NHS Devon

NICE Update Bulletin: May 2026

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

1. **Amivantamab with carboplatin and pemetrexed for untreated EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer TA1158**
2. **Givinostat for treating Duchenne muscular dystrophy in people 6 years and over TA1157**
3. **Osimertinib for treating EGFR mutation-positive unresectable locally advanced non-small-cell lung cancer after platinum-based chemoradiotherapy TA1156**
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Technology Appraisals (TAs)

Amivantamab with carboplatin and pemetrexed for untreated EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer TA1158

Recommendation

Amivantamab with carboplatin and pemetrexed **can be used** during the managed access period as an option for untreated advanced non-small-cell lung cancer (NSCLC) with activating EGFR exon 20 insertion (ex20ins) mutations in adults. It can only be used if the conditions in the managed access agreement for amivantamab with carboplatin and pemetrexed are followed.

This recommendation is not intended to affect treatment with amivantamab with carboplatin and pemetrexed 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

Lung cancer is the third most common cancer and the most common cause of cancer death in the UK, accounting for 10% of all new cancer cases and 20% of all cancer deaths in 2020. There were around 37,000 new lung cancer cases diagnosed in 20222 and 27,000 deaths from lung cancer in England in 2020 (most recent available data). Most lung cancers are diagnosed at an advanced stage, when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage 3) or to other parts of the body (metastatic disease; stage 4). In 2022, around 92% (~34,000) of people diagnosed with lung cancer in England had NSCLC.

Around 12 to 14% of people with NSCLC in Europe have mutations in the gene coding the epidermal growth factor receptor (EGFR). Exon 20 is part of the EGFR gene that can be mutated by an addition to the DNA sequence (an insertion mutation). Mutations in exon 20 occur in 0.7% (around 170) of people diagnosed with NSCLC (this is around 6-9% of people with an EGFR mutation). However, they are associated with poorer outcomes than other EGFR mutations.

The general treatment pathway for NSCLC can be divided into interconnected decision points based on the number staging system and line of therapy. Treatment choices are influenced by the presence of biological markers (including programmed cell death 1 ligand [PD-L1] status), oncogenic driver genetic alterations, histology (squamous or non-squamous) and previous treatment.

There is no standard treatment pathway, and no NICE recommended targeted treatment options, for treating exon 20 insertion mutation-positive NSCLC. For people with EGFR-positive NSCLC who have not previously had treatment, NICE guidance recommends the TKIs osimertinib, dacomitinib, afatinib, erlotinib, and gefitinib as treatment options (NICE technology appraisal guidance **TA654**, **TA595**, **TA310**, **TA258**, and **TA192** respectively). However, they are reported as having limited efficacy when EGFR exon 20 insertions are present and people with NSCLC

that is EGFR exon 20 positive continue to have poor prognosis. Platinum doublet chemotherapy and atezolizumab in combination are also treatment options (**NG122** and **TA584**).

Amivantamab in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor (EGFR) Exon 20 insertion mutations.

Financial Factors

This technology is commissioned by NHS England.

The list price for amivantamab is £1,079 per 350-mg vial.

The company has a commercial arrangement. This makes amivantamab with carboplatin and pemetrexed 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:

- Usual treatment for untreated advanced non-small-cell lung cancer (NSCLC) with exon 20 insertion mutations is carboplatin with pemetrexed or best supportive care. The introduction of amivantamab will therefore incur additional drug costs by introducing a new treatment option and potentially increasing the number of cycles of pemetrexed.
- There will be an increase in drug administration costs, with amivantamab having a minimum infusion time of 2 hours.
- Amivantamab will require pharmacy preparation, and treatment with amivantamab will need infusion chair time, nursing time, toxicity monitoring and management of any infusion-related reactions.
- Clinical trial evidence shows that amivantamab with carboplatin and pemetrexed increases how long people have before their condition gets worse compared with carboplatin with pemetrexed.

Givinostat for treating Duchenne muscular dystrophy in people 6 years and over TA1157

Recommendation

Givinostat **can be used** as an option to treat Duchenne muscular dystrophy in people 6 years and over who are ambulant (able to walk or stand, with or without support) at the start of treatment. Givinostat can only be used if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with givinostat 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

Duchenne muscular dystrophy is a fatal, rare genetic disorder that begins in childhood and causes systemic loss of muscle function and progressive disability. It is caused by mutations in the dystrophin gene, which is essential for maintaining the structural integrity of muscle fibres. Without dystrophin, muscles gradually weaken and deteriorate, which affects the entire body. Because the dystrophin gene is on the X chromosome, the condition primarily affects boys and young men, although in rare cases girls may also be affected. In the UK, it is estimated that around 100 people are born with Duchenne muscular dystrophy each year and around 1,183 people are currently living with the condition. Symptoms typically begin when a child is between 2 and 5 years old and include delayed walking, frequent falls, and difficulty rising from the floor.

Duchenne muscular dystrophy is a systemic condition, affecting multiple body systems. As it advances, people lose the ability to walk and use their arms. It can cause skin complications due to pressures applied by having limited mobility. Breathing muscles become progressively weaker, making it harder to breathe. The heart's ability to pump blood effectively is also reduced and cardiac problems can lead to unexpected death. Duchenne muscular dystrophy is also associated with neurobehavioural comorbidities, including intellectual disability, attention deficit disorders, and autism spectrum disorder. When walking is no longer possible, people with Duchenne muscular dystrophy must use mobility aids such as wheelchairs. They also need regular healthcare appointments to monitor their spine, heart, and breathing during sleep. The spine can develop scoliosis, which may need surgery. By their teens or early twenties, most people with Duchenne muscular dystrophy need night-time non-invasive ventilation (NIV). This involves wearing a mask or mouthpiece connected to a machine that helps maintain oxygen levels and reduce the strain on their lungs while sleeping.

In the most advanced stages, people need continuous ventilatory support (full-time ventilation). Cough assistance is also often needed to help clear the airways. By adulthood, most people with Duchenne muscular dystrophy need help with all aspects of self-care, including eating, drinking, using the toilet, dressing, washing, and moving. People with Duchenne muscular dystrophy become increasingly dependent on others, including their families and carers, because they need continuous, day-and-night care to support them in their daily lives. Despite improvements in supportive care, Duchenne muscular dystrophy remains a fatal condition, with life expectancy typically under 30 years, most often due to respiratory or cardiac failure.

Givinostat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

The treatment options for the eligible population are vamorolone, ataluren and corticosteroids, such as prednisolone and deflazacort, used in established clinical management. Givinostat and the other treatment options are administered orally.

Givinostat has additional monitoring requirements relative to comparators because it requires an ECG when initiating treatment and additional blood counts and follow-up appointments throughout treatment.

Financial Factors

This technology is commissioned by NHS England.

The price of givinostat is £13,846 per 140 ml of 8.86 mg/ml oral suspension.

The company has a commercial arrangement. This makes givinostat available to the NHS for this indication 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:

- The monitoring requirements and the associated costs for givinostat are greater than comparator treatments.
- People on givinostat are expected to have slower disease progression, which may increase the duration and cost of associated care, but this would primarily transact outside of the 3-year resource impact assessment period.
- Most of the additional capacity requirements associated with using givinostat are already in practice for people having treatment through the early access programme. However, this may vary based on local practice and current levels of uptake.

NICE estimate that in year 3, 23 people in Devon will be eligible for treatment, with 4 people having givinostat each year.

Osimertinib for treating EGFR mutation-positive unresectable locally advanced non-small-cell lung cancer after platinum-based chemoradiotherapy TA1156

Recommendation

Osimertinib **can be used**, within its marketing authorisation, as an option to treat unresectable locally advanced (stage 3) non-small-cell lung cancer (NSCLC) in adults. It is an option when:

- the tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, and
- the cancer has not progressed during or after platinum-based chemoradiotherapy.

Osimertinib can only be used if the company provides it according to the commercial arrangement.

The Technology

Non-small-cell lung cancer (NSCLC) is the third most common cancer in the UK and the leading cause of cancer-related death. It is epidermal growth factor receptor mutation-positive (EGFRm-positive) in around 10% of cases. This subtype is more common in women, people who do not smoke, and East or South Asian ethnic groups. Locally advanced (stage 3) cancer means the cancer has spread into tissues around the lungs and might have spread into nearby lymph nodes. Unresectable means that the cancer cannot be removed by surgery.

People with EGFRm-positive locally advanced unresectable NSCLC typically have definitive chemoradiotherapy (CRT). After this, there are no targeted maintenance treatment options. After CRT, the condition is managed with best supportive care (BSC). This includes active surveillance imaging (for example, CT scans every 3 months), symptom management and biopsies to confirm recurrence. Osimertinib is proposed as a maintenance treatment after CRT. Once the cancer progresses, people are considered for subsequent systemic treatments. This may include EGFR tyrosine kinase inhibitors (TKIs) such as osimertinib or chemotherapy, depending on prior exposure.

Osimertinib is indicated for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy.

Osimertinib is an oral tablet taken once daily with each pack containing 30 tablets.

Financial Factors

This technology is commissioned by NHS England.

The list price of osimertinib (40 mg or 80 mg) is £5,770 per 30-tablet pack.

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

The key drivers of resource impact are that:

- Prior to this recommendation, there were no effective maintenance treatments for EGFR mutation-positive locally advanced unresectable non-small-cell lung cancer (NSCLC) following treatment with platinum-based chemoradiotherapy. Treatment with osimertinib will therefore result in additional drug costs.
- Treatment with osimertinib is associated with an increased risk of cardiotoxicity and will require additional cardiac monitoring, with either an electrocardiogram (ECG) or echocardiogram. The frequency of monitoring may be dependent on the person's pre-existing cardiovascular function.

- Treatment with osimertinib can improve outcomes including progression-free survival and may impact subsequent treatment decisions. As people who have osimertinib as maintenance treatment are unlikely to have retreatment with an EGFR tyrosine kinase inhibitor (TKI) after progression, use of osimertinib at a later stage in the pathway is likely to decline.

NICE estimate that in year 3, 10 people in Devon will be eligible for treatment, with 8 people having osimertinib each year.

Rozanolixizumab for treating antibody-positive generalised myasthenia gravis TA1155

Recommendation

Rozanolixizumab, as an add-on to standard treatment, **can be used** as an option to treat generalised myasthenia gravis in adults who test positive for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies. It can only be used if:

- the condition is classified as Myasthenia Gravis Foundation of America (MGFA) class 2 to 4a
- the condition is uncontrolled after 2 or more treatments, excluding acetylcholinesterase inhibitors, and
- intravenous immunoglobulin (IVIg) or plasma exchange (PLEX) would otherwise be offered, or has been tried and stopped because of side effects or because it did not work well enough.

Rozanolixizumab can only be used if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with rozanolixizumab 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

Myasthenia gravis (MG) is a rare autoimmune condition that can affect multiple muscle groups and causes muscle weakness and fatigue. At first, it usually only affects the eye muscles. But in around 80% of people it will affect other muscle groups and become generalised MG (gMG). Most people with gMG have anti-acetylcholine receptor (AChR) antibodies, but a small proportion have anti-muscle-specific tyrosine kinase (MuSK) antibodies.

The condition is highly variable and unpredictable, with symptoms typically including fatigue, and problems with breathing, speaking, seeing and concentrating. It substantially affects daily activities and the person's ability to work. The symptoms have a substantial impact on quality of

life, and many people regularly need a high level of care. There is no cure for gMG. All current treatments for gMG aim to reduce symptoms.

Many people with gMG take corticosteroids. But it can be difficult to optimise the lowest effective dose, to minimise side effects, without increasing the risk of exacerbations (an acute worsening of symptoms) or myasthenic crisis. A myasthenic crisis is a life-threatening complication of gMG which affects the muscles that are used for breathing and requires hospitalisation. The patient experts explained that there are limited options available for people whose condition does not improve with standard treatment (refractory gMG).

Typically, people with refractory gMG will have intravenous immunoglobulin (IVIg) or plasma exchange (PLEX) or will try a different type of immunosuppressant. IVIg and PLEX both require regular hospital visits or stays. These can be difficult to fit around work and family commitments and place a substantial burden on carers.

Rozanolixizumab is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Financial Factors

This technology is commissioned by NHS England.

The list price of rozanolixizumab is £17,883.19 per 560 mg/4 ml vial of solution for injection.

The company has a commercial arrangement. This makes rozanolixizumab 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 the technology being classified as high cost.

Clinical trial evidence suggests that rozanolixizumab plus standard treatment reduces symptoms and improves people's ability to carry out their normal activities compared with standard treatment alone. But it is uncertain if this improvement lasts in the longer term. Indirect comparisons suggest that rozanolixizumab works better than intravenous immunoglobulin (IVIg) or plasma exchange (PLEX), but the extent of the benefit is uncertain.

Rozanolixizumab is administered as a short subcutaneous infusion given weekly, for 6 weeks, equivalent to 1 treatment cycle. As a once-weekly subcutaneous infusion, rozanolixizumab may avoid the need for frequent IV administration and procedures while minimising the treatment burden to patients.

Subsequent treatment cycles of rozanolixizumab should be administered according to clinical evaluation. The frequency of treatment cycles may vary by patient. In the clinical development programme, most patients had treatment-free intervals of 4 to 13 weeks between cycles.

Clinical experts estimate 4 cycles for rozanolixizumab per year which incorporates treatment-free intervals. Users can amend the number of cycles to reflect local assumptions.

Administration of rozanolixizumab is assumed to require 60 minutes of nurse time on treatment initiation, then reduced to 30 minutes in subsequent model cycles. After the first cycle, rozanolixizumab can be self-administered at home. Users can update the proportion of cycles prescribed in secondary care and at home in the resource impact template.

The annual drug cost for rozanolixizumab is based on a weighted average of doses, reflecting the patient weight distribution observed in the MycarinG clinical trial.

Oxybutynin hydrochloride for managing neurogenic detrusor overactivity in people 6 years and over with spinal cord injury or spina bifida (terminated appraisal) TA1154

NICE is **unable to make a recommendation** on oxybutynin hydrochloride for managing neurogenic detrusor overactivity. This is because the company did not provide an evidence submission.

Zanidatamab for treating HER2-positive advanced biliary tract cancer after 1 or more lines of systemic treatment TA1153

Recommendation

Zanidatamab **can be used**, within its marketing authorisation, to treat HER2-positive (defined as immunohistochemistry 3 [IHC3] positive) unresectable locally advanced or metastatic biliary tract cancer in adults after at least 1 line of systemic treatment. Zanidatamab can only be used if the company provides it according to the commercial arrangement.

The Technology

Biliary tract cancer includes bile duct cancer (cholangiocarcinoma), gallbladder cancer and ampullary cancer.

In England in 2021, around 2,800 people were diagnosed with cholangiocarcinoma, 1,100 people were diagnosed with gallbladder cancer and 500 people were diagnosed with ampullary cancer. In 2019, there were 2,754 deaths from cholangiocarcinoma in England. Most people in England are diagnosed at stage 3 or 4. Diagnosis at later stages is associated with poorer survival outcomes. Human epidermal growth factor receptor 2 (HER2) is a receptor for a growth factor which occurs naturally in the body. When human epidermal growth factor attaches itself to HER2 receptors on cancer cells it can stimulate the cells to divide and grow. High levels of HER2 expression are found in 4-16% of biliary tract cancers – these are known as HER2-positive cancers.

Zanidatamab as monotherapy is indicated for the treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) biliary tract cancer (BTC) previously treated with at least one prior line of systemic therapy.

The comparator treatment for the eligible population is FOLFOX, which is administered intravenously, and active symptom control, which includes a range of supportive measures.

Financial Factors

This technology is commissioned by NHS England.

The list price per pack of 2 vials of 300 mg zanidatamab is currently confidential.

The company has a commercial arrangement. This makes zanidatamab 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:

- Zanidatamab has a longer average treatment duration than FOLFOX, the comparator treatment, and therefore requires additional IV administration appointments.
- Zanidatamab does not require a long-term implanted central venous access device for IV administration unlike FOLFOX that requires a PICC (peripherally inserted central catheter), Portacath or Hickman line. So zanidatamab requires less administration time, and will have fewer incidences of adverse events associated with having a central line than FOLFOX.
- Zanidatamab may have a higher relative dose intensity compared with FOLFOX because it is better tolerated.

Semaglutide for reducing the risk of major adverse cardiovascular events in people with cardiovascular disease and overweight or obesity TA1152

Recommendation

Semaglutide (up to a maintenance dose of 2.4 mg once weekly) **can be used**, within its marketing authorisation, alongside a reduced-calorie diet and increased physical activity, as an option for reducing the risk of a major adverse cardiovascular event (that is, cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with both:

- established cardiovascular disease (CVD), defined as at least 1 of the following:
    - previous myocardial infarction
    - previous ischaemic or haemorrhagic stroke
    - symptomatic peripheral arterial disease (they have intermittent claudication with an ankle-brachial index of less than 0.85 at rest, or have had a peripheral arterial revascularisation procedure or an amputation because of atherosclerotic disease), and
- a body mass index (BMI) of at least 27 kg/m^2.

Semaglutide can only be used if the company provides it according to the commercial arrangement.

The Technology

Cardiovascular disease (CVD) is usually associated with atherosclerosis, hypertension and an increased risk of thrombosis. The population in this evaluation includes people with established CVD. For the purposes of this evaluation, this is defined as people who have already had a myocardial infarction (MI) or an ischaemic or haemorrhagic stroke, or who have symptomatic peripheral arterial disease (PAD). People with established CVD are at high risk of having secondary cardiovascular events. Having a higher body mass index (BMI) also increases the risk of cardiovascular events.

Standard care for CVD includes lifestyle changes and medicines aimed at reducing the risk of secondary cardiovascular events. Lifestyle changes include improving diet, increasing physical activity, reducing alcohol intake, stopping smoking and managing weight. Medicines may include antihypertensive, lipid-lowering, antiplatelet and anticoagulant treatments. Semaglutide is positioned as another treatment option alongside standard care for the secondary prevention of cardiovascular events.

Semaglutide (Wegovy) is indicated as an adjunct to a reduced-calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight (body mass index [BMI] ≥27 kg/m^2).

The comparator treatment for the eligible population is standard care. Semaglutide is given in addition to standard care.

Financial Factors

This technology is commissioned by ICBs.

The list price of semaglutide 2.4 mg is £175.80 per pack, of 1.7 mg is £124.53 per pack, and of 0.25 mg, 0.5 mg and 1.0 mg is £73.25 per pack. Each pack contains 1 pen that delivers 4 doses.

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

Use of GLP-1 receptor agonists in other indications (diabetes, obesity and overweight management) is expected to increase each year. People who are already having a GLP-1 receptor agonist for another indication will not be eligible for semaglutide for secondary cardiac event prevention.

It is estimated there are 53,449 people in Devon with established cardiovascular disease. About half of these people have a body mass index (BMI) of 27.0 kg/m^2 or more and are eligible for semaglutide.

It is estimated in year 3, 2,275 people in Devon will be having semaglutide each year.

Inebilizumab for treating immunoglobulin G4-related disease (terminated appraisal) TA1151

NICE is **unable to make a recommendation** on inebilizumab for immunoglobulin G4-related disease. This is because the company did not provide an evidence submission.

Encorafenib with binimetinib for treating BRAF V600E mutation-positive advanced non-small-cell lung cancer TA1150

Recommendation

Encorafenib plus binimetinib **can be used** as an option to treat BRAF V600E mutation-positive advanced non-small-cell lung cancer (NSCLC) in adults, only if:

- it is used at first line, and
- the company provides them according to the commercial arrangements.

This recommendation is not intended to affect treatment with encorafenib plus binimetinib 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

Non-small-cell lung cancer (NSCLC) accounts for around 91% of all lung cancers. People with advanced NSCLC generally have a poor prognosis. The symptoms can be hard to treat, and distressing for the person with the condition and their family members. The BRAF V600E mutation is 1 of many that can stimulate cancer growth.

BRAF V600E mutation is not common in NSCLC, and no more than 2% of all lung cancers have this mutation. A third to half of all BRAF mutations are V600 mutations, and most BRAF V600 mutations are V600E mutations.

Because of the rarity of BRAF V600E mutation in NSCLC, clinical experts highlighted that people with the condition can feel isolated even within the wider lung cancer community.

Encorafenib plus binimetinib is indicated for the treatment of adult patients with advanced non-small-cell lung cancer with a BRAF V600E mutation.

The comparator treatment for the eligible population is dabrafenib plus trametinib. All treatment options are administered orally.

Financial Factors

This technology is commissioned by NHS England.

Encorafenib costs £1,400 for a 42-pack of 75 mg capsules and binimetinib costs £2,240 per 84-pack of 15 mg tablets.

The company has commercial arrangements for encorafenib and binimetinib. These make encorafenib and binimetinib 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:

- Encorafenib plus binimetinib has a longer median treatment duration than dabrafenib plus trametinib.
- The clinical experts stated that less than 10% of people are unable to tolerate encorafenib plus binimetinib but 33% of people are unable to tolerate dabrafenib plus trametinib.

NICE expects that the resource impact of implementing the recommendations in England will be less than £5 million per year (or about £8,700 per 100,000 people in the population, based on a population in England of 57.7 million people). This is because the technology is an additional treatment option, the overall cost of treatment will be similar for this population and the population size is small.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Anaphylaxis: assessment and referral after emergency treatment NG258

This guideline updates and replaces NICE guideline CG134 (December 2011).

This guideline covers assessment and referral for anaphylaxis. It aims to improve the quality of care for people with suspected anaphylaxis by detailing the assessments that are needed and recommending referral to specialist allergy services.

Neonatal infection: antibiotics for prevention and treatment NG195 (UPDATE)

May 2026: NICE have reviewed the evidence on the time between prelabour rupture of membranes and birth (at term) to see if this affects the risk of early-onset neonatal infection. NICE have also amended the risk factors related to fever and chorioamnionitis because of safety concerns.

This guideline covers preventing bacterial infection in healthy babies of up to and including 28 days corrected gestational age, treating pregnant women and pregnant trans men and non-binary people whose unborn baby is at risk of infection, and caring for babies of up to and including 28 days corrected gestational age with a suspected or confirmed bacterial infection. It aims to reduce delays in recognising and treating infection and prevent unnecessary use of antibiotics. The guideline does not cover viral infections.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

HealthTech guidance (HTGs)

Artificial intelligence (AI)-assisted echocardiography analysis and reporting to support the diagnosis and monitoring of heart failure: early-use assessment HTG779

Recommendations

More research is needed on the following artificial intelligence (AI)-assisted echocardiography analysis and reporting technologies to support the diagnosis and monitoring of heart failure before they can be funded by the NHS:

- EchoConfidence
- EchoGo Heart Failure
- Ligence Heart
- Us2.ai

The Condition

Heart failure is common. It affects over 1 million people in the UK, with 200,000 new diagnoses annually and 800,000 people with the condition on GP registers (British Heart Foundation Statistics Factsheet – UK, 2026). Heart failure is when the heart cannot pump blood effectively because of structural or functional abnormalities. This may develop gradually (chronic, often linked to hypertension or diabetes) or suddenly (acute, for example after myocardial infarction, arrhythmia, infection, or uncontrolled hypertension).

Heart failure significantly impacts quality of life, and can lead to disability and early death. Around 80% of heart failure diagnoses in England happen in hospital, despite 40% of people having symptoms that could have prompted earlier assessment (British Heart Foundation Statistics Factsheet – UK, 2026). Heart failure is classified by left ventricular ejection fraction (LVEF) measured using echocardiography. Heart failure with:

- preserved ejection fraction (HFpEF) is defined as an LVEF of 50% or more
- reduced ejection fraction (HFrEF) is defined as an LVEF of 40% or less
- mildly reduced ejection fraction (HFmrEF) is an intermediate category with an LVEF of 41% to 49%.

The Technologies

Details of the 4 technologies are included in the table below:

Technology (company)	Regulatory and DTAC status	Intended use	Target population
EchoConfidence (MyCardium)	CE class 2b DTAC in place	Detecting and diagnosing heart failure through screening or clinical echocardiograms. Stratifying heart failure. Monitoring disease progression and treatment response.	Adults with or without underlying cardiac disease
EchoGo Heart Failure (Ultromics)	UKCA/CE class 2a (expected June 2026) DTAC not in place	Providing adjunctive information on a cardiovascular condition to detect HFpEF	Adults over 25 years having routine functional cardiovascular assessment or with suspected heart failure
Ligence Heart (Ligence UAB)	CE class 2a DTAC not in place	Detecting, measuring and calculating various specifications of structure and function of the heart	Adults who are not in a life-threatening state of health, when time is not critical for medical decisions and no major therapeutic interventions are needed

Technology (company)	Regulatory and DTAC status	Intended use	Target population
Us2.ai (EKO Pte Ltd)	CE/UKCA class 2b DTAC in place	Processing, analysing and measuring TTE images to provide automated estimation of several cardiac structural and functional parameters. Detecting most forms of heart failure, independent of ejection fraction.	Adults, as decision support for detecting heart failure, pulmonary hypertension, cardiac amyloidosis, hypertrophic cardiomyopathy and valve disease (for example, aortic stenosis and mitral regurgitation)

Digital technologies to support self-management of asthma: early-use assessment HTG778

Recommendations

Seven digital technologies can be used in the NHS during the evidence generation period as options to support self-management of asthma. The technologies are:

- Asthmahub
- Asthmahub for parents
- Digital Health Passport
- Luscii
- myAsthma
- RDMP (Respiratory Disease Management Platform)
- Smart Asthma.

These technologies can only be used:

- if the evidence outlined in the evidence generation plan for technologies to support self-management of asthma is being generated
- as long as they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

The companies are responsible for ensuring that data collection and analysis takes place. They 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 (3 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.

The Technologies

Digital technologies aim to support self-management of asthma by providing a digital personalised asthma action plan (PAAP), tailored education and tools for tracking symptoms and medicines. These features may improve medicine adherence and asthma control, reduce exacerbations and improve quality of life.

Details of the 7 recommended technologies are included in the table below:

Technology (company)	CE or UKCA mark	Target users	Upfront cost per person, including hardware, £	Ongoing costs per person, £
Asthmahub (ICST)	I	People aged 18 years and over	29	0
Asthmahub for parents (ICST)	I	Children and parents or carers	29	0
Digital Health Passport (Tiny Medical Apps)	I	People aged 5 years and over and parents or carers	77	0
Luscii (Luscii Healthtech BV)	IIa	All age groups and healthcare professionals	8.50	180 per year
myAsthma (My MHealth Limited)	I	People aged 13 years and over	35	30 per year
RDMP (Aptar Digital Health)	I	People aged 16 years and over and healthcare professionals	112	180 per year
Smart Asthma (Smart Respiratory Products Ltd)	IIa	People aged 5 years and over and parents or carers	66.65	0

Financial Factors

Respiratory services are commissioned by ICBs.

Poor asthma control is common and can lead to emergency department visits, hospital stays and even avoidable deaths. Many people do not have structured self-management support.

Experts say people can have poor engagement with written action plans, incorrect inhaler technique and non-adherence with medications. They also point out that there is a high unmet need for effective self-management support for asthma control.

Digital health technologies may help support self-management of asthma by providing personalised, accessible tools that support key aspects of self-management, including real-time tracking of symptoms and medication use.

NICE Quality Standards

None published this month.

Current NICE Consultations

Title/link	End date of consultation
Nirogacestat for treating desmoid tumours [ID6453]	01/06/2026
Daratumumab with bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when an autologous stem cell transplant is suitable [ID6249]	04/06/2026
Ianalumab for treating active Sjogren's syndrome ID6634	04/06/2026
Ciltacabtagene autoleucel for treating relapsed and lenalidomide-refractory multiple myeloma after 1 to 3 therapies [ID4012]	08/06/2026
Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain	10/06/2026
Ex-situ machine perfusion devices to preserve deceased donor livers for transplantation	10/06/2026
Zanidatamab with chemotherapy with or without tislelizumab for untreated HER2-positive unresectable advanced gastro-oesophageal adenocarcinoma ID6672	15/06/2026
Atezolizumab with chemotherapy for adjuvant treatment of stage 3 colorectal cancer with high microsatellite instability or mismatch repair deficiency [ID6646]	16/06/2026
Tafasitamab with lenalidomide and rituximab for treating relapsed or refractory follicular lymphoma after 1 or more systemic treatments [ID6413]	17/06/2026
Inavolisib with palbociclib and fulvestrant for treating recurrent hormone receptor-positive HER2-negative PIK3CA-positive advanced breast cancer after adjuvant endocrine treatment [ID6425]	18/06/2026
Avapritinib for treating inadequately controlled moderate to severe indolent systemic mastocytosis [ID6578]	18/06/2026
Zongertinib for treating HER2-mutated unresectable or metastatic non-small-cell lung cancer ID6573	18/06/2026
Niraparib with abiraterone acetate and prednisone for treating hormone-sensitive metastatic prostate cancer [ID6595]	19/06/2026
NICE Funding Variation Request Consultation	19/06/2026
Vamikibart for treating uveitic macular oedema ID6671	25/06/2026
Semaglutide 7.2 mg dose for managing obesity ID6699	25/06/2026
Xanomeline tartrate–trospium chloride for treating schizophrenia ID6716	26/06/2026