NHS Devon

NICE Update Bulletin: September 2025

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

1. **Isatuximab in combination for untreated multiple myeloma when a stem cell transplant is unsuitable TA1098**
2. **Enfortumab vedotin with pembrolizumab for untreated unresectable or metastatic urothelial cancer when platinum-based chemotherapy is suitable TA1097**
3. **Benralizumab for treating relapsing or refractory eosinophilic granulomatosis with polyangiitis TA1096**
4. **Tirzepatide for managing overweight and obesity TA1026 (UPDATE)**
5. **Tirzepatide for treating type 2 diabetes TA924 (UPDATE)**
6. **DMD Care UK's guideline on cardiac care of children with dystrophinopathy and females carrying DMD-gene variations: NICE review NG251**
7. **Pneumonia: diagnosis and management NG250**
8. **Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management NG237 (UPDATE)**
9. **Bipolar disorder: assessment and management CG185 (UPDATE)**
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11. **HIV testing: increasing uptake among people who may have undiagnosed HIV NG60 (UPDATE)**
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13. **Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD: early value assessment HTE18 (UPDATE)**
14. **Digital technologies to support self-management of COPD: early value assessment HTE19 (UPDATE)**
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Technology Appraisals (TAs)

Isatuximab in combination for untreated multiple myeloma when a stem cell transplant is unsuitable TA1098

Recommendation

Isatuximab plus bortezomib, lenalidomide and dexamethasone **can be used**, within its marketing authorisation, as an option for untreated multiple myeloma in adults when an autologous stem cell transplant is unsuitable. It can only be used if the company provides it according to the commercial arrangement.

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 suppress 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 (as a result of 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 and incidence rates are reported to be higher in people of African ethnic group. The 5-year survival rate for adults with multiple myeloma in England and Wales is about 56%.

Usual treatment for untreated multiple myeloma when an autologous stem cell transplant is unsuitable is 1 of several combination treatments, most commonly daratumumab, lenalidomide and dexamethasone.

Isatuximab is indicated in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Isatuximab is administered intravenously, whereas the main comparator is delivered subcutaneously.

Financial Factors

This technology is commissioned by NHS England.

The company has a commercial arrangement (commercial access agreement). This makes isatuximab 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.

Isatuximab plus bortezomib, lenalidomide and dexamethasone has not been directly compared in a clinical trial with daratumumab, lenalidomide and dexamethasone (most commonly used treatment combination). But the results of an indirect comparison suggest it may increase how long people live compared with them.

NICE estimate that in year 5, 72 people in Devon will be eligible for treatment, with 22 people choosing isatuximab in combination with bortezomib, lenalidomide and dexamethasone.

Enfortumab vedotin with pembrolizumab for untreated unresectable or metastatic urothelial cancer when platinum-based chemotherapy is suitable TA1097

Recommendation

Enfortumab vedotin with pembrolizumab **can be used**, within its marketing authorisation, as an option for untreated unresectable or metastatic urothelial cancer in adults when platinum-based chemotherapy is suitable.

Enfortumab vedotin with pembrolizumab can only be used if the companies provide them according to their commercial arrangements.

The Technology

Urothelial carcinoma is cancer of the transitional cells which form the inner lining of the bladder, urethra, ureter, or renal pelvis. Urothelial carcinoma accounts for approximately 90% of bladder cancers. Urothelial cancer can also originate in the upper urinary tract. Urothelial carcinomas can be described as non-invasive or invasive depending on how far the carcinomas invade the tissues. Non-invasive urothelial carcinomas can be further split into papillary carcinomas or flat carcinomas. Papillary carcinomas often grow towards the hollow part of the organ (for example bladder and ureter), without going into deeper layers. Flat carcinomas remain in the inner layers. Both papillary and flat carcinomas can become invasive.

In 2020, 16,547 new bladder cancers were diagnosed in England. Bladder cancer is the 11th most common cancer in the UK. The majority of cases are in those over the age of 75 but can also affect young people too and is more common in men than women with incidences of 22.8 and 8.3 per 100,000 respectively. Smoking is a major factor in the cause of bladder cancer.

People with urothelial carcinoma may receive treatment with surgery and/or radiotherapy. Treatment may be given before (neoadjuvant) or after surgery and/or radiotherapy in an attempt to improve cure rates. If the cancer is too advanced for surgery/radiotherapy, treatments can be used to improve quality of life and survival.

Enfortumab vedotin with pembrolizumab is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy.

The comparator treatments for the eligible population are cisplatin with gemcitabine or cisplatin with carboplatin, followed by avelumab maintenance treatment if there is no disease progression.

Financial Factors

This technology is commissioned by NHS England.

The companies have commercial arrangements. These make enfortumab vedotin and pembrolizumab available to the NHS with a discount.

The payment mechanism for the enfortumab vedotin is determined by the responsible commissioner and depends on the enfortumab vedotin being classified as high cost.

NICE estimate that in year 5, 30 people in Devon will be eligible for treatment, with 24 people choosing enfortumab vedotin.

Benralizumab for treating relapsing or refractory eosinophilic granulomatosis with polyangiitis TA1096

Recommendation

Benralizumab as an add-on to standard care **can be used**, within its marketing authorisation, as an option to treat relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) in adults.

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

Stop benralizumab after 52 weeks if the EGPA has not responded. Response is:

- a Birmingham Vasculitis Activity Score (BVAS) score of 0, and
- a reduction in oral corticosteroid use, either:
    - by 50% or more since starting benralizumab, or
    - to 7.5 mg or less per day.

This recommendation is not intended to affect treatment with benralizumab 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

Eosinophilic granulomatosis with polyangiitis (EGPA) is a rare autoimmune disease that causes inflammation of the blood vessels. It is characterised by high levels of white blood cells called eosinophils and mainly affects small to medium-sized blood vessels. Asthma is one of the key features of EGPA. Asthma may begin many years before any other symptoms.

Most people with EGPA also have upper airway involvement. Later symptoms may include rashes, joint pain and swelling, peripheral neuropathy, abdominal pain, diarrhoea, shortness of breath, arrhythmia, presence of red blood cells in urine, chest pain, and heart failure.

EGPA affects around 1 in 22,000 people in the UK. Based on this estimated prevalence, there are around 2,600 people in England with EGPA. In the first 12 months following an EGPA diagnosis, around 19% of people had an inpatient stay in hospital related to the condition. Over 50% of people experience a relapse after treatment within 5 years.

The aim of treatment is initially to induce remission, then to maintain remission and treat relapse when necessary. Without treatment, life-threatening complications may develop and the condition can be fatal.

Benralizumab is indicated as an add-on treatment for adult patients with relapsing or refractory eosinophilic granulomatosis with polyangiitis.

There are no approved medicines specifically for EGPA in the UK. The main treatment is oral corticosteroids, which are associated with severe side effects including diabetes, cardiovascular disease, osteoporosis, eye problems, peptic ulcers, pneumonia and renal impairment. Immunosuppressants can be added if necessary for relapsing or refractory EGPA.

Benralizumab plus standard care has not been directly compared in a clinical trial with standard care alone. But indirect comparisons suggest that benralizumab plus standard care increases the likelihood of remission (having fewer or no symptoms of EGPA) and reduces relapse (having worse symptoms) compared with standard care alone.

Financial Factors

This technology is commissioned by NHS England.

The company has a commercial arrangement (commercial access agreement). This makes benralizumab 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.

Treatment with benralizumab may result in fewer appointments with specialists and GPs compared with standard care. The reduction in oral corticosteroid use seen with benralizumab may result in fewer adverse events.

The use of these drugs in combination with benralizumab may reduce but the cost impact is expected to be minimal.

NICE estimate that in year 5, 31 people in Devon will be eligible for treatment, with 25 people choosing benralizumab.

Tirzepatide for managing overweight and obesity TA1026 (UPDATE)

September 2025: NICE added the commercial arrangement to the recommendation. NICE also updated the prices and details of the commercial arrangement in the information on tirzepatide section.

Recommendation

Tirzepatide is **recommended** as an option for managing overweight and obesity, alongside a reduced-calorie diet and increased physical activity in adults, only if they have:

- an initial body mass index (BMI) of at least 35 kg/m^2 and
- at least 1 weight-related comorbidity and
- the company provides it according to the commercial arrangement.

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

If less than 5% of the initial weight has been lost after 6 months on the highest tolerated dose, decide whether to continue treatment, taking into account the benefits and risks of treatment for the person.

These recommendations are not intended to affect treatment with tirzepatide 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.

Tirzepatide for treating type 2 diabetes TA924 (UPDATE)

September 2025: NICE added the commercial arrangement to the recommendation. NICE also updated the prices and details of the commercial arrangement in the information on tirzepatide section.

Recommendation

Tirzepatide is **recommended** for treating type 2 diabetes alongside diet and exercise in adults when it is insufficiently controlled only if:

- triple therapy with metformin and 2 other oral antidiabetic drugs is ineffective, not tolerated or contraindicated, and
- they have a body mass index (BMI) of 35 kg/m^2 or more, and specific psychological or other medical problems associated with obesity, or
- they have a BMI of less than 35 kg/m^2, and:
    - insulin therapy would have significant occupational implications, or
    - weight loss would benefit other significant obesity-related complications.

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

Tirzepatide is only recommended if the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with tirzepatide 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.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

DMD Care UK's guideline on cardiac care of children with dystrophinopathy and females carrying DMD-gene variations: NICE review NG251

NICE has reviewed DMD Care UK's guideline on cardiac care of children with dystrophinopathy and females carrying DMD-gene variations. NICE think the guideline from DMD Care UK is a useful resource that will help clinicians improve care in this area.

NICE has carried out this review to support improved care and outcomes for people with Duchenne muscular dystrophy (DMD), and to assist health and care practitioners in their decision making. However, NICE has not developed its own recommendations for this topic.

Pneumonia: diagnosis and management NG250

This guideline covers diagnosing, assessing, and treating community-acquired and hospital-acquired pneumonia, including bacterial pneumonia secondary to COVID-19, in babies over 1 month (corrected gestational age), children, young people and adults. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline updates and replaces:

- CG191 (published December 2014),
- NG138 (published September 2019),
- NG139 (both published September 2019).

Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management NG237 (UPDATE)

This guideline covers assessment of people aged 16 and over with symptoms and signs of acute respiratory infection (bacterial or viral) at first remote or in-person contact with NHS services. It also covers the initial management of any infections. It aims to support healthcare practitioners in making sure that people's treatment follows the best care pathway. It forms part of a suite of work on virtual wards being undertaken by NICE.

September 2025: NICE removed the section on clinical diagnosis of community-acquired pneumonia in primary care. This information is covered by NICE's guideline on pneumonia.

Bipolar disorder: assessment and management CG185 (UPDATE)

This guideline covers recognising, assessing and treating bipolar disorder (formerly known as manic depression) in children, young people and adults. The recommendations apply to bipolar I, bipolar II, mixed affective and rapid cycling disorders. It aims to improve access to treatment and quality of life in people with bipolar disorder.

September 2025: NICE updated recommendations on using valproate in line with Medicines and Healthcare products Regulatory Agency (MHRA) safety advice on valproate use in men.

Chronic heart failure in adults: diagnosis and management NG106 (UPDATE)

This guideline covers diagnosing and managing chronic heart failure in people aged 18 and over. It aims to improve diagnosis and treatment to increase the length and quality of life for people with heart failure.

September 2025: NICE have reviewed the evidence on treating and monitoring heart failure with reduced ejection fraction, mildly reduced ejection fraction and preserved ejection fraction.

HIV testing: increasing uptake among people who may have undiagnosed HIV NG60 (UPDATE)

This guideline covers how to increase the uptake of HIV testing in primary and secondary care, specialist sexual health services and the community. It describes how to plan and deliver services that are tailored to the local prevalence of HIV, promote awareness of HIV testing and increase opportunities to offer testing to people who may have undiagnosed HIV.

September 2025: NICE amended recommendation 1.1.1 to recommend the use of UK Health Security Agency HIV surveillance data to establish local HIV prevalence and rates of HIV in different groups and communities. NICE also changed references to 'Public Health England' to 'UK Health Security Agency' in this recommendation and the terms used section of the guideline.

Atopic eczema in under 12s: diagnosis and management CG57 (UPDATE)

This guideline covers diagnosing and managing atopic eczema in children under 12. It aims to improve care for children with atopic eczema by making detailed recommendations on treatment and specialist referral. The guideline also explains how healthcare professionals should assess the effect eczema has on quality of life, in addition to its physical severity.

September 2025: NICE amended recommendation 1.5.1.45 to include advice on frequency of bathing or showering, and the use of ion exchange water softeners and silk clothing, following the publication of new evidence on these interventions.

NICE Rapid COVID-19 Guidelines

None published this month.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

None published this month.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

Health Technology Evaluations (HTE)

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD: early value assessment HTE18 (UPDATE)

Early value assessment (EVA) guidance on digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD.

September 2025: NICE removed Active+me REMOTE from recommendation 1.4 because it is no longer available to the NHS. This is because the company for the technology, Aseptika Ltd, is no longer trading.

Digital technologies to support self-management of COPD: early value assessment HTE19 (UPDATE)

Early value assessment guidance on digital technologies to support self-management of COPD.

September 2025: NICE removed Active+me REMOTE from recommendation 1.4 because it is no longer available to the NHS. This is because the company for the technology, Aseptika Ltd, is no longer trading.

NICE Quality Standards

Pneumonia: diagnosis and management QS110 (UPDATE)

This quality standard covers diagnosing, assessing and treating community-acquired and hospital-acquired pneumonia in babies over 1 month (corrected gestational age), children, young people and adults. It describes high-quality care in priority areas for improvement. It does not cover ventilator associated pneumonia or COVID-19 pneumonia.

September 2025: This quality standard was updated and statements prioritised in 2016 were replaced. The topic was identified for update because the NICE guideline has been updated to include recommendations on babies, children and young people and hospital-acquired pneumonia.

Chronic heart failure in adults QS9 (UPDATE)

This quality standard covers assessing, diagnosing and managing chronic heart failure in adults (aged 18 and over). It describes high-quality care in priority areas for improvement. Statements cover adults with chronic heart failure with reduced ejection fraction and adults with chronic heart failure with preserved ejection fraction, unless otherwise stated.

September 2025: Changes have been made to align this quality standard with the updated NICE guideline on chronic heart failure in adults. Statement 3 on medication for chronic heart failure with reduced ejection fraction has been updated to reflect changes to the guidance. Links, definitions and source guidance sections have been updated throughout.

Current NICE Consultations

Title/link	End date of consultation
Balloon cryoablation for treating Barrett's oesophagus	01/10/2025
Type 2 diabetes in adults: management (medicines update)	02/10/2025
Familial Breast Cancer: initial assessment and genetic testing (update)	03/10/2025
Fertility problems: assessment and treatment - update 1 and 2	21/10/2025
Epcoritamab for treating relapsed or refractory follicular lymphoma after 2 or more systemic treatments [ID6338]	22/10/2025
Cabozantinib for treating advanced neuroendocrine tumours that have progressed after systemic treatment [ID6474]	22/10/2025
NICE health technology evaluations: the manual (HealthTech update)	22/10/2025
Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for postcardiotomy cardiogenic shock in adults	23/10/2025
Transcatheter tricuspid valve implantation for symptomatic severe tricuspid regurgitation	28/10/2025
Off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation	28/10/2025
Kidney Cancer Quality Standard	28/10/2025
Kidney Cancer	28/10/2025
Quality standards: process guide	31/10/2025