NHS Devon

NICE Update Bulletin: March 2024

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

1. **Human alpha1-proteinase inhibitor for treating emphysema (*terminated appraisal*) TA965**
2. **Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy TA962**
3. **Sebelipase alfa for treating lysosomal acid lipase deficiency that is not Wolman disease (*terminated appraisal*) TA961**
4. **Satralizumab for preventing relapses in neuromyelitis optica spectrum disorders (*terminated appraisal*) TA960**
5. **Daratumumab in combination for treating newly diagnosed systemic amyloid light-chain amyloidosis TA959**
6. **Ritlecitinib for treating severe alopecia areata in people 12 years and over TA958**
7. **Momelotinib for treating myelofibrosis- related splenomegaly or symptoms TA957**
8. **Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over TA956**
9. **Dupilumab for treating moderate to severe prurigo nodularis TA955**
10. **Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments TA954**
11. **Fluocinolene acetonide intravitreal implant for treating chronic diabetic macular oedema TA953**
12. **Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 TA878 (UPDATE)**
13. **Ovarian cancer: identifying and managing familial and genetic risk NG241**
14. **Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management NG240**
15. **Vitamin B12 deficiency in over 16s: diagnosis and management NG239**

16. **Lung cancer: diagnosis and management NG122 (UPDATE)**
17. **Suspected sepsis: recognition, diagnosis and early management NG51 (UPDATE)**
18. **COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)**
19. **Neonatal infection: antibiotics for prevention and treatment NG195 (UPDATE)**
20. **Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: early value assessment HTE17**
21. **Digital technologies for managing non-specific low back pain: early value assessment HTE16**
22. **Digital technologies for delivering multidisciplinary weight-management services: early value assessment HTE14 (UPDATE)**
23. **ProKnow cloud-based system for radiotherapy data storage, communication and management: early value assessment HTE5 (UPDATE)**
24. **Current NICE Consultations**

Technology Appraisals (TAs)

Human alpha1-proteinase inhibitor for treating emphysema (*terminated appraisal*) TA965

NICE is **unable to make a recommendation** on human alpa1-proteinase inhibitor for treating emphysema in adults. The company has confirmed that it does not intend to launch the product in England and Wales. The reasons for this decision are primarily related to the company's inability to offer the product at a price to meet the current threshold of cost effectiveness.

The context for this decision is important and related to the unique, complex and high-cost nature of plasma-derived therapy production.

If the company wishes to make a submission to NICE in the future for this topic it will be rescheduled back into the work programme.

Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy TA962

This guidance updates and replaces TA598 (published August 2019)

Recommendations

Olaparib is **recommended**, within its marketing authorisation, as an option for maintenance treatment of BRCA mutation-positive, advanced (FIFO stages 3 and 4), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults. It is only recommended if the company provides it according to the commercial arrangement.

The Technology

Ovarian cancer is a cancerous growth that occurs in the ovary or fallopian tubes. The most common type of ovarian cancer, high-grade serous type, is thought to arise from the peritoneum or fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage 1 to stage 4. Most people are diagnosed with stage 3 and 4 disease, in which the disease has spread outside of the pelvis. Some people have gene mutations that may increase the risk of ovarian cancer. Mutated inherited genes that increase the risk of ovarian cancer include BRCA 1 and 2.

For first-line chemotherapy (usually following surgery) **TA55** recommends paclitaxel in combination with a platinum-based compound or platinum-based therapy alone.

After response to first-line platinum-based chemotherapy, maintenance treatment options include, **TA673**. Where there has been a complete or partial response after first-line platinum-based chemotherapy plus bevacizumab and the cancer is associated with homologous recombination deficiency (HRD), **TA946** recommends olaparib plus bevacizumab.

Olaparib is an oral administration treatment.

Financial Factors

This technology is commissioned by NHS England.

This guidance evaluation reviews the evidence for olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy (**TA598**). It also reviews new evidence collected as part of the managed access agreement. The new evidence includes data from clinical trials and from people having treatment in the NHS in England.

The new clinical evidence shows that people having olaparib live longer and have more time before their cancer gets worse compared with people having placebo.

The most likely cost-effectiveness estimates for olaparib is within the range that NICE considers an acceptable use of NHS resources, therefore, it is recommended for routine use.

NICE estimate that, in Devon, 8 people will be eligible for treatment with olaparib.

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

Sebelipase alfa for treating lysosomal acid lipase deficiency that is not Wolman disease (*terminated appraisal*) TA961

NICE is **unable to make a recommendation** on sebelipase alfa for treating lysosomal lipase deficiency that is not Wolman disease in adults. The Wolman disease population was evaluated separately in NICE highly specialised technology guidance on sebelipase alfa (**HST30**). The cost effectiveness of the remaining non-Wolman population has not been demonstrated at this stage. NICE will review this decision if the company makes a submission in the remaining non-Wolman disease population.

Satralizumab for preventing relapses in neuromyelitis optica spectrum disorders (*terminated appraisal*) TA960

NICE is **unable to make a recommendation** on satralizumab for preventing relapses in neuromyelitis optica spectrum disorders in adults. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Daratumumab in combination for treating newly diagnosed systemic amyloid light-chain amyloidosis TA959

Recommendations

Daratumumab plus bortezomib, cyclophosphamide and dexamethasone is **recommended** as an option for treating newly diagnosed systemic amyloid light-chain (AL) amyloidosis in adults. It is recommended only if:

- daratumumab is topped after 24 cycles of treatment, or earlier if the condition progresses and
- the company provides daratumumab according to the commercial arrangement

This recommendation is not intended to affect treatment with daratumumab plus bortezomib, cyclophosphamide 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 clinician consider it appropriate to stop.

The Technology

Amyloid light-chain (AL) amyloidosis is caused by plasma cells in the bone marrow producing abnormal forms of light-chain proteins. These can form amyloid deposits, which clump together into amyloid fibrils and build up as deposits in tissue and organs, gradually stopping them from functioning normally. AL amyloidosis usually affects multiple organs, but one of them is often more affected than others. Any organ except the brain can be involved, including the heart, kidneys, stomach, intestines, liver, nerves or skin.

Multiple organ damage and heart dysfunction have a negative impact on survival. AL amyloidosis can cause general symptoms such as weight loss, fatigue, weakness, loss of appetite and bruising.

There is no standard treatment AL amyloidosis. Current treatment options are based on anti-myeloma therapy, including immunomodulatory drugs and proteasome inhibitors. A person's age, comorbidities, the extent of organ involvement and personal treatment preferences are taken into account when considering treatment options. Autologous stem cell transplant with high dose melphalan may be an option for some people aged up to 65 to 70 years.

A palliative treatment approach may be appropriate for people with worse disease. Best supportive care is dependant on individuals' organ involvement but includes renal and/or heart failure therapy.

Daratumumab is a monoclonal antibody that binds to the cell surface protein CD38, inhibiting the growth of these cells. CD38 is expressed on the plasma cells that produce the abnormal light-chain proteins, so inhibiting the growth of these cells may reduce the production of these proteins. It is available as an intravenous infusion or a subcutaneous formulation.

Financial Factors

This technology is commissioned by NHS England.

Clinical evidence suggests that daratumumab in combination increases the time until systemic AL amyloidosis gets worse compared with bortezomib plus cyclophosphamide and dexamethasone. People whose condition responds to daratumumab in combination may live longer, but this is uncertain.

The cost-effectiveness estimates for daratumumab are within the range NICE considers an acceptable use of NHS resources, therefore, daratumumab in combination is recommended.

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

Ritlecitinib for treating severe alopecia areata in people 12 years and over TA958

Recommendations

Ritlecitinib is **recommended**, within its marketing authorisation, as an option for treating severe alopecia areata in people 12 years and over. Ritlecitinib is only recommended if the company provides it according to the commercial arrangement.

The Technology

Alopecia areata is a chronic, inflammatory, autoimmune condition affecting the hair follicles leading to a sudden onset of hair loss. It does not cause scarring or permanent damage to the hair follicles. It can affect any hair-bearing skin such as the scalp, beard, eyebrows, eyelashes, body and limbs. The most common presentation of alopecia areata is small, round or oval patches of baldness on the scalp. Rarely, it may affect the whole scalp or even the entire body and scalp. For some people, patchy hair loss may continue over a long period of time, referred to as persistent patchy or chronic alopecia areata. Other types of alopecia areata are characterised by different patterns of hair loss.

Alopecia areata occurs when hair follicles change from growth phase to the loss phase prematurely, but the exact cause is unknown. While there is a genetic predisposition, it can occur at any age, affecting both male and females equally. Alopecia areata is also associated with higher rates of atopic and other autoimmune conditions.

Alopecia areata is typically diagnosed clinically based on presenting features such as patterns of hair loss, exclamation mark hairs and a positive pull test. Prognosis is unpredictable and varies, depending on severity and duration of the condition. Spontaneous remission within one year is seen in up to 80% of people with limited patches of hair loss of less than one year duration. However, hair pattern regrowth is variable and unpredictable when hair loss become extensive, spontaneous regrowth is rare.

Clinical management depends on the severity of hair loss. Management may include advice on cosmetic options to camouflage hair loss and watchful waiting. Treatment options in primary care may include topical corticosteroids. If hair loss does not respond to treatment, people may be referred to a dermatologist. Specialist management depends on disease duration, activity, location, extent and the person's age and individual preference. It may include local steroid injections or oral corticosteroids, dithranol, contact sensitisation treatment, psorelan plus ultraviolet A light therapy, minoxidil, immunosuppressive drugs and prostaglandin analogues.

Financial Factors

This technology is commissioned by ICBs.

There is no standard treatment for severe alopecia areata and access to treatment varies widely. Hair loss can cause severe psychological distress. Evidence from clinical trials shows that ritlecitinib is more effective than placebo at improving hair regrowth for up to 24 weeks.

The most likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. Therefore, ritlecitinib is recommended.

NICE estimate that in Devon, 286 adults and 1,130 adolescents will be eligible for treatment.

The company has a commercial arrangement. This make ritlecitinib available to the NHS with a discount.

Momelotinib for treating myelofibrosis- related splenomegaly or symptoms TA957

Recommendations

Momelotinib is **recommended** as an option for treating myelofibrosis-related splenomegaly or symptoms in adults with moderate to severe anaemia who have not had a JAK inhibitor or have had ruxolitinib, only if:

- they have intermediate-2 or high-risk myelofibrosis and
- the company provides momelotinib according to the commercial arrangement.

This recommendation is not intended to affect treatment with momelotinib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

The Technology

Myelofibrosis is a cancer of the bone marrow in which the marrow is replaced by scar tissue. Myelofibrosis may be primarily or secondary to either polycythaemia vera (a disorder in which the bone marrow makes too many red blood cells, known as post polycythaemia vera myelofibrosis) **or** essential thrombocythaemia (a disorder in which the bone marrow makes too many platelets; known as post essential thrombocythemia myelofibrosis).

The early stages of myelofibrosis may be asymptomatic in some people, while others may have severe symptoms from the onset. As the bone marrow becomes more scarred, it is less able to produce blood cells. To compensate for this, blood cell production occurs in the spleen and liver, causing these organs to enlarge. Enlargement of spleen may cause abdominal pain, dyspnoea, early satiety and faecal incontinence, along with progressive anaemia. Splenomegaly can also lead to problems with blood circulation in the liver and spleen. Other symptoms include, incurable itch, general malaise, weight loss, night sweats, low grade fever, anaemia, fatigue and pallor.

Many people with myelofibrosis have mutations in a gene known as Janus-associated kinase 2 (JAK2) gene. JAK signalling controls cytokines and growth factors that are important for blood cell production and immune function. Regardless of mutational status, loss of regulation of the JAK signalling is thought to be the underlying mechanism of the disease in myelofibrosis.

Allogeneic stem cell transplant is the only potential curative treatment for myelofibrosis, however, it is only suitable for people who are fit enough to undergo treatment. **TA386** recommends ruxolitinib as a treatment option. **TA756** recommends fedratinib for use within the Cancer Drug Fund. Other treatment options include hydroxycarbamide, other chemotherapies, androgens, splenectomy, radiation therapy, erythropoietin and red blood cell transfusion.

Financial Factors

This technology is commissioned by NHS England.

Momelotinib works in a similar way to ruxolitinib and would be offered to the same population. Clinical trial evidence shows that momelotinib is likely to work as well as ruxolitinib for people who have not had a JAK inhibitor. A cost comparison suggests momelotinib has similar costs to ruxolitinib in this population

Clinical trial evidence suggests that momelotinib is likely to work as well as best available therapy for people who have had ruxolitinib. The cost-effectiveness estimates for momelotinib in this population are within the range that NICE considers an acceptable use of NHS resources.

NICE estimate that in Devon, 8 people will be eligible for treatment.

Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over TA956

Recommendations

Etrasimod is **recommended**, within its marketing authorisation, as an option for moderately to severely active ulcerative colitis in people aged 16 years and over when:

- conventional or biological treatments cannot be tolerated or
- the condition has not responded well enough, or lost response to treatment.

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

If people with the condition and their clinicians consider etrasimod to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

The Technology

Ulcerative colitis is the most common inflammatory bowel disease. The cause of ulcerative colitis is unknown. Hereditary, infectious and immunological factors have been proposed as possible causes. It can develop at any age, but peak incidence is between the ages of 15 and 25 years, with a second smaller peak between 55 and 65 years.

Ulcerative colitis can cause inflammation in the inner lining of the large intestine. This is usually restricted to the mucosal surface. This usually affects the rectum and extends proximally throughout the colon. The symptoms of ulcerative colitis include bloody diarrhoea, colicky abdominal pain, urgency, ulceration, tenesmus, fatigue and anaemia. Ulcerative colitis is associated with significant morbidity; symptoms can have a debilitating impact on quality of life and daily life, including physical, social and mental wellbeing. It is a lifelong disease and symptoms can recur, or the disease can go into remission for months or even years.

Ulcerative colitis can be defined as mild or moderate to severe. Complications of ulcerative colitis may include haemorrhage, bowel perforation, stricture formation, abscess formation and anorectal disease. Some people may also develop primary sclerosing cholangitis, osteoporosis and toxic megacolon. People with long standing disease have an increased risk of bowel cancer.

The aim of treatment in active disease is to improve quality of life through addressing symptoms of bloody diarrhoea, urgent need to defecate and abdominal pain and thereafter to maintain remission. Initial management depends on clinical severity, extent of disease and the person's preference and may include aminosalicylates and biologics. An immunosuppressant may be considered to maintain remission if aminosalicylates fail to do so.

Treatments appraised by NICE for moderately to severely active ulcerative colitis include: **TA329, TA342, TA547, TA633, TA792, TA828, TA856.**

Etrasimod is a sphingosine-1-phosphate receptor agonist.

Financial Factors

This technology is commissioned by ICBs.

NICE do not expect this guidance to have a significant impact on resources. This is because the technology is a further treatment option and the overall cost of treatment for this patient group will be similar.

A cost comparison suggests etrasimod has lower or similar costs to adalimumab and other advanced treatments, therefore, etrasimod is recommended.

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

NICE estimate that in Devon, 512 people will be eligible for treatment with etrasimod at year five.

Dupilumab for treating moderate to severe prurigo nodularis TA955

Recommendations

Dupilumab is **not recommended**, within its marketing authorisation, for treating moderate to severe prurigo nodularis in adults when systemic treatment is suitable.

This recommendation is not intended to affect treatment with dupilumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

The Technology

Prurigo nodularis, also known as nodular prurigo, is a chronic inflammatory skin condition. Prurigo describes the changes that appear on the skin after it has been scratched for a long time due to intense itchiness (pruritus). In prurigo nodularis, firm itchy bumps form on the skin's surface caused by itching. The rash can range in severity from a few to several hundred nodules which appear most commonly on the arms, legs, upper back and abdomen. It may appear on its own or be associated with other skin diseases or underlying conditions. It may occur in episodes or be continuous. The itch associated with prurigo nodularis can interfere with sleep and affect psychological wellbeing.

The cause of prurigo nodularis is unknown. However, it is associated with abnormal levels of nerve fibres and neuropeptides which may contribute to itchiness. People with prurigo nodularis also have higher levels of immune cells which produce cytokines associated with inflammatory responses that may contribute to increased itchiness.

Any age group can be affected, but it is more common in older people and affects more females than males.

The treatments for prurigo nodularis aim to stop the skin itching. These include emollients, corticosteroid creams, ointments such as tacrolimus, antihistamines, oral steroids and ultraviolet light treatment. Immunosuppressants such as azathioprine, ciclosporin or methotrexate may be used if the condition is severe and has not responded to previous treatments.

Financial Factors

This technology is commissioned by ICBs.

The clinical trial evidence shows that dupilumab improves symptoms of prurigo nodularis compared with best supportive care. But in trials, this care did not include many of the treatments

that are usually used in the NHS. So, the trial results are uncertain and may not be generalisable to the NHS.

The results from the economic analysis are uncertain because of several concerns with the model, including:

- that different utility values were applied for dupilumab and for best supportive care after 24 weeks of treatment for people whose condition had not responded.
- the way that loss of treatment response was modelled for people having best supportive care.

The cost-effectiveness estimates are uncertain because of the concerns about the economic model and because the clinical evidence is uncertain. The estimates are also above the range the NICE considers to be an acceptable use of NHS resources. Therefore, dupilumab cannot be recommended for routine use in the NHS.

Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments TA954

Recommendations

Epcoritamab is **recommended** as an option for treating relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in adults after 2 or more systemic treatments, only if:

- they have had polatuzumab vedotin, or if polatuzumab vedotin is contraindicated or not tolerated and
- the company provides epcoritamab according to the commercial arrangement.

This recommendation is not intended to affect treatment with epcoritamab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinicians consider it appropriate to stop.

The Technology

Lymphomas are cancers of the lymphatic system, which is part of the immune system. Lymphomas are divided into:

- Hodgkin lymphoma and
- non-Hodgkin lymphoma.

Non-Hodgkin lymphomas (NHL) are a diverse group of conditions categorised according to the cell type affected (B-cell or T-cell), as well as the clinical features and rate of progression of the disease.

The most common B-cell lymphomas are:

- follicular lymphoma, a slow growing, low grade form of NHL and
- diffuse large B-cell lymphoma (DLBCL), a fast growing, high grade form of NHL.

Some follicular lymphomas transform into high grade DLBCL (transformed high grade follicular lymphoma). The symptoms differ depending on which organ or tissues are affected by the lymphoma. NHL often presents as painless lumps in the neck and armpit or groin, but it can start in other parts of the body such as the stomach or bowel. People may have loss of appetite, tiredness or night sweats.

The most widely used first-line treatment for DLBCL is R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone). Sometimes etoposide is added to this regime.

NICE has published guidance on the diagnosis and management of non-Hodgkin's lymphoma (**NG52**).

The following technology appraisals have also been published: **TA649**, **TA306**, **TA872**, **TA933**

Financial Factors

This technology is commissioned by NHS England.

Epcoritamab is administered subcutaneously. All other treatment options are administered by intravenous injection. Epcoritamab needs less hospital time per administration and is easier to deliver because it does not need a cannula to be put in, unlike current treatments.

The summary of market product characteristics for epcoritamab states that patients should be hospitalised for 24 hours after administration of the cycle 1 day 15 dose of 48 mg to monitor for signs and symptoms of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).

There is a no stopping rule for epcoritamab except for disease progression or toxicity. The comparators are each taken for a fixed duration. Treatment with epcoritamab may have more administrations than existing treatment options based on assumed numbers of cycles.

NICE estimate that in Devon, 23 people will be eligible for treatment with epcoritamab.

Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema TA953

This guidance updates and replaces TA613 (published November 2019) and TA301 (published November 2013).

Recommendations

Fluocinolone acetonide intravitreal implant is **recommended**, within its marketing authorisation, as an option for treating visual impairment caused by chronic diabetic macular oedema that has not responded well enough to available treatments in adults. It is recommended only if the company provides it according to the commercial arrangement.

For people with the condition in an eye with a natural (phakic) lens, if the person and the clinicians consider fluocinolone acetonide intravitreal implant to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the option, use the least expensive. Take account of administration costs, dosage, price per dose, duration of effect and commercial arrangements.

The Technology

Diabetic macular oedema (DMO) is a common complication associated with diabetic retinopathy and is the most common cause of visual impairment in diabetes mellitus. It occurs as a result of changes in retinal blood vessels in people with diabetes. Disruption of the blood-retinal barrier allows fluid to leak from blood vessels in the central part of the retina (the macula), leading to fluid accumulation and thickening of the macula. This can lead to severe visual impairment in the affected eye.

DMO can be classed as focal, diffuse or ischaemic. The majority of vision loss occurs when DMO involves the centre of the macula. This is known as clinically significant macular oedema (CSMO) and is regarded as the threshold for treatment. DMO can be categorised as either phakic or pseudophakic. these are terms used to describe the status of a person's lens. Phakic refers to an eye with an intact natural lens, while pseudophakic refers to eyes that have had the lens extracted and replaced with an artificial (intraocular) lens. DMO can also be classified as either centre involving or non-centre involving. If the centre of the macular, known as the fovea, is affected this is called centre involving DMO. If the fovea is not affected, it is known as non-centre-involving DMO.

Good management of diabetes and other risk factors may delay the onset and progression of DMO. This includes diet and lifestyle modification, blood pressure control and pharmacological treatments.

For DMO specifically, TA274, TA346, TA799 and TA820 recommend anti vascular endothelial growth factors (anti-VEGF) as options for treating visual impairment due to DMO.

TA824 recommends dexamethasone intravitreal implant as an option for DMO in adults.

Financial Factors

This technology is commissioned by ICBs.

NICE do not expect this guidance to have a significant impact on resources. This is because the fluocinolone acetonide intravitreal implant is a further treatment option and the overall cost of treatment will be similar for this patient group.

Usual treatment for visual impairment caused by diabetic macular oedema that has not responded well enough to available treatments in people with a natural lens is dexamethasone intravitreal implant. Fluocinolone acetonide and dexamethasone are both corticosteroid treatments.

Fluocinolone acetonide intravitreal implant works in a similar way to dexamethasone intravitreal implant and would be offered to the same population. Fluocinolone acetonide is released from the implant for up to 36 months, whereas dexamethasone is released over 6 months. So, fluocinolone acetonide intravitreal implant needs to be replaced less frequently than dexamethasone intravitreal implant.

The company has a commercial arrangement. This makes fluocinolone acetonide intravitreal implant available to the NHS with a discount.

Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 TA878 (UPDATE)

March 2024: After a partial review of this guidance, NICE updated the recommendation on nirmatrelvir plus ritonavir to include additional groups eligible for treatment (people with diabetes, obesity or heart failure, or aged 70 years or over).

NICE removed the recommendation on casirivimab plus imdevimab because the conditional marketing authorisation for casirivimab plus imdevimab for treating COVID-19 was withdrawn.

Recommendations

Nirmatrelvir plus ritonavir is **recommended** as an option for treating COVID-19 in adults, only if they:

- do not need supplemental oxygen for COVID-19 and
- they have any of the following:
    - an increased risk for progression to severe COVID-19
    - age 70 years and over
    - a body mass index (BMI) of 35 kg/m^2 or more

- diabetes
- heart failure.

Sotrovimab is **recommended** as an option for treating COVID-19 in adults and young people aged 12 years and over and weighing at least 40 kg, only if:

- they do not need supplemental oxygen for COVID-19 and
- they have an increased risk for progression to severe COVID-19 and
- nirmatrelvir plus ritonavir is contraindicated or unsuitable.

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

Tocilizumab is **recommended**, within its marketing authorisation, as an option for treating COVID-19 in adults who:

- are having systemic corticosteroids and
- need supplemental oxygen or mechanical ventilation.

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

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Ovarian cancer: identifying and managing familial and genetic risk NG241

This guideline covers assessing the familial and genetic risk of having a pathogenic variant associated with ovarian cancer in adults.

Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management NG240

This guideline updates and replaces CG102 (published June 2010)

This guideline covers recognising, diagnosing and managing bacterial meningitis and meningococcal disease in babies, children, young people and adults. It aims to reduce death and disability by helping healthcare professionals recognise meningitis and treat it quickly and effectively.

Vitamin B12 deficiency in over 16s: diagnosis and management NG239

This guideline covers recognising, diagnosing and managing vitamin B12 deficiency in people aged 16 and over, including deficiency caused by autoimmune gastritis. It also covers monitoring for gastric cancer in people with autoimmune gastritis.

Lung cancer: diagnosis and management NG122 (UPDATE)

This guideline cover diagnosing and managing non-small-cell and small-cell lung cancer. It aims to improve outcomes for patients by ensuring that the most effective tests and treatments are used and that people have access to suitable palliative care and follow-up.

March 2024: NICE updated the systemic anti-cancer therapy treatment pathways for advanced non-small-cell lung cancer following the withdrawal of the NICE technology appraisal on mobocertinib.

Suspected sepsis: recognition, diagnosis and early management NG51 (UPDATE)

This guideline covers the recognition, diagnosis and early management of suspected sepsis. It includes recommendations on recognition and early assessment, initial treatment, escalating care, finding and controlling the source of infection, early monitoring, information and support and training and education.

March 2024: NICE replaced a recommendation on contraindications to lumbar puncture with a link to the section on lumbar puncture in the updated NICE guideline on bacterial meningitis and meningococcal disease (NG240).

NICE Rapid COVID-19 Guidelines

COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)

This guideline covers managing COVID-19 in babies, children, young people and adults in community and hospital settings. It includes recommendations on communication, assessment, therapeutics for COVID-19, non-invasive respiratory support, preventing and managing acute complications and identifying and managing co-infections.

March 2024: In the section on therapeutics, NICE updated recommendations on nirmatrelvir and ritonavir, sotrovimab, casirivimab and imdevimab and tocilizumab in line with updated NICE technology appraisal guidance on nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 (TA878).

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

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

This guideline covers preventing bacterial infection in healthy babies of up to and including 28 days corrected gestational age, treating pregnant women whose unborn baby is at risk of infection and caring for babies of up to and including 28 days corrected gestational age with 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.

March 2024: The updated NICE guideline on bacterial meningitis and meningococcal disease (NG240) made new recommendations for newborn babies. NICE have moved these recommendations from the meningitis guideline into this neonatal infection guideline, so that all the recommendations for newborn babies are in one place.

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 health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: early value assessment HTE17

Recommendations

Adults

Three digital health technologies **can be used** as an option in the NHS while more evidence is generated, to help manage symptoms of psychosis or prevent relapse for adults. The technologies are:

- AVATAR Therapy, for managing auditory verbal hallucinations (hearing voices)
- SlowMo, for managing distressing thoughts or paranoia
- CareLoop, for monitoring symptoms of psychosis to prevent relapse.

These technologies should be delivered or supported by a mental health professional trained in the technology. They can only be used once they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

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

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

Young People

Research is needed on 3 digital health technologies to help manage symptoms of psychosis or prevent relapse for young people. The technologies are:

- AVATAR Therapy, for managing auditory verbal hallucinations (hearing voices)
- SlowMo, for managing distressing thoughts or paranoia
- CareLoop, for monitoring symptoms of psychosis to prevent relapse.

Access to the technologies for the population and indications above should be through company, research, or non-core NHS funding and clinical and financial risks should be appropriately managed.

Evidence generation and more research

Evidence generation and more research are needed on:

- change in the target symptoms managed by the technology, including long-term benefits and who may benefit most from using the technologies.
- rates of relapse or worsening of symptoms
- the effect of the technology on functional outcomes, including social functioning and personal recovery (for example, the person's perception of how they are feeling)
- adverse events
- resource use, including healthcare professional grade and time needed to deliver treatment or support
- implementation and training costs associated with the use of the technology
- resource costs associated with relapse, such as hospital stay costs
- adherence, including frequency of use and completion rates

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

The Technology

Psychosis is a state of mind where a person's abilities to understand and test reality are impaired. Conditions with psychosis as a main feature are called psychotic disorders and these are characterised by 'positive' and 'negative' symptoms, not caused by a substance or medication and not secondary to another medical condition or mood disorder. Psychosis caused by medications or medical conditions is called 'secondary psychosis.' Positive symptoms of psychosis include delusions or hallucinations where an individual believes implausible ideas usually with strong paranoia or hearing voices. Negative symptoms include impaired ability to perform everyday tasks, language impairment, abnormal motor behaviour and negative symptoms such as avolition, alogia and anhedonia.

There is evidence linking the onset of psychotic disorders with the social environment, such as; inner city living, deprivation, population density, social fragmentation and ethnic density; and individual life experiences such as childhood adversity and abuse, discrimination and adult social disadvantage.

CG178 provides recommendations on the management of the condition at different stages. Management of psychosis usually requires early intervention in psychosis (EIP) specialist teams for the first episode, or a specialist community mental health team (CMHT) for longer-term psychosis.

Current practice for treatment of psychosis is with an antipsychotic medication alongside psychological and social support. **CG178** states that standard psychological support should include provision of cognitive based therapy (CBT) to all people with psychosis delivered on a one-to-one basis over at least 16 planned sessions.

The proposed technologies for symptom management would usually be used as part of the psychological support provided by the EIP team or the CMHT. If these technologies are used as a component of the CBT for psychosis programme, they could reduce the number of CBT for psychosis sessions required. The trained therapist who would deliver the digital technologies could be less specialised than the therapists providing CBT for psychosis. Expert advice is that there is significant unmet demand for CBT for psychosis within the NHS. These technologies could also be used for people waiting to receive CBT for psychosis.

Financial Factors

These technologies are commissioned by ICBs.

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

- digital health technology software and technology costs.

Implementing the guideline may:

- offer another option for adults with psychosis who may otherwise not have psychological interventions
- detect early signs of relapse, which could allow quicker access to treatment when needed
- improve symptoms of psychosis or prevent relapse in adults
- AVATAR Therapy and SlowMo may use less staff resource and time than CBT for psychosis
- CareLoop may detect relapse and enable earlier treatment, which could reduce hospital stays and demand on crisis intervention services.

These benefits may provide savings to offset against technology costs.

Digital technologies for managing non-specific low back pain: early value assessment HTE16

Recommendations

Can be used in the NHS with evidence generation

Five digital technologies can be used in the NHS while more evidence is generated to manage non-specific low back pain in people 16 years and over. The technologies are:

- getUBetter
- Hinge Health
- Kaia
- Pathway through pain
- selfBACK

These technologies can be used once they have appropriate regulatory approval and meet the standards within /NHS England's Digital Technology Assessment Criteria (DTAC)

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

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

Can only be used in research

More research is needed on 5 digital technologies to manage non-specific low back pain in people 16 years and over. The technologies are:

- Ascenti Reach
- Digital Therapist
- Flok Health
- Phio Engage
- Joint Academy

Access to the 5 technologies should be through company, research or non-core NHS funding and clinical or financial risks should be appropriately managed. Centres already using these technologies may continue to do so but are encouraged to collect data or do further research.

Evidence generation and more research

Evidence generation and more research are needed on:

- pain and disability using the same outcome measure (Musculoskeletal Health Questionnaire)
- quality of life using the same outcome measure (EQ-5D-5L)
- patient characteristics (such as type of back pain and severity)
- time until return to normal daily activity
- treatment adherence, that is, the number of people:
    - using a technology at baseline, 30 days and between 6 months and 1 year
    - who stop using a technology and their reasons for stopping
- adverse events related to using the technology
- healthcare resource use, including:
    - GP appointments
    - physiotherapy appointments
    - emergency department visits
- how many people have self-referred for the technology and how many have been referred by a healthcare practitioner
- the position of the technology in the care pathway
- patients' view on the effects of the technologies collected using a qualitative survey or through interviews.

The Technology

Low back pain (LBP) is soreness or stiffness in the back, between the bottom of the rib cage and the top of the legs. It is characterised by pain and discomfort with or without leg pain. LBP is a common musculoskeletal (MSK) condition which affects a significant proportion of people in the UK. It increases in prevalence with age and has a negative impact on health and national productivity. LBP can be acute or chronic. Acute LBP is defined as that lasting less than 3 month and chronic LBP as lasting 3 months or more. Non-specific LBP describes pain not attributable to an underlying cause and is sometimes referred to in literature as 'mechanical,' 'musculoskeletal' or 'simple.'

LBP is a leading and long-standing cause of morbidity. Over 30 million working days are lost due to MSK conditions every year in the UK and they account for 30 % of GP consultations in England.

The majority of non-urgent LBP cases are managed in primary or community care, which has limited workforce capacity and resources to meet the needs of patients. Provision of services for MSK-related pain varies across the UK and there is an opportunity to integrate digital technology to increase access and reduce waiting lists by promoting supported self-management.

Digital technologies for managing LBP can provide rapid access to specialist advice and guidance, remote pain management support including physical activity recommendations and psychological therapy via web-based applications and digital platforms. These technologies offer greater flexibility as individuals can work through the recommendations in their own time with varying levels of health practitioner support. The use of these technologies could reduce the number of GP or first contact practitioner visits and he need for onward referral to MSK providers, support recovery, improve psychological impact of pain and aid quicker return to full activity.

Financial Factors

These technologies are commissioned by ICBs.

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

- software costs of the technologies
- time needed for training NHS staff, so they are conversant with the product offering
- any costs associated with lack of interoperability of the digital technology with electronic patient record systems
- other costs such as IT equipment may be needed for those who do not have access to internet, smartphones, tablets or a computer.

Implementing the guidance may:

- provide rapid access to specialist advice and guidance with greater flexibility
- provide better health outcomes and care experience
- reduce waiting lists, referrals for physiotherapy and the number of physiotherapy appointments and GP visits, medication use and the need for surgery.

Digital technologies for delivering multidisciplinary weight-management services: early value assessment HTE14 (UPDATE)

March 2024: NICE updated the guidance to include recommendations for digital weight-management technologies when they are not used to prescribed and monitor weight-management medicine.

Recommendations

Can be used in the NHS with evidence generation

When technologies prescribe and monitor weight-management medicine

Seven digital weight-management technologies **can be used** in the NHS, while more evidence is generated. They can be used to prescribe and monitor weight-management medicine and deliver multi-disciplinary weight-management services for managing overweight and obesity in adults. The technologies are:

- CheqUp
- Gro Health W8Buddy
- Juniper
- Liva
- Oviva
- Roczen
- Second Nature

When technologies are not used to prescribe and monitor weight-management medicine

Nine digital weight-management technologies can be used in the NHS, while more evidence is generated. They can be used to deliver multidisciplinary weight-management services for managing overweight and obesity in adults, when they are not used to prescribe and monitor weight-management medicine. The technologies are:

- CheqUp
- Counterweight
- Gro Health W8Buddy
- Juniper
- Liva
- Oviva

- Roczen
- Second Nature
- Weight Loss Clinic

  These technologies provide multidisciplinary programmes to increase physical activity levels and improve eating behaviour and diet.

The technologies above can only be used once they have appropriate regulatory approval, including Digital Technology Assessment Criteria (DTAC) approval. The CE mark regulatory classification for the 12 digital weight-management technologies varies. The classification can depend on the levels of monitoring, decision making attributed to the technology rather than the healthcare professional using the technology and the direct impact of the technology on clinical outcomes. The regulatory requirements for services involving these technologies, such as CQC approval, should also be considered before use.

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

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

Can only be used in research

More **research** is needed on using the following digital weight-management technologies:

- Gloji
- Habitual
- Wellbeing Way

Access to the technologies above should be through company, research, or non-core NHS funding and clinical and financial risks should be appropriately managed.

Evidence generation and research

More evidence generation and research are needed on:

- Change in weight
- Adherence and completion rates, including reasons for stopping a programme
- How the technologies monitor and report adverse events

- Health-related quality-of-life and psychological outcomes
- Impact on resource use, including the number and type of healthcare appointments, cost of the medicine and NHS staff time needed to support using the digital technologies.

  The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

ProKnow cloud-based system for radiotherapy data storage, communication and management: early value assessment HTE5 (UPDATE)

Recommendations

ProKnow **can be used** while further evidence is generated. This includes use of all 3 ProKnow modules:

- ProKnow DS – a database used for importing, analysing and storing patient data
- ProKnow CA – a contouring accuracy tool to practise, study and improve anatomical contouring
- ProKnow PS – a platform for creating and comparing radiotherapy treatment plans.

March 2024: NICE added the evidence generation plan to the guidance. This gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

NICE Quality Standards

None published this month.

Current NICE Consultations

Title/link	End date of consultation
NICE integrated topic prioritisation and strategic principles	04/04/2024
Methods and processes for including NICE technology appraisal recommendations in guidelines	05/04/2024
Exagamglogene autotemcel for treating sickle cell disease [ID4016]	11/04/2024
Endometriosis: diagnosis and management - diagnosing endometriosis	16/04/2024
Adrenal insufficiency: identification and management	19/04/2024
Early and locally advanced breast cancer: diagnosis and management - Neoadjuvant chemotherapy and ovarian function suppression (update)	19/04/2024
Relugolix–estradiol–norethisterone acetate for treating pain associated with endometriosis [ID3982]	22/04/2024
Phrenic nerve pacing for ventilator-dependent high cervical spinal cord injury	23/04/2024
Phrenic nerve pacing for congenital central hypoventilation syndrome	23/04/2024
Bicaval valve implantation for tricuspid regurgitation	23/04/2024
Vamorolone for treating Duchenne muscular dystrophy [ID4024]	24/04/2024
Falls: assessment and prevention in older people and people 50 and over at higher risk (update)	08/11/2024