimination of the mitral regurgitation, as confirmed on transoesophageal echocardiography imaging. The endings of the chordae sutures are then secured to the outside of the heart.

This procedure has a lower risk of compromising subsequent surgical mitral valve repair than some other techniques for mitral regurgitation. It may also be suitable for people for whom open-heart surgery is not considered safe because of other health conditions.

Artificial intelligence (AI) technologies for assessing and triaging skin lesions referred to the urgent suspected skin cancer pathway: early value assessment HTG746 (UPDATE)

March 2026: NICE updated the 'what evidence generation is needed' section and added section 3.19 to reflect the updated evidence generation plan. NICE also updated information on spectrophotometry in section 3.9 in line with feedback on clinical practice.

Recommendations

Deep Ensemble for Recognition of Malignancy (DERM, an artificial intelligence [AI] technology) can be used within teledermatology services in the NHS during the evidence generation period as an option to assess and triage skin lesions in adults referred to the urgent suspected skin cancer pathway. It can only be used:

- if the evidence outlined in the evidence generation plan is being generated
- once it has appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

Mitigate the potential risk of missed or delayed cancer diagnoses when using DERM during the evidence generation period by:

- doing a healthcare professional review for people with black or brown skin
- regular monitoring of DERM's performance to maintain accuracy.
- using additional protocols when necessary, such as:
    - a national governance framework to ensure local oversight of use of DERM
    - a healthcare professional review.

The company must confirm that agreements are in place to generate the evidence. NICE will contact the company annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

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

The Technologies

DERM is an artificial intelligence (AI)-based skin lesion analysis technology intended for use in the screening, triage and assessment of suspected skin cancer lesions in people aged 18 or over. DERM can be used within teledermatology services after referral from primary care. It is intended to be used as an automated tool or with a healthcare professional review (known as a second read), to decide if further assessment by a dermatologist is needed. A smartphone is used to take images of skin lesions using a dermoscopic lens attachment, and the images are uploaded to the online platform. The DERM platform uses an AI-based fixed algorithm (it does not update itself automatically) to analyse the dermoscopic images and provide a suspected diagnosis of the lesion. If DERM labels the lesion as benign, the person is discharged from the urgent suspected skin cancer pathway and is sent the results with safety-netting advice. If DERM labels the lesion as pre-cancer or cancer, an NHS dermatologist reviews the case virtually and decides on a management plan for the person. DERM can classify lesions as one of the following types: melanoma, squamous cell carcinoma, basal cell carcinoma, intra-epidermal carcinoma, actinic keratosis, atypical nevus or benign lesions (this includes benign vascular lesion, seborrheic keratosis, dermatofibroma, solar lentigo and melanocytic benign nevus). If a lesion has features of more than 1 lesion type, DERM uses a risk hierarchy to classify it as the more severe suspected lesion type.

The cost of an assessment using the online DERM platform is £30 per referral. There is an extra cost of £8.20 per referral if NHS teledermatology staff virtually review a case to decide on the most appropriate outcome. The total price can be discounted to £35.90 per referral if the subsequent biopsy results from the lesions that have been assessed by DERM are shared with the company. It costs an extra £17 to have a case reviewed by the company's second-read dermatologist. The company states that these costs include training and data storage. DERM has a class III CE-mark certification.

NICE Quality Standards

Kidney cancer QS215

This quality standard covers diagnosing and managing renal cell carcinoma in adults (aged 18 and over). It describes high-quality care in priority areas for improvement.

Fertility problems QS73 (UPDATE)

March 2026: Changes have been made to align this quality standard with the updated NICE guideline on fertility problems. Statement 1 on lifestyle advice has been removed because of measurability issues. Statement 4 on semen analysis and statement 8 on the number of embryos transferred have been removed because these are now routine practice. All remaining statements have been updated to reflect changes to the guidance on fertility. Links, definitions and source guidance sections have also been updated throughout.

This quality standard covers assessing and treating fertility problems in people with explained and unexplained infertility, including access to IVF treatment. It also covers cryopreservation before cancer treatment that may affect fertility. It describes high-quality care in priority areas for improvement.

Current NICE Consultations

Title/link	End date of consultation
Rebisufligene etisparvovec for treating mucopolysaccharidosis type IIIA [ID6540]	01/04/2026
Gender Incongruence Services for Children and Young People	02/04/2026
Bepirovirsen for treating chronic hepatitis B [ID6608]	07/04/2026
Acalabrutinib and venetoclax with or without obinutuzumab for untreated chronic lymphocytic leukaemia [ID6232]	07/04/2026
Pegcetacoplan for treating complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis in people 12 years and over [ID6489]	07/04/2026
Norucholic acid for treating primary sclerosing cholangitis [ID6583]	08/04/2026
Vorasidenib for treating astrocytoma or oligodendroglioma with IDH1 or IDH2 mutations after surgery in people 12 years and over [ID6407]	09/04/2026
Ripretinib for treating advanced gastrointestinal stromal tumours after 3 or more kinase inhibitors (review of TA881) [ID6496]	09/04/2026
Extravascular implantable cardioverter defibrillator insertion for preventing sudden cardiac death	10/04/2026
Brentuximab vedotin with etoposide, cyclophosphamide, doxorubicin, dacarbazine and dexamethasone for untreated advanced classical Hodgkin lymphoma [ID6437]	14/04/2026
Sonrotoclax for treating relapsed or refractory mantle cell lymphoma after an anti-CD20 treatment and a BTK inhibitor [ID6654]	14/04/2026
Percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism	14/04/2026
Linvoseltamab for treating relapsed or refractory multiple myeloma after 3 or more treatments [ID6609]	16/04/2026
Anitocabtagene autoleucel for treating relapsed or refractory multiple myeloma ID6549	16/04/2026
Semaglutide for reducing the risk of major adverse cardiovascular events in people with cardiovascular disease and overweight or obesity [ID6441]	17/04/2026

Lutetium-177 vipivotide tetraxetan in combination for treating PSMA-positive hormone-sensitive metastatic prostate cancer [ID6589]	20/04/2026
Larotrectinib for treating NTRK fusion-positive advanced solid tumours (MA review of TA630) [ID6292]	24/04/2026
Lecanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease [ID4043]	28/04/2026
Donanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease [ID6222]	28/04/2026
Tislelizumab with chemotherapy for untreated recurrent or metastatic nasopharyngeal cancer ID6304	28/04/2026