NHS Devon

NICE Update Bulletin: June 2026

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Technology Appraisals (TAs)

Atogepant for treating migraine TA1172

Recommendation

Atogepant **can be used** as an option for the acute treatment of migraine with or without aura in adults, only if, for previous migraines:

- at least 2 triptans were tried and they did not work well enough, or
- triptans were contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.

Use the least expensive option of the suitable treatments (including atogepant and rimegepant), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Take account of administration costs, dosages, price per dose and commercial arrangements.

This recommendation is not intended to affect treatment with atogepant 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

Migraine is primarily a headache disorder manifesting as recurring attacks usually lasting between 4 and 72 hours involving throbbing head pain of moderate to severe intensity. It is often accompanied by nausea, sometimes vomiting, sensitivity to light, sensitivity to sounds, and/or other sensory stimuli. Migraine can have significant impacts on quality of life and ability to carry out normal activities. Some people can have warning symptoms called an aura, before the start of a headache.

In the UK, it is estimated that 1 in 5 people, or 14%, live with migraine. It is estimated that there are 190,000 migraine attacks experienced every day in England. Prevalence has been reported to be 5 to 25% in women and 2 to 10% in men. Migraine is the second highest cause of global disability in the general population but first in females aged between 15 to 49 years.

Treatments for acute migraine attacks include analgesics, triptans and anti-emetics. NICE CG150 and the NICE pathway on the management of migraine (with or without aura) recommend an oral triptan with either a nonsteroidal anti-inflammatory drug (NSAID) or paracetamol, taking into account patient preferences, comorbidities and the risk of adverse events. For people who prefer to take only one drug, monotherapy with an oral triptan, NSAID, high dose aspirin or paracetamol should be considered. Anti-emetics should be considered in addition to other acute migraine treatment even in the absence of nausea and vomiting. Some people are unable to have triptans because they are ineffective or not well tolerated.

NICE **TA919** recommends rimegepant as an option for the acute treatment of migraine with or without aura in adults, only if for previous migraines:

- at least 2 triptans were tried and they did not work well enough or
- triptans were contraindicated or not tolerated, and NSAIDs and paracetamol were tried but did not work well enough.

Atogepant is indicated for the acute treatment of migraine with or without aura in adults.

Atogepant is also indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month. This is covered in NICE's technology appraisal guidance on atogepant for preventing migraine.

Financial Factors

This technology is commissioned by ICBs.

The list price of atogepant 60 mg is £25.78 for a 2 tablet pack and £90.23 for a 7 tablet pack. The list price of atogepant 28 x 60 mg tablets is £182.16

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:

- Rimegepant is the usual acute treatment for migraine after at least 2 triptans have not worked well enough, or if people cannot have triptans, and non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol do not work well enough. Atogepant is likely to have similar clinical effectiveness to rimegepant and would be used in the same place in the treatment pathway. The recommendations introduce a further oral treatment option.
- There is a recommendation to use the least expensive option of the suitable treatments (including atogepant and rimegepant), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Administration costs, dosages, price per dose and commercial arrangements should be considered.
- Costs may vary in different settings because of negotiated procurement discounts.

NICE expect 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, and the recommendation is to use the least expensive option.

NICE estimate that in year 3, 1,087 people in Devon will be eligible for treatment.

Seladelpar for previously treated primary biliary cholangitis TA1171

Recommendation

Seladelpar **can be used**, within its marketing authorisation, as an option to treat primary biliary cholangitis, including associated pruritus, in adults. It can be used:

- with ursodeoxycholic acid (UDCA), if UDCA alone has not worked well enough, or
- alone, if UDCA cannot be tolerated.

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

The Technology

Primary biliary cholangitis (PBC), previously known as primary biliary cirrhosis, is a chronic and progressive autoimmune disease. PBC leads to a build-up of bile in the liver. It causes damage to the liver and to the small interlobular bile ducts, leading to impairment of bile flow from the liver to the small intestine (cholestasis). PBC can cause the formation of excess fibrous connective tissue (fibrosis) and can lead to scarring of the liver (cirrhosis). The cause of PBC is unknown but is thought to be a mix of environmental and genetic triggers. Not all people with PBC experience symptoms, and many do not have any symptoms until significant liver damage has occurred. The most common symptoms are fatigue and itchy skin (pruritus).

There are around 20,000 people living with PBC in the UK. It has a prevalence of around 35 per 100,000 people and an annual incidence of 2 to 3 per 100,000 people. Approximately 90% of the people who have PBC are women, with 25% of these being under 40 years of age.

Treatment for PBC aims to alleviate symptoms and slow disease progression. Treatments for PBC in the UK include ursodeoxycholic acid and obeticholic acid. Ursodeoxycholic acid is the preferred first-line treatment, however some people's disease does not respond completely to it, or they cannot tolerate it. NICE technology appraisal (TA443) also recommends obeticholic acid in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or as monotherapy for people who cannot tolerate ursodeoxycholic acid. Treatments are also available for some symptoms associated with PBC. Itching can be treated with colestyramine (previously cholestyramine) and rifampicin. There are currently no known treatments for fatigue related to PBC. A liver transplant is the only treatment when significant liver damage endangerers life. A transplant will cure itching and other symptoms, but fatigue may persist.

Seladelpar is indicated for the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.

The comparator treatments for the eligible population are elafibranor with or with without UDCA, or OCA with or without UDCA.

Financial Factors

This technology is commissioned by NHS England.

The list price of seladelpar is £3,155.00 per 30-tablet pack of 10 mg tablets.

The company has a commercial arrangement. This makes seladelpar 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:

- Seladelpar and the comparator treatments are oral treatments.
- Seladelpar has not been directly compared in a clinical trial with obeticholic acid (OCA) or elafibranor. But the results of indirect comparisons suggest that seladelpar may reduce itch more than obeticholic acid, and it may reduce liver enzymes more than obeticholic acid or elafibranor.
- As regional variations in population and standard care exist, the impact should be reviewed locally.

Daratumumab with bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable TA1170

Recommendation

Daratumumab with bortezomib, lenalidomide and dexamethasone **can be used** as an option for untreated multiple myeloma in adults when an autologous stem cell transplant (ASCT) is unsuitable. Daratumumab can only be used if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with daratumumab with bortezomib, lenalidomide and dexamethasone 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

Multiple myeloma is a form of cancer that arises from plasma cells (a type of white blood cell) in the bone marrow. Myeloma cells supress the development of normal blood cells that are responsible for fighting infection (white blood cells), carrying oxygen around the body (red blood cells) and blood clotting (platelets). The term multiple myeloma refers to the presence of more than one site of affected bone at the time of diagnosis. People with multiple myeloma can

experience bone pain, bone fractures, tiredness (due to anaemia), infections, hypercalcaemia (too much calcium in the blood) and kidney problems.

There were around 5,000 newly diagnosed cases of multiple myeloma in England in 2021, mostly in people aged 65 years and over. Multiple myeloma is more common in men than in women. The 5-year survival rate for adults with multiple myeloma in England and Wales is about 56%.

Multiple myeloma is an incurable disease. Therapy aims to prolong survival and maintain a good quality of life by controlling the disease and relieving symptoms. High-dose chemotherapy with autologous stem-cell transplantation may be an option for people with multiple myeloma in good general health; however, this is an intensive treatment, which is not considered appropriate for most people with multiple myeloma.

Daratumumab is indicated in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma.

Usual treatment for adults with untreated multiple myeloma when an ASCT is unsuitable includes:

- daratumumab plus lenalidomide and dexamethasone (**TA917**)
- isatuximab plus bortezomib, lenalidomide and dexamethasone (**TA1098**).

Financial Factors

This technology is commissioned by NHS England.

The list price for daratumumab is £4,320 per 1,800 mg/15 ml vial.

The company has a commercial arrangement. This makes daratumumab 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 shows that daratumumab plus bortezomib, lenalidomide and dexamethasone increases how long people have before their condition gets worse and how long they live compared with bortezomib, lenalidomide and dexamethasone.

NICE estimate that in year 3, 70 people in Devon will be eligible for treatment with 28 starting daratumumab with bortezomib, lenalidomide and dexamethasone each year.

Mirvetuximab soravtansine for treating folate receptor-alpha-positive platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer TA1169

Recommendation

Mirvetuximab soravtansine **can be used**, within its marketing authorisation, as an option to treat folate receptor-alpha (FR-alpha)-positive, platinum-resistant, high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer in adults after 1 to 3 lines of systemic treatment. Mirvetuximab soravtansine can only be used if the company provides it according to the commercial arrangement.

The Technology

Ovarian cancer is cancer that occurs in the ovary or fallopian tubes. The most common type, high-grade serous carcinoma, is thought to arise from the fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage I to stage IV. In stage I, the cancer is confined to one or both ovaries. In stage II the disease has grown outside the ovaries but is still within the pelvic area. Stage III denotes disease that is locally advanced and has spread outside the pelvis into the abdominal cavity, and stage IV denotes that distant metastasis to other body organs has occurred. Stages II to IV are considered advanced ovarian cancer. Symptoms of ovarian cancer include bloating, pelvic pain, frequent urination, constipation, and feeling full quickly after eating. In the early stages symptoms can be vague or not noticeable, so most people are diagnosed once the cancer has progressed to an advanced stage.

Mirvetuximab soravtansine for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.

The comparator treatments for the eligible population are paclitaxel, pegylated liposomal doxorubicin and topotecan.

All of the treatment options are administered by IV infusion but some (paclitaxel and topotecan) have multiple administrations per cycle.

Financial Factors

This technology is commissioned by NHS England.

The list price of mirvetuximab soravtansine is £4,950 per 100-mg vial.

The company has a commercial arrangement. This makes mirvetuximab soravtansine 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:

- The treatment duration of mirvetuximab soravtansine is longer than most comparator treatments.
- The administration time for mirvetuximab soravtansine is longer than comparator treatments.
- There are more adverse events associated with mirvetuximab soravtansine than with comparator treatments but the cost of treating the adverse events is lower.

NICE estimate that in year 3, 6 people in Devon will be eligible for treatment with 4 having mirvetuximab soravtansine each year.

Imlunestrant for treating oestrogen receptor-positive HER2-negative advanced breast cancer after endocrine therapy (terminated evaluation) TA1168

NICE **is unable to make a recommendation** on imlunestrant for treating oestrogen receptor-positive HER2-negative advanced breast cancer after endocrine therapy in adults. This is because the company did not provide an evidence submission.

Serplulimab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer TA1167

Recommendation

Serplulimab with carboplatin and etoposide **can be used**, within its marketing authorisation, as an option for untreated extensive-stage small-cell lung cancer in adults. Serplulimab with carboplatin and etoposide can only be used if the company provides it according to the commercial arrangement.

The Technology

Lung cancer falls into two main histological categories: non-small-cell lung cancers and small-cell lung cancers. Small-cell lung cancer (SCLC) is a type of cancer that grows rapidly and spreads quickly to other parts of the body. It can be classified as limited or extensive disease. Extensive disease is when the cancer has spread beyond one lung and nearby lymph nodes, making radiotherapy unsuitable. Common symptoms of SCLC include weight loss, malaise, bone pain, breathlessness and haemoptysis.

Lung cancer is the 3rd most common cancer in the UK, accounting for 13% of all new cancer cases between 2017 and 2019. In 2022, 36,886 people were diagnosed with lung cancer in England, of which 6.8% were SCLC. The prognosis for patients with extensive-stage SCLC is poor, with a 5-year survival rate of 10%.

Serplulimab in combination with carboplatin and etoposide is indicated for the first-line treatment of adult patients with extensive-stage small-cell lung cancer (ES-SCLC).

Financial Factors

This technology is commissioned by NHS England.

The list price of serplulimab is £1,321.83 per 100-mg vial.

The company has a commercial arrangement. This makes serplulimab available to the NHS at a discount.

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, based on a low uptake of serplulimab, are that:

- Current first-line treatment for extensive-stage small-cell lung cancer (ES-SCLC) is an immunotherapy plus chemotherapy, and this is well established in NHS practice. Given the low expected uptake of serplulimab, minimal additional changes are anticipated.
- Serplulimab is administered by intravenous infusion. Atezolizumab is the most relevant comparator in this evaluation. Atezolizumab can be administered subcutaneously or by intravenous infusion. There may be service implications because serplulimab requires intravenous administration, but these are expected to have a minor impact given the low numbers projected to have serplulimab.
- Serplulimab has similar toxicity profiles to atezolizumab and durvalumab and clinical experts expect similar efficacy between the immunotherapies.

NICE estimate that in year 3, 25 people in Devon will be eligible for treatment with 1 having serplulimab with carboplatin and etoposide each year.

Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils TA1166

Recommendation

Mepolizumab **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 (ICS), a long-acting beta-2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), and
- the company provides mepolizumab 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 a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).

Assess response to mepolizumab at 12 months. Stop mepolizumab 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 mepolizumab 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 healthcare professional consider it appropriate to stop.

The Technology

Chronic obstructive pulmonary disease (COPD) is a group of lung conditions that cause breathing difficulties. It includes chronic bronchitis, emphysema, chronic obstructive airways disease and chronic airflow limitation. Smoking is the main cause, but it can also be caused by long-term exposure to harmful fumes or dust. Symptoms include breathlessness, a chronic, productive cough, and difficulty exercising. Lung function usually worsens over time and cannot be fully restored. 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). COPD exacerbations can increase the chance of hospital admission, cardiovascular events, and mortality. They contribute to disease progression and increase the risk of future exacerbations.

There is an estimated 1.2 million people in England with a COPD diagnosis. In 2023 in England, nearly 27,000 people died from it. It is the second most common lung disease in the UK after asthma. COPD is more common in men and the over 40s and becomes more common with increasing age.

Treatment for COPD aims to slow its progressions, control symptoms and reduce exacerbations. It includes treatment and support to stop smoking, pneumococcal and influenza vaccinations, pulmonary rehabilitation, a personalised self-management plan, and optimised treatment for comorbidities (see NICE's guideline on diagnosing and managing COPD in over 16s). If people have stable COPD but are breathless and have limited exercise capacity, they can be offered short-acting beta2 agonists (SABA) or short-acting muscarinic antagonists (SAMA). If they continue to have limiting symptoms or exacerbations, they can have dual therapy with:

- long-acting beta2 agonists (LABA) plus long-acting muscarinic antagonists (LAMA), or
- LABA plus inhaled corticosteroids (ICS).

Mepolizumab is indicated for add-on maintenance treatment of adult patients with uncontrolled COPD of an eosinophilic phenotype on a combination of an inhaled corticosteroid (ICS), a long acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA).

The comparator treatments for the eligible population are triple therapy (composed of a LAMA, a LABA and an inhaled corticosteroid) and dupilumab with triple therapy. Dupilumab is also recommended in combination with dual therapy (composed of a LAMA and a LABA when inhaled corticosteroids are unsuitable). This population is also included in these tools.

Triple therapy is a combination of 3 medicines which are administered via an inhaler. Mepolizumab and dupilumab are subcutaneous injections.

Financial Factors

This technology is commissioned by NHS England.

The list price of mepolizumab is £840.00 for a 100-mg per 1-ml prefilled pen or prefilled syringe.

The company has a commercial arrangement. This makes mepolizumab available to the NHS at a discount.

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:

- Mepolizumab is given in addition to triple therapy, so the cost of mepolizumab is in addition to triple therapy.
- There are fewer exacerbation events associated with mepolizumab in addition to triple therapy than with triple therapy alone.
- As the resource impact template also shows increasing dupilumab use as mepolizumab use increases, not all of the resource impact can be attributed to mepolizumab.

Cemiplimab with platinum-based chemotherapy for untreated advanced non-small-cell lung cancer TA1165

Recommendation

Cemiplimab with platinum-based chemotherapy **can be used** as an option for untreated non-small-cell lung cancer (NSCLC) in adults:

- if they would otherwise be offered pembrolizumab with platinum-based chemotherapy, and
- when the cancer:
    - is locally advanced and not suitable for definitive chemoradiation, or is metastatic
    - has PD-L1 in 1% or more of the tumour cells, and
    - has no EGFR, ALK or ROS-1 aberrations.

Cemiplimab with platinum-based chemotherapy can only be used if the company provides cemiplimab according to the commercial arrangement.

This recommendation is not intended to affect treatment with cemiplimab with platinum-based chemotherapy 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) is staged from 1A to 4B according to the size of the tumour, location of involved lymph nodes and the presence of distant metastases. Stage 3 (locally advanced) or stage 4 (metastatic) NSCLC is considered advanced. People with locally advanced NSCLC commonly present with a cough. Other symptoms include shortness of breath, coughing up blood, and pain. People with metastatic NSCLC may also have headaches, an enlarged liver, changes in mental health, weakness and seizures.

Cemiplimab plus platinum-based chemotherapy is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have:

- locally advanced NSCLC who are not candidates for definitive chemoradiation, or
- metastatic NSCLC.

Financial Factors

This technology is commissioned by NHS England.

The list price of cemiplimab is £4,650 for a vial of 350 mg per 7 ml concentrate for solution for infusion.

The company has a commercial arrangement. This makes cemiplimab available to the NHS at a discount.

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.
- Cemiplimab is only licensed to be given every 3 weeks. The comparator, pembrolizumab, is given every 3 weeks with chemotherapy but in the monotherapy phase it is given every 6 weeks.
- Cemiplimab and pembrolizumab have similar toxicity profiles and both are administered intravenously. The infusion time for cemiplimab and pembrolizumab is 30 minutes.
- Chemotherapy regimens given with pembrolizumab may differ from the chemotherapy regimens given with cemiplimab in clinical practice.

NICE estimate that in year 3, 63 people in Devon will be eligible for treatment with 2 having cemiplimab each year.

Tisotumab vedotin for treating recurrent or metastatic cervical cancer that has progressed on or after systemic treatment TA1164

Recommendation

Tisotumab vedotin **can be used**, within its marketing authorisation, to treat recurrent or metastatic cervical cancer that has progressed on or after systemic treatment in adults. Tisotumab vedotin can only be used if the company provides it according to the commercial arrangement.

The Technology

Cervical cancer develops when abnormal cells in the lining of the cervix (the entrance to the womb from the vagina) grow in an uncontrolled way and eventually form a tumour. It can start from different types of cells in different parts of the cervix, which gives rise to 2 main subtypes of cancer. The most common subtype, called squamous cell carcinoma, develops from skin-like cells present on the outer surface of the cervix (ectocervix). The other subtype is called adenocarcinoma and it develops from glandular cells that produce mucus inside the cervix (endocervix). The human papilloma virus (HPV) is the main cause of cervical cancer and has been detected in 99% of cases. HPV types 16 and 18 account for at least two-thirds of cases.

Cervical cancer is said to be recurrent when it has returned following treatment, and metastatic when it has spread beyond the pelvis and pelvic lymph nodes to other places in the body such as the abdomen, liver, intestinal tract, or lungs.

In England in 2022, there were 2,641 newly diagnosed cases of cervical cancer, and 737 recorded deaths from cervical cancer. 4 Survival rates for metastatic or recurrent cervical cancer are significantly lower than for early stage cervical cancer. About 15% of people diagnosed with stage 4 (metastatic) disease survive for 5 years or more after diagnosis compared with 95% of people diagnosed at stage 1.

Tisotumab vedotin is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy.

The alternative treatment options for the eligible population are gemcitabine and paclitaxel. All 3 drugs are administered by intravenous infusion. But tisotumab vedotin is administered in a single infusion per cycle while paclitaxel is given on days 1, 8 and 15 of a 21-day cycle and gemcitabine is given on days 1 and 8. Other regimens such as topotecan may be used locally but are not included in the resource impact template.

Financial Factors

This technology is commissioned by NHS England.

The list price for tisotumab vedotin is £1,995 per 40 mg powder vial.

The company has a commercial arrangement. This makes tisotumab vedotin available to the NHS at a discount.

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 treatment duration of tisotumab vedotin is longer than that of comparator treatments.
- The number of administrations per cycle of tisotumab vedotin is fewer than that of comparator treatments.
- The number of ophthalmology appointments for people having tisotumab vedotin is greater than that for comparator treatments.
- The price of tisotumab vedotin is different than that of comparator treatments.

NICE estimate that in year 3, 6 people in Devon will be eligible for treatment with 4 having tisotumab vedotin each year.

Nogapendekin alfa inbakicept with BCG for non-muscle-invasive bladder cancer with carcinoma in situ that is unresponsive to BCG (terminated evaluation) TA1163

NICE is **unable to make a recommendation** on nogapendekin alfa inbakicept with Bacillus Calmette-Guérin (BCG) for non-muscle-invasive bladder cancer with carcinoma in situ, with or without papillary tumours, that is unresponsive to BCG in adults. This is because the company did not provide an evidence submission.

Nusinersen and risdiplam for treating spinal muscular atrophy TA1162

Recommendation

Nusinersen

Nusinersen **can be used** as an option to treat 5q spinal muscular atrophy (SMA), only if:

- it has not been successfully treated with onasemnogene abeparvovec
- nusinersen is not used with risdiplam, and
- the company provides nusinersen according to the commercial arrangement.

Stop nusinersen if there is sustained deterioration across a range of clinical measures and the treatment is not providing benefit. Assess whether the person is benefitting from treatment based on clinical judgement of their individual needs.

Risdiplam

Risdiplam **can be used** as an option to treat 5q SMA type 1, 2 or 3 or with 1 to 4 SMN2 copies, only if:

- it has not been successfully treated with onasemnogene abeparvovec
- risdiplam is not used:
    - with nusinersen
    - for presymptomatic SMA when onasemnogene abeparvovec is suitable, and
- the company provides risdiplam according to the commercial arrangement.

Stop risdiplam if there is sustained deterioration across a range of clinical measures and the treatment is not providing benefit. Assess whether the person is benefitting from treatment based on clinical judgement of their individual needs.

This recommendation is not intended to prevent risdiplam being used as a bridging therapy until treatment with onasemnogene abeparvovec is possible.

The Technology

Spinal muscular atrophy (SMA) is a rare genetic disorder that causes muscle weakness and progressive loss of movement. It is most commonly caused by defects in the gene SMN1, which leads to degeneration of motor neurones in the spinal cord (this is termed '5q SMA'). The motor neurones most affected by this condition are those that allow walking, crawling, arm movement, head and neck movement, swallowing and breathing. SMA causes substantial disability, and may lead to increased mortality and reduced life expectancy. The most severe forms of SMA typically cause death before age 2 years, although people with later-onset types of SMA usually live into adolescence or adulthood. SMA also has substantial effects on families and carers, including the impact of caring for the patient, the need for specialist equipment and ongoing emotional, financial and social impacts.

SMA symptom severity varies substantially and is often grouped into SMA types based on the age of onset of symptoms and the best motor function the person obtained. The types of SMA decrease in severity from type 0, in which symptoms arise before birth and babies survive for only a few weeks, to type 4 (adult-onset) which is associated with mild motor impairment and a normal life span.

Nusinersen is indicated for the treatment of 5q Spinal Muscular Atrophy.

Risdiplam is indicated for the treatment of 5q spinal muscular atrophy (SMA) in patients with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to 4 SMN2 copies.

The comparator treatments for the eligible population are onasemnogene abeparvovec, which is administered as a one-time intravenous infusion, or best supportive care. Nusinersen is

administered via intrathecal injection and risdiplam is administered orally. Both are ongoing treatments.

Financial Factors

This technology is commissioned by NHS England.

The list price of nusinersen is £75,000 for 1 vial of 12 mg/5 ml solution for injection, £78,000 for 1 vial of 28 mg/5 ml solution, and £139,286 for 1 vial of 50 mg/5 ml of solution. The company has a commercial arrangement. This makes nusinersen available to the NHS with a discount. The size of the discount is commercial in confidence.

The list price of risdiplam is £7,900 per 60 mg/80 ml oral solution and £18,433.00 for a pack of 5 mg tablets. The company has a commercial arrangement. This makes risdiplam 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:

- Both nusinersen and risdiplam have been available through managed access and treatments will now be routinely commissioned.
- The estimated average dose for risdiplam.
- The proportion of people having year 1 or year 2 plus treatment for nusinersen.
- The proportion of people having high-dose nusinersen relative to low-dose nusinersen.
- The expansion of eligibility criteria from managed access may increase the level of uptake for nusinersen and risdiplam.

NICE estimate that in year 3, 29 people in Devon will be eligible for treatment with 3 having nusinersen and 11 people having risdiplam each year.

Sotatercept for treating pulmonary arterial hypertension TA1161

Recommendation

Sotatercept, with other pulmonary arterial hypertension (PAH) treatments, **can be used** as an option to treat PAH in adults with World Health Organization functional class (WHO FC) 2 or 3, to improve exercise capacity. WHO FC 2 or 3 corresponds to low, intermediate–low or intermediate–high risk on the European Society of Cardiology and European Respiratory Society (ESC/ERS) risk-stratification framework. Sotatercept can be used if:

- it is started when the PAH is at intermediate–low risk at follow up after usual treatment for PAH

- the PAH has progressed to intermediate–high risk, if treatment with sotatercept was started when the PAH was intermediate–low risk.

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

This recommendation is not intended to affect treatment with sotatercept 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

Pulmonary hypertension is characterised by high blood pressure in the pulmonary arteries, the blood vessels that supply the lungs. Pulmonary arterial hypertension (PAH) is a rare, severe and progressive form of pulmonary hypertension caused by changes in the smaller branches of the pulmonary arteries, restricting blood flow through the lungs. The condition causes the walls of the pulmonary arteries to become thick and stiff, narrowing the space for blood to pass through and increasing blood pressure. As the pulmonary arteries are less able to stretch, the heart has to work harder to pump blood to the lungs, which causes damage to the heart, and makes it less efficient at pumping blood around the body and getting oxygen to the muscles. People with PAH experience increasingly debilitating symptoms which severely impact day to day living and quality of life, including breathlessness during exercise and sometimes during rest, extreme tiredness, weakness and chest pain. PAH is a progressive illness, meaning that people with PAH are at increased risk of frequent hospitalisations and other illnesses, such as pneumonia, and ultimately, right heart failure leading to premature death.

Data from the most recent National Audit of Pulmonary Hypertension (2021-2022) demonstrate that there are currently 4,269 patients living with PAH in the UK, with 568 new diagnoses each year, equating to a prevalence and incidence of 64 and 8.5 per 1,000,000 respectively.

Sotatercept is indicated in combination with other pulmonary arterial hypertension (PAH) therapies for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity.

The comparator treatment for the eligible population is selexipag. It is an oral tablet which is self-administered.

Financial Factors

This technology is commissioned by NHS England.

The list price of sotatercept is £5,422.50 for a 45-mg vial and £7,230.00 for a 60-mg vial.

The company has a commercial arrangement. This makes sotatercept 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.

NICE estimate that in year 3, 17 people in Devon will be eligible for treatment with 15 having sotatercept each year.

Durvalumab with chemotherapy for neoadjuvant and adjuvant treatment then alone for adjuvant treatment of resectable gastric or gastro-oesophageal junction adenocarcinoma TA1160

Recommendation

Durvalumab **can be used**, within its marketing authorisation, as an option for neoadjuvant and adjuvant treatment with 5-fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) chemotherapy, then alone as adjuvant treatment, for resectable gastric or gastro-oesophageal junction adenocarcinoma in adults. Durvalumab can only be used if the company provides it according to the commercial arrangement.

The Technology

Gastric cancer is a malignant tumour arising from cells in the stomach. Gastro oesophageal junction cancer describes cancers where the centre of the tumour is less than 5cm above or below where the oesophagus meets the stomach. The most common histological subtype of gastric and gastro-oesophageal junction cancer is adenocarcinoma, with 95% of gastric cancers being adenocarcinomas.

Initial symptoms of gastric or gastro-oesophageal junction adenocarcinoma are non-specific and are similar to other stomach conditions. Symptoms of advanced stages may include a lack of appetite and subsequent weight loss, fluid in the abdomen, vomiting blood, blood in the stool or black stool. Because of the nature of symptoms, gastric and gastro-oesophageal junction adenocarcinoma are often diagnosed at an advanced stage. Between 2018 and 2020 there were an average of 5,250 new stomach cancer diagnoses in England each year. Gastric cancer is more common in men than women.

Durvalumab with FLOT chemotherapy as neoadjuvant and adjuvant treatment, then alone as adjuvant treatment, is indicated for the treatment of adults with resectable gastric or gastro-oesophageal junction adenocarcinoma.

Usual treatment for resectable gastric or gastro-oesophageal junction adenocarcinoma before surgery (neoadjuvant) and after surgery (adjuvant) is FLOT chemotherapy.

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 5-fluorouracil, leucovorin, oxaliplatin and docetaxel 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 the technology being classified as high cost.

NICE estimate that in year 3, 36 people in Devon will be eligible for treatment with 32 having durvalumab each year.

Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia TA694 (UPDATE)

June 2026: NICE updated recommendation 1.1, and sections 2.5 and 2.6, to remove reference to a commercial arrangement and to update the list price for bempedoic acid and bempedoic acid–ezetimibe.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Intrapartum care NG235 (UPDATE)

June 2026: NICE has reintroduced recommendations on prevention of vitamin K deficiency bleeding.

This guideline covers the care of pregnant women and pregnant trans and non-binary people and their babies during labour and immediately after birth. It focuses on women and pregnant people who give birth between 37 and 42 weeks of pregnancy (‘term’). The guideline helps women and pregnant people 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.

Multiple sclerosis in adults: management NG220 (UPDATE)

June 2026: NICE has updated recommendations on diagnosis to refer to the revised 2024 McDonald criteria, instead of the 2017 criteria.

This guideline covers diagnosing and managing multiple sclerosis in people aged 18 and over. It aims to improve the quality of life for people with multiple sclerosis by promoting prompt and effective symptom management and relapse treatment, and comprehensive reviews.

Postnatal care NG194 (UPDATE)

June 2026: A recommendation was added to cross-reference to recommendations on vitamin K prophylaxis in the section on care of the newborn baby in NICE's guideline on intrapartum care.

This guideline covers the routine postnatal care that women and their babies should receive in the first 8 weeks after the birth. It includes the organisation and delivery of postnatal care, identifying and managing common and serious health problems in women and their babies, how to help parents form strong relationships with their babies, and baby feeding. The recommendations on emotional attachment and baby feeding also cover the antenatal period.

Ectopic pregnancy and miscarriage: diagnosis and initial management NG126 (UPDATE)

June 2026: NICE has reviewed the evidence and made new recommendations on anti-D immunoglobulin prophylaxis.

This guideline covers diagnosing and managing ectopic pregnancy and miscarriage in women, trans men and non-binary people with complications, such as pain and bleeding, in early pregnancy (that is, up to 13 completed weeks of pregnancy). It aims to improve how early pregnancy loss is diagnosed, and the support that is given, to limit the psychological impact of their loss.

Advanced breast cancer: diagnosis and treatment CG81 (UPDATE)

June 2026: NICE reviewed the evidence and made new and updated recommendations and recommendations for research on providing information and supportive care, diagnosis and assessment, and systemic anticancer therapy. NICE also added links to relevant technology appraisal guidance in the sections on diagnosis and assessment and systemic anticancer therapy. Some recommendations have been stood down as they no longer reflect current practice.

This guideline covers care and support for people with advanced (unresectable or metastatic) breast cancer. It aims to help them and their healthcare professionals make shared decisions about tests and treatments to improve outcomes and quality of life.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

HealthTech guidance (HTGs)

None published this month.

NICE Quality Standards

Ectopic pregnancy and miscarriage QS69 (UPDATE)

June 2026: Changes have been made to align this quality standard with the updated NICE guideline on ectopic pregnancy and miscarriage. Statement 4 has been added to highlight that this is a key area for quality improvement. Gender language, links, definitions and source guidance sections have also been updated throughout.

This quality standard covers the diagnosis and initial management of ectopic pregnancy and miscarriage in women, trans men and non-binary people in their first trimester (up to 13 completed weeks of pregnancy). It includes assessment and diagnosis for people with suspected early pregnancy loss. It describes high-quality care in priority areas for improvement.

Breast cancer QS12 (UPDATE)

June 2026: Changes have been made to align this quality standard with the updated NICE guideline on advanced breast cancer, including wording changes to statements 4 and 6. Measures and source guidance references have been updated throughout as appropriate.

This quality standard covers the care of people with breast cancer after they have been referred to a specialist team. It includes the management of early (ductal carcinoma in situ and invasive), locally advanced and advanced breast cancer; recurrent breast cancer; and familial breast cancer. It describes high-quality care in priority areas for improvement.

Current NICE Consultations

Title/link	End date of consultation
Topical tapinarof for treating atopic dermatitis in people 2 years and over ID6713	01/07/2026
Digital technologies to aid the scoring and interpretation of diagnostic sleep studies for obstructive sleep apnoea and rare sleep disorders	03/07/2026
Digital technologies to support home monitoring of vision changes for people with advanced dry age-related macular degeneration: early-use assessment	06/07/2026
Blood-based biomarker tests for surveillance in people at risk of hepatocellular carcinoma	06/07/2026
Melphalan chemosaturation with percutaneous hepatic artery perfusion and hepatic vein isolation for primary or metastatic cancer in the liver	07/07/2026
Suspected sepsis: recognition, diagnosis and early management - procalcitonin testing	10/07/2026
Beremagene geperpavec for treating skin wounds associated with dystrophic epidermolysis bullosa [ID3959]	17/07/2026
Ibrutinib with R-CHOP for untreated mantle cell lymphoma when an autologous stem cell transplant is suitable [ID6596]	21/07/2026
Secukinumab for treating relapsed polymyalgia rheumatica ID6599	22/07/2026