NHS Devon

NICE Update Bulletin: October 2023

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

1. **Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments TA927**
2. **Baricitinib for treating severe alopecia areata TA926**
3. **Mirikizumab for treating moderately to severely active ulcerative colitis TA925**
4. **Tirzepatide for treating type 2 diabetes TA924**
5. **Tabelecleucel for treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus *(terminated appraisal)* TA923**
6. **Daridorexant for treating long-term insomnia TA922**
7. **Ruxolitinib for treating polycythaemia vera TA921**
8. **Tofacitinib for treating active ankylosing spondylitis TA920**
9. **Rimegepant for treating migraine TA919**
10. **Bimekizumab for treating axial spondyloarthritis TA918**
11. **Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable TA917**
12. **Bimekizumab for treating active psoriatic arthritis TA916**
13. **Pegunigalsidase alfa for treating Fabry disease TA915**
14. **Ranibizumab for treating diabetic macular oedema TA274 (UPDATE)**
15. **Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management NG237**
16. **Stroke rehabilitation in adults NG236**
17. **Thyroid disease: assessment and management NG145 (UPDATE)**
18. **Suspected neurological conditions: recognition and referral NG127 (UPDATE)**
19. **Hearing loss in adults: assessment and management NG98 (UPDATE)**
20. **Suspected cancer: recognition and referral NG12 (UPDATE)**

21. **Pneumonia in adults: diagnosis and management CG191 (UPDATE)**
22. **Urinary incontinence in neurological disease: assessment and management CG148 (UPDATE)**
23. **Ovarian cancer: recognition and initial management CG122 (UPDATE)**
24. **Jaundice in newborn babies under 28 days CG98 (UPDATE)**
25. **Vaginal transluminal endoscopic hysterectomy and adnexal surgery for benign gynaecological conditions IPG774**
26. **Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia (IPG773)**
27. **Digital technologies for delivering specialist weight-management services to manage weight-management medicine HTE14**
28. **Virtual ward platform technologies for acute respiratory infections HTE13**
29. **Acute respiratory infection in over 16s: initial assessment and management including virtual wards (hospital at home) QS210**
30. **Current NICE Consultations**

Technology Appraisals (TAs)

Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments TA927

Recommendations

Glofitamab is **recommended**, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma in adults after 2 or more systemic treatments. Glofitamab is only recommended if the company provides it according to the commercial arrangement.

The Technology

Lymphomas are cancers of the lymphatic system, which is a 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 which are 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 which is a slow growing, low grade form of NHL and diffuse large B-cell lymphomas (DLBCL), a fast growing, high grade form of NHL.

The symptoms of DLBCL differ depending on which organ or tissues are affected by the lymphoma. NHL often presents as painless lumps in the neck, armpit or groin but sometimes may start in other parts of the body such as the stomach or bowel. People may also 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), which may be followed by radiotherapy. Sometimes etoposide is added to this regimen. NG52 recommends multi-agent chemotherapy in combination with rituximab for relapsed or refractory disease potentially followed by stem cell transplantation for people who are fit enough to have it. Chemotherapy regimens commonly used in clinical practice include DHAP, GDP, ICE and IVE. If stem cell transplantation is not suitable, further chemotherapy or immunotherapy may be used alone.

For those with relapsed or refractory DLBCL, the following treatments are recommended by NICE:

- TA649 polatuzumab vedotin with rituximab and bendamustine
- TA567 tisagenlecleucel
- TA559 axicabtagene ciloleuce
- TA306 pixantrone monotherapy

Financial Factors

This technology is commissioned by NHS England.

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.

NICE estimate that in Devon, 16 people will be eligible for treatment.

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

Baricitinib for treating severe alopecia areata TA926

Recommendations

Baricitinib is **not recommended**, within its marketing authorisation, for treating severe alopecia areata in adults.

This recommendation is not intended to affect treatment with baricitinib 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

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 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 (alopecia totalis) or even the entire body and scalp (alopecia universalis).

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. For example, diffuse alopecia areata is characterised by sudden thinning of the hair all over the scalp, rather than in patches. Alopecia areata ophiasis refers to hair loss from the sides and lower back of the scalp, alopecia areata sisaipho refers to hair loss from the front of the scalp, forehead and rarely the eyebrows while alopecia barbae refers to hair loss in the beard and moustache area.

Alopecia areata occurs when hair follicles change from the 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 males and females equally. It is suggested that there may be higher

incidence in children and young adults and there may also be a link to social deprivation. 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.

When hair loss becomes extensive, spontaneous re-growth is rare. Clinical management depends on the severity of hair loss. If there is evidence of hair regrowth or there is less than 50% hair loss, management may include advice on cosmetic options to camouflage hair loss and watchful waiting. If there is no hair regrowth and more than 50% hair loss, treatment options in primary care may include topical corticosteroids, the only treatment currently licensed for use in alopecia areata.

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 corticosteroid injections or oral corticosteroids, dithranol, contact sensitisation treatment, psoralen plus ultraviolet A light therapy, minoxidil, immunosuppressive drugs such as oral azathioprine, ciclosporin, methotrexate and sulfasalazine and prostaglandin analogues such as bimatoprost and latanoprost.

Baricitinib is a selective and reversible inhibitor of Janus Kinase (JAK) 1 and JAK2. JAKs are enzymes that mediate the transduction of intracellular signals involved in the process of inflammatory disease. Baricitinib is administered orally.

Financial Factors

This technology is commissioned by ICBs.

Evidence from clinical trials suggests that baricitinib improves hair regrowth after 36 weeks of treatment compared with placebo. But treatment needs to be continued to prevent hair loss. Hair loss can cause severe psychological distress, but baricitinib did not show a meaningful improvement in most of the health-related quality-of-life assessments done in the trials compared with placebo.

The cost-effectiveness estimates for baricitinib are uncertain and are higher than what NICE normally considers an acceptable use of NHS resources. Therefore, baricitinib is not recommended.

Mirikizumab for treating moderately to severely active ulcerative colitis TA925

Recommendations

Mirikizumab is **recommended** as an option for treating moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or lost response to treatment, only if:

- a tumour necrosis factor (TNF)-alpha inhibitor has not worked (that is the condition has not responded well enough or has lost response to treatment) or
- a TNF-alpha inhibitor cannot be tolerated or is not suitable and
- the company provides it according to the commercial arrangement.

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

These recommendations are not intended to affect treatment with mirikizumab 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 clinician consider it appropriate to stop.

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, pain, urgency, ulceration, tenesmus, fatigue, and anaemia. Up to 50% will experience extra-intestinal manifestations involving joints, eyes, skin, and liver.

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 address 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, corticosteroids and biologics. An immunosuppressant may be considered to maintain remission if aminosalicylates fail to do so.

Current treatment for moderately to severely active ulcerative colitis also includes:

- TA329 recommends infliximab, adalimumab and golimumab
- TA342 recommends vedolizumab
- TA547 recommends tofacitinib
- TA633 recommends ustekinumab

For people admitted to hospital with acute severe ulcerative colitis, NG130 recommends offering intravenous corticosteroids to induce remission and assessing the need for surgery. Surgery may be considered as emergency treatment for severe ulcerative colitis that does not respond to drug treatment. People may also choose to have elective surgery for unresponsive or frequently relapsing disease that is affecting their quality of life.

Mirikizumab is a humanized monoclonal antibody that inhibits the activity of IL-23, a cytokine that plays a key role in the stimulation of many innate immune cells that are important in the pathogenesis of chronic inflammatory diseases. It is administered intravenously.

Financial Factors

This technology is commissioned by ICBs.

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

NICE estimate that in Devon, 512 people will be eligible for treatment and that the proportion that will receive treatment with mirikizumab will be 5% (26 people) of the market share.

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

Tirzepatide for treating type 2 diabetes TA924

Recommendations

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.

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.

The Technology

Diabetes mellitus is a chronic metabolic disorder characterised by elevated blood glucose levels (hyperglycaemia) resulting from a lack of the hormone insulin or resistance to its action. Type 2 diabetes results from reduced insulin secretion or reduced tissue sensitivity to insulin (known as insulin resistance). If not managed effectively, diabetes mellitus can lead to kidney failure, blindness, foot problems and damage to the nervous system. People with diabetes are also more at risk of cardiovascular disease.

NG28 recommends reinforcing advice on diet, lifestyle and adherence to drug treatment for all people with type 2 diabetes. If blood glucose levels are not controlled by diet and exercise alone:

- NG28 recommends first-line drug treatment with standard release metformin. For people with chronic heart failure, cardiovascular disease or at high risk of cardiovascular disease, it recommends considering a selective sodium glucose-cotransporter 2 (SGLT2) inhibitor in addition to metformin.
- When metformin is contraindicated or not tolerated a dipeptidyl peptidase-4 (DPP-4) inhibitor, pioglitazone or a sulfonylurea is recommended.

- For people with chronic heart failure, cardiovascular disease or at high risk of cardiovascular disease, or for people who meet the criteria in TA390 or TA572, an SGLT2 inhibitor is recommended.

When there is inadequate glycaemic control following first-line treatment, treatment is intensified:

- NG28 recommends adding a DPP-4 inhibitor, pioglitazone or a sulfonylurea, or an SGLT2 inhibitor for people who meet the criteria in TA315, TA572, TA288, or TA336.

If there is inadequate glycaemic control with dual therapy, treatment is intensified further:

- NG28 recommends triple therapy by adding a DPP-4 inhibitor, pioglitazone or a sulfonylurea, or an SGLT2 inhibitor for people who meet the criteria in TA315, TA418, TA336, or TA583, or starting insulin-based treatment.
- If metformin is contraindicated or not tolerated, NG28 recommends insulin-based treatment.
- If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, NG28 recommends switching one drug for a glucagon-like peptide-1 (GLP-1) mimetic for some groups of people.

Tirzepatide is a dual receptor agonist that acts at the receptors of both the GIP and GLP-1 hormones. These hormones act to stimulate insulin secretion. It is administered by subcutaneous injection.

Financial Factors

This technology is commissioned by ICBs.

Clinical trial results suggest that tirzepatide reduces blood glucose levels and body weight compared with semaglutide, insulin therapy or placebo. There is only an indirect comparison of tirzepatide with other GLP-1 receptor agonists, which suggests similar benefits, although these results are less certain.

Additional analyses provided by the company after consultation improved confidence in the clinical- and cost-effectiveness evidence. The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. Therefore, tirzepatide is recommended for routine use in the NHS.

NICE estimate that in Devon, 3,974 people will be eligible for treatment with tirzepatide.

Tabelecleucel for treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus *(terminated appraisal)* TA923

NICE is **unable to make a recommendation** on tabelecleucel for treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Daridorexant for treating long-term insomnia TA922

Recommendations

Daridorexant is **recommended** for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:

- cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
- CBTi is not available or is unsuitable.

The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.

This recommendation is not intended to affect treatment with daridorexant 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

Insomnia is difficulty in getting to sleep, difficulty maintaining sleep, early wakening, or non-restorative sleep which occurs despite adequate opportunity for sleep. It results in impaired daytime functioning. Daytime symptoms typically include poor concentration, mood disturbance, and fatigue. Sleep disturbance in the absence of daytime impairment is not considered to be insomnia disorder. Insomnia is classed as short-term when symptoms occur for less than 3 months and chronic when symptoms persist for more than 3 months. Insomnia disorder refers to chronic insomnia.

Insomnia is associated with comorbid conditions such as chronic obstructive pulmonary disease, heart failure, chronic pain, and psychiatric conditions (depression, anxiety, substance abuse, and post-traumatic stress disorder).

Cognitive behavioural therapy for insomnia (CBT-I) is recommended as first-line treatment for people with chronic or acute insomnia for whom sleep hygiene measures have failed and insomnia is not likely to resolve soon. Short-term pharmacotherapy with non-benzodiazepine

hypnotic medication can be considered as a temporary adjunct to behavioural and cognitive treatments for people with chronic insomnia who have severe symptoms or an acute exacerbation. Short term pharmacotherapy can also be an option for people with acute insomnia if sleep hygiene measures fail and daytime impairment is severe causing significant distress. TA77 recommends hypnotic drugs zolpidem or zopiclone as treatment options for insomnia in adults. Benzodiazepines or melatonin for those aged 55 or older may also be used.

Daridorexant is a dual orexin receptor antagonist (DORA). In contrast to treatments of insomnia that act via broad sedation of the central nervous system, DORAs specifically target excessive alertness. Daridorexant is administered orally.

Financial Factors

This technology is commissioned by ICBs.

Clinical trial evidence shows that daridorexant improves symptoms of insomnia compared with placebo for 12 months. The most likely cost-effectiveness estimate is within what NICE considers an acceptable use of NHS resources, therefore, daridorexant is recommended for routine use in the NHS.

NICE estimate that in Devon, 22,002 people will be eligible for treatment and that of these, 2,578 people will receive treatment with daridorexant.

Ruxolitinib for treating polycythaemia vera TA921

This guidance updates and replaces TA356 (terminated appraisal, published September 2015)

Recommendations

Ruxolitinib is **recommended**, within its marketing authorisation, for treating polycythaemia vera in adults who cannot tolerate hydroxycarbamide (also called hydroxyurea) or when the condition is resistant to it. It is only recommended if the company provides it according to the commercial arrangement.

The Technology

Polycythaemia vera is a bone marrow disease that leads to an increase in the number of blood cells. As more red blood cells are made, the blood becomes thicker which can lead to complications such as gout, bleeding problems and blood clots. Blood clots can cause strokes, heart attacks, or blockage of an artery in your lungs or in a vein deep within a muscle. Polycythaemia vera can also cause an increase in white blood cells which can lead to severe itching. In some cases, the extra cells collect in the spleen which may then become enlarged. Polycythaemia vera can lead to other problems such as scarring of the bone marrow and acute myeloid leukaemia.

Polycythaemia vera can affect people of any age but is most prevalent in people aged over 60 and in men.

Current treatments for polycythaemia vera aim to prevent symptoms and complications and to minimise the risk of transformation to acute myeloid leukaemia or myelofibrosis, therefore improving survival. The British Committee for Standards in Haematology's guidelines for polycythaemia vera recommend a range of treatments including periodic phlebotomy, hydroxycarbamide, interferon, anagrelide, radioactive phosphorus or low dose busulphan. In addition, melphalan has a license for treating polycythaemia vera in the UK but is rarely used in clinical practice.

Ruxolitinib is an inhibitor of the Janus-associated kinases (JAKs), which are involved in blood cells differentiation. Ruxolitinib is administered orally.

Financial Factors

This technology is commissioned by NHS England.

Results from clinical trials suggest that ruxolitinib is more effective than standard treatment at controlling blood cell counts and reducing spleen size. But whether it increases how long people live is uncertain.

Because of the uncertainty in the clinical-effectiveness evidence, the cost-effectiveness estimates need to be towards the lower end of the range that NICE considers an acceptable use of NHS resources. They are below this lower end, therefore, ruxolitinib is recommended.

NICE estimate that in Devon, 656 people will be eligible for treatment and that 328 people will receive treatment with ruxolitinib.

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

Tofacitinib for treating active ankylosing spondylitis TA920

Recommendations

Tofacitinib is **recommended** as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy in adults, only if:

- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough and
- the company provides tofacitinib according to the commercial arrangement.

If people with the condition and their clinicians consider tofacitinib to be 1 of a range of suitable treatments (including secukinumab and ixekizumab), 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.

Assess response to tofacitinib after 16 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

Take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the BASDAI and make any adjustments needed.

These recommendations are not intended to affect treatment with tofacitinib 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 clinician consider it appropriate to stop.

The Technology

Axial spondyloarthritis belongs to a clinically heterogeneous group of inflammatory rheumatologic diseases which share common genetic, histological and clinical features (also including psoriatic arthritis, arthritis associated with inflammatory bowel disease, reactive arthritis and undifferentiated spondyloarthritis).

Axial spondyloarthritis involves inflammation of the sacroiliac joints and spine. If inflammation is visible on xray, the disease is classified as radiographic axial spondyloarthritis (also known as **ankylosing spondylitis**). If x-rays of the sacroiliac joints and spine are normal, but there are other objective signs of inflammation (elevated C-reactive protein or evidence on magnetic resonance imaging) the disease is classified as non-radiographic axial spondyloarthritis.

The clinical symptoms of axial spondyloarthritis can vary from person to person, but usually develop slowly over several months or years. The main symptoms can include back pain, usually inflammatory in nature, arthritis, enthesitis (inflammation where a bone is joined to a tendon), and fatigue. Extra-articular manifestations include uveitis, inflammatory bowel disease and psoriasis. The onset of symptoms typically occurs in the third decade of life, but it can be 7–10 years before a diagnosis is made. Many patients with mild disease may remain undiagnosed.

Conventional therapy for radiographic axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. Tumour necrosis factor-alpha (TNF-alpha) inhibitors are typically used when the disease has not responded adequately to conventional therapy.

NICE recommends a number of different options for treating ankylosing spondylitis:

- TA383 recommends adalimumab, certolizumab pegol, etanercept, golimumab and infliximab
- TA407 recommends the interleukin17A (IL-17A) inhibitor secukinumab as an alternative to, or after inadequate response to TNF-alpha inhibitors.

Tofacitinib is a Janus kinase-1 (JAK-1) and JAK-3 inhibitor and is a targeted synthetic small molecule. Janus kinases are intracellular enzymes that transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of creating new blood cells in the body and immune cell function. It is administered orally.

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 will be similar. Tofacitinib represents an additional treatment option for those patients with active ankylosing spondylitis, where tumour necrosis factor alpha inhibitors are not suitable or do not control the condition well enough and who would benefit from or prefer an oral treatment, as opposed to injectable treatments.

NICE estimate that in Devon, 156 people will be eligible for treatment with tofacitinib.

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

Rimegepant for treating migraine TA919

Recommendations

Rimegepant is **recommended** 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.

This recommendation is not intended to affect treatment with rimegepant 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

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.

Factors that can trigger attacks in people susceptible to migraines include stress, change in sleep pattern, overtiredness, menstruation, consumption of caffeine or alcohol, climatic conditions and use of visual display units.

Migraine is on a continuum and it is possible for people to move between episodic and chronic migraine:

- **Episodic migraine** is defined as the occurrence of headaches on less than 15 days per month
- **Chronic migraine** is defined by the International Classification of Headache Disorders 3rd edition (ICHD-3). It is described as headache occurring on 15 or more days a month for more than 3 months, which, on at least 8 days a month, has the features of migraine headache.

Treatments for acute migraine attacks include analgesics, triptans and anti-emetics. CG150 recommends an oral triptan with either an NSAID or paracetamol. 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.

Preventive treatment of migraines can take many forms including nutritional supplements, lifestyle alterations such as increased exercise and avoidance of migraine triggers. It can also include medications, which are generally considered for people depending on their disease burden and frequency of attacks. CG150 recommends offering topiramate or propranolol and considering amitriptyline, for preventing migraine.

NICE recommends a number of different options for treating/preventing migraine:

- TA682 erenumab
- TA764 fremanezumab
- TA659 galcanezumab
- TA260 botulinum toxin type A

Rimegepant is a calcitonin gene-related peptide receptor antagonist. It inhibits the action of calcitonin gene related peptide, which is believed to transmit signals that can cause severe pain. Rimegepant is administered orally.

Financial Factors

This technology is commissioned by ICBs.

NICE do not expect this guidance to have a significant impact on resources. This is because rimegepant is a further treatment option and is for use after other options have been tried or are contraindicated or not tolerated.

In the preventing migraine setting, rimegepant and other treatments (such as galcanezumab, erenumab and fremanezumab) are also recommended. In clinical practice, when a person is having migraines sufficiently often to benefit from a preventative effect, there is a reasonable likelihood that they will be having 1 of the approved preventative treatments which have the same mechanism of action to rimegepant for preventing migraine. Given there is current use of rimegepant and its position in the pathway, it is not anticipated there will be a significant resource impact as a result of this guidance.

Bimekizumab for treating axial spondyloarthritis TA918

Recommendations

Bimekizumab is **recommended** as an option in adults for treating active ankylosing spondylitis (AS) when conventional therapy has not worked well enough or is not tolerated, or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation (shown by elevated C-reactive protein or MRI) when non-steroidal anti-inflammatory drugs (NSAIDs), have not worked well enough or are not tolerated. It is recommended only if:

- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough, and
- the company provides it according to the commercial arrangement.

Assess response to bimekizumab after 16 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires and make any appropriate adjustments.

If people with the condition and their clinicians consider bimekizumab to be 1 of a range of suitable treatments (including ixekizumab and secukinumab), 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.

This recommendation is not intended to affect treatment with bimekizumab 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

Axial spondyloarthritis belongs to a clinically heterogeneous group of inflammatory rheumatologic diseases which share common genetic, histological and clinical features (also including psoriatic arthritis, arthritis associated with inflammatory bowel disease, reactive arthritis and undifferentiated spondylarthritis).

Axial spondyloarthritis involves inflammation of the sacroiliac joints and spine. If inflammation is visible on x-ray, the disease is classified as radiographic axial spondyloarthritis (also known as ankylosing spondylitis). If x-rays of the sacroiliac joints and spine are normal, but there are other objective signs of inflammation the disease is classified as nonradiographic axial spondyloarthritis.

The clinical symptoms of axial spondyloarthritis can vary from person to person, but usually develop slowly over several months or years. The main symptoms can include back pain, which will be inflammatory in nature, peripheral arthritis, enthesitis and fatigue. Extra-articular manifestations include uveitis, inflammatory bowel disease and psoriasis. The average age of onset of symptoms is 24 years, with an average of 8.5 years before a diagnosis is made, by which time damage to the spine, which can be irreversible, may have occurred.

Conventional therapy for non-radiographic axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and Physiotherapy. Conventional therapy for ankylosing spondylitis is the same as for non-radiographic axial spondylitis.

NICE recommends a number of different options for treating axial spondyloarthritis:

- TA383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis
- TA497 Golimumab for treating non-radiographic axial spondyloarthritis
- TA719 Secukinumab for treating non-radiographic axial spondyloarthritis
- TA718 Ixekizumab for treating axial spondyloarthritis
- TA407 Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors
- TA829 Upadacitinib for treating active ankylosing spondylitis

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 will be similar.

A cost comparison suggests bimekizumab has lower costs than ixekizumab but higher costs than secukinumab. Using NICE's cost-comparison methods, bimekizumab only needs to cost less than 1 relevant comparator that is established practice in the NHS, to be recommended as a treatment option. Therefore, bimekizumab is recommended.

NICE estimate that in Devon, 156 people will be eligible for treatment with bimekizumab.

The company has a commercial agreement. This makes bimekizumab available to the NHS with a discount.

Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable TA917

Recommendations

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

The Technology

Multiple myeloma is a form of cancer that arises from plasma cells in the bone marrow. Myeloma cells suppress the development of normal blood cells that are responsible for fighting infection, carrying oxygen around the body and blood clotting. 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 infections, hypercalcaemia and kidney problems.

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.

TA228 recommends thalidomide in combination with an alkylating agent and a corticosteroid for the first-line treatment of multiple myeloma in people for whom high-dose chemotherapy when stem cell transplantation is considered inappropriate. If the person is unable to tolerate or has contraindications to thalidomide, treatment options include bortezomib in combination with an

alkylating agent and a corticosteroid and lenalidomide plus dexamethasone (TA587).

Daratumumab is a humanised monoclonal antibody that kills multiple myeloma cells, targeting the CD38 protein. It is administered intravenously or subcutaneously.

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence shows that daratumumab plus lenalidomide and dexamethasone increases the amount of time people have before their condition gets worse compared with lenalidomide plus dexamethasone. Clinical trial evidence also shows it increases how long people live compared with lenalidomide plus dexamethasone, but by how much is uncertain. There is no direct evidence comparing daratumumab plus lenalidomide and dexamethasone with bortezomib plus an alkylating agent and a corticosteroid, but indirect comparisons suggest that it is more effective.

The most likely cost-effectiveness estimates for daratumumab plus lenalidomide and dexamethasone are within the range that NICE normally considers an acceptable use of NHS resources, therefore it is recommended.

NICE estimate that in Devon, 52 people will be eligible for treatment and that 34 people will receive daratumumab with lenalidomide and dexamethasone.

Bimekizumab for treating active psoriatic arthritis TA916

Recommendations

Bimekizumab alone or with methotrexate, is **recommended** as an option for treating active psoriatic arthritis (defined as peripheral arthritis with 3 or more tender joints and 3 or more swollen joints) in adults whose condition has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and:

- at least 1 biological DMARD or
- tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis).

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

Assess response to bimekizumab after 16 weeks of treatment. Stop bimekizumab if the psoriatic arthritis has not responded adequately using the Psoriatic Arthritis Response Criteria (PsARC; an adequate response is an improvement in at least 2 of the 4 criteria, 1 of which must be joint

tenderness or swelling score, with no worsening in any of the 4 criteria). If the PsARC response is not adequate but there is a Psoriasis Area and Severity Index (PASI) 75 response, a dermatologist should decide whether continuing treatment is appropriate based on skin response.

Take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the PsARC and make any adjustments needed.

Take into account how skin colour could affect the PASI score and make any adjustments needed.

If people with the condition and their clinicians consider bimekizumab to be 1 of a range of suitable treatments (including ixekizumab and secukinumab), 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.

These recommendations are not intended to affect treatment with bimekizumab 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 clinician consider it appropriate to stop.

The Technology

Psoriatic arthritis is an inflammatory arthritis closely associated with psoriasis. It is estimated that around 1 in 5 people with psoriasis develop psoriatic arthritis. Around 70% of people have psoriasis before psoriatic arthritis. Men and women are equally likely to develop psoriatic arthritis with peak onset being between the ages of 30 and 50.

Although psoriatic arthritis is a chronic condition that progresses in the joints, its course may be erratic, with flare-ups and remissions. Arthritis symptoms can range from inflammation of the synovial membrane surrounding a joint, ligaments and tendons and inflammation of digits to severe progressive erosion of the joints. Axial inflammation might also occur in some cases. Skin symptoms include the presence of patchy, raised, red areas of skin inflammation with scaling. This can affect any part of the body but is most commonly found on the elbows, knees, scalp and ears, the navel, and around the genital areas or anus. Nail symptoms include swelling, discolouration and pitting.

The aim of treatment is to suppress joint, tendon and ligament inflammation and to manage the skin symptoms of the disease. Current practice involves early diagnosis and early use of non-biological disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate, sulfasalazine and leflunomide, in order to minimise damage to joints. Non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy and intraarticular corticosteroid injections may also be used.

NICE recommends a number of different options for treating psoriatic arthritis:

- TA199 Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis
- TA220 Golimumab for the treatment of psoriatic arthritis
- TA445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs
- TA433 Apremilast for treating active psoriatic arthritis
- TA537 Ixekizumab for treating active psoriatic arthritis after inadequate response to DMARDs
- TA543 Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs
- TA340 Ustekinumab for treating active psoriatic arthritis
- TA803 Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs
- TA815 Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs
- TA768 Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs

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 is available at a similar price to the current treatment options. Bimekizumab works in a similar way to ixekizumab and secukinumab and would be offered to the same population.

Bimekizumab and the other treatment options have discounts that are commercial in confidence. This makes bimekizumab available to the NHS with a discount.

Pegunigalsidase alfa for treating Fabry disease TA915

Recommendations

Pegunigalsidase alfa is **recommended**, within its marketing authorisation, as an option for treating Fabry disease (also known as alpha-galactosidase deficiency) in adults. It is recommended only if the company provides it according to the commercial arrangement.

The Technology

Fabry disease (also known as Anderson–Fabry disease) is an X-linked inherited lysosomal storage disorder. It is caused by mutations in the GLA gene, which encodes the enzyme alpha-galactosidase A (α-Gal A). Mutations in the GLA gene cause the enzyme to be lacking or have reduced activity, preventing it from breaking down a fat called globotriaosylceramide (Gb3). Gb3

then progressively accumulates in cells and tissues, causing progressive damage to multiple organs.

Symptoms can include short term severe pain or burning sensation, which starts at the extremities and spreads throughout the rest of the body (often referred to as a 'Fabry crisis'), gastrointestinal complications such as diarrhoea, nausea and abdominal pain, headaches, inability to sweat properly, vertigo and hearing impairment. Other body sites that can also be affected include the skin, eyes, kidneys, heart, brain and nervous system. Fabry disease can lead to potentially life-threatening complications such as heart and renal failure and an increased risk of stroke.

There is no cure for Fabry disease, but treatments are available which relieve the symptoms and prevent progression of damage to organs such as the kidney and the heart. Current treatment options include infusions with enzyme replacement therapies, agalsidase alfa and agalsidase beta, which replace the non-functioning enzyme. For people over 16 with amenable mutations, HST4 recommends migalastat as an alternative treatment option to enzyme replacement therapy. Adjunctive therapies include treatment of pain, hypertension and cutaneous lesion of capillaries known as angiokeratoma.

Pegunigalsidase alfa is a novel enzyme replacement therapy for the treatment of adults with Fabry disease. It would be offered to those people who would usually be offered ERT or migalastat. It is produced in a plant cell-based system, in contrast to the existing therapies which are produced in hamster or human cell lines. It is administered via intravenous infusion and delivers a modified version of α-Gal A, which is lacking in people with Fabry disease. The enzyme is chemically modified in a way that makes it more stable than current enzyme replacement therapies, potentially extending the time between treatments. The treatment can be administered in the patient's home by healthcare professionals.

Financial Factors

This technology is commissioned by NHS England.

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.

Evidence shows pegunigalsidase alfa is similarly clinically effective and similarly tolerable as the treatments currently used in the NHS. Economic evidence suggests that pegunigalsidase alfa is cost saving when compared with other enzyme replacement therapies and migalastat.

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

Ranibizumab for treating diabetic macular oedema TA274 (UPDATE)

October 2023: NICE updated the wording of the recommendations describing the patient access scheme and have also updated their website section on 'The Technology' to include procurement information about ranibizumab biosimilars.

Recommendations

Ranibizumab is **recommended** as an option for treating visual impairment due to diabetic macular oedema only if:

- the eye has a central retinal thickness of 400 micrometres or more at the start of treatment and
- the manufacturers of ranibizumab (branded or biosimilar) provide it at a discount level no lower than the discount agreed in the patient access scheme **[2023]**.

People currently receiving ranibizumab for treating visual impairment due to diabetic macular oedema whose disease does not meet the criteria should be able to continue treatment until they and their clinician consider it appropriate to stop.

The Technology

Diabetic macular oedema affects sight in people with diabetes. The macular is the central part of the retina at the back of the eye. In diabetic macular oedema, there is abnormal growth of new blood vessels in the macular. These vessels leak fluid, causing the macular to swell and leading to problems with sight.

Ranibizumab works by blocking a substance called vascular endothelial growth factor (VEGF) that, in people with diabetic macular oedema, causes the abnormal growth of new blood vessels in the eye. Ranibizumab is given by injection into the eye.

Financial Factors

This technology is commissioned by ICBs.

Ranibizumab costs may vary in different settings because of negotiated procurement discounts. The manufacturer of branded ranibizumab has agreed a patient access scheme with the Department of Health which makes ranibizumab available with a discount applied to all invoices. The size of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS. The manufacturer has agreed that the patient access scheme will remain in place until any review of this NICE technology appraisal guidance is published. NHS England has completed a national procurement for medical retinal vascular medicines, which includes the biosimilar versions of ranibizumab. Prices paid for the originator or biosimilar ranibizumab should be in line with the

national procurement outcome and should be no higher than that provided through the original patient access scheme.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

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

This guideline replaces recommendation 1.1.1, and updates recommendations 1.2.1 and 1.2.2 CG191 (published December 2014).

This guideline covers assessment of people aged 16 and over with symptoms and signs of an acute respiratory infection (both bacterial and 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.

Stroke rehabilitation in adults NG236

This guideline updates and replaces CG162 (published June 2013)

This guideline covers rehabilitation after stroke for over 16s. It aims to ensure people are assessed for common problems and conditions linked to stroke and get the care and therapy they need. It includes recommendations on the organisation and delivery of rehabilitation in hospital and the community.

Thyroid disease: assessment and management NG145 (UPDATE)

This guideline covers investigating all suspected thyroid disease and managing primary thyroid disease (related to the thyroid rather than the pituitary gland). It does not cover managing thyroid cancer or thyroid disease in pregnancy. It aims to improve quality of life by making recommendations on diagnosis, treatment, long-term care and support.

October 2023: NICE updated recommendations on investigating suspected thyroid dysfunction to highlight the potential for biotin in dietary supplements to affect the results of thyroid function tests.

Suspected neurological conditions: recognition and referral NG127 (UPDATE)

This guideline covers the initial assessment of symptoms and signs that might indicate a neurological condition. It helps non-specialist healthcare professionals to identify people who should be offered referral for specialist investigation.

October 2023: NICE updated recommendations on suspected cancer pathway referrals for facial pain, gait unsteadiness and single limb weakness or hemiparesis in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

Hearing loss in adults: assessment and management NG98 (UPDATE)

This guideline covers some aspects of assessing and managing hearing loss in primary, community and secondary care. It aims to improve the quality of life for adults with hearing loss by advising healthcare staff on assessing hearing difficulties, managing earwax and referring people for audiological or specialist assessment and management.

October 2023: NICE updated the recommendation on considering suspected cancer pathway referral for adults of Chinese or south-east Asian family origin with hearing loss and a middle ear effusion not associated with an upper respiratory tract infection in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

Suspected cancer: recognition and referral NG12 (UPDATE)

This guideline covers identifying children, young people and adults with symptoms that could be caused by cancer. It outlines appropriate investigations in primary care, and selection of people to refer for a specialist opinion. It aims to help people understand what to expect if they have symptoms that may suggest cancer.

October 2023: NICE updated recommendations on suspected cancer pathway referrals in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

Pneumonia in adults: diagnosis and management CG191 (UPDATE)

This guideline was developed before the COVID-19 pandemic. It covers diagnosing and managing pneumonia in adults who do not have COVID-19. It aims to improve accurate assessment and diagnosis of pneumonia to help guide antibiotic prescribing and ensure that people receive the right treatment.

October 2023: NICE replaced the recommendation on lower respiratory tract infection with a link to NICE's guideline on suspected acute respiratory infection in over 16s (ARI) (NG237). NICE updated the recommendations on severity assessment outside hospital in line with the ARI guideline.

Urinary incontinence in neurological disease: assessment and management CG148 (UPDATE)

This guideline covers assessing and managing urinary incontinence in children, young people and adults with neurological disease. It aims to improve care by recommending specific treatments based on what symptoms and neurological conditions people have.

October 2023: NICE updated the recommendation on suspected cancer pathway referral for possible bladder cancer in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

Ovarian cancer: recognition and initial management CG122 (UPDATE)

This guideline covers detecting, diagnosing and treating women (18 years and older) who have, or are suspected of having, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer or borderline ovarian cancer. It aims to enable earlier detection of ovarian cancer and improve initial treatment.

October 2023: updated recommendations on suspected cancer pathway referrals from primary care in line with NHS England's standard on faster diagnosis of cancer. People should have a diagnosis or ruling out of cancer within 28 days of referral.

Jaundice in newborn babies under 28 days CG98 (UPDATE)

This guideline covers diagnosing and treating jaundice, which is caused by increased levels of bilirubin in the blood, in newborn babies (neonates). It aims to help detect or prevent very high levels of bilirubin, which can be harmful if not treated.

October 2023: NICE updated recommendations on looking for jaundice to highlight that skin pigmentation changes may be harder to see in darker skin and managing prolonged jaundice to advise that urine culture should only be considered if there is clinical suspicion of urinary tract infection.

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)

Vaginal transluminal endoscopic hysterectomy and adnexal surgery for benign gynaecological conditions IPG774

Recommendations

Vaginal transluminal endoscopic hysterectomy and adnexal surgery for benign gynaecological conditions should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do vaginal transluminal endoscopic hysterectomy and adnexal surgery for benign gynaecological conditions should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Patient selection should be done by a multidisciplinary team including clinicians with specific training in patient selection and the procedure.

This procedure should only be done by an experienced surgeon and theatre team with specific training in this procedure (which may include mentoring) and the ability to convert it to a conventional hysterectomy if needed.

NICE encourages further research into vaginal transluminal endoscopic hysterectomy and adnexal surgery for benign gynaecological conditions and may update the guidance on publication of further evidence.

The Condition

Benign gynaecological conditions refer to non-cancerous conditions affecting the female reproductive systems. These include, but are not limited to, chronic pelvic pain, uterine prolapse, fibroids and abnormal vaginal bleeding. Left untreated, these conditions can lead to severe and prolonged pain, infections and reduced quality of life.

The current surgical treatments for this set of conditions includes hysterectomy, adnexectomy and myomectomy. Conventional hysterectomy is done through a cut in the abdomen or through the vagina. There are also laparoscopic approaches.

An adnexectomy involves removing the ovaries or fallopian tubes. This can be done alongside a hysterectomy or on its own.

Myomectomies are keyhole or open surgeries which remove fibroids that develop around the womb.

The Procedure

The vaginal transluminal endoscopic hysterectomy procedure is done in a similar way to a conventional vaginal hysterectomy but uses an endoscopic view and laparoscopic instruments. The patient is placed in the lithotomy position. Under general anaesthesia, a circular incision is made in the vagina. Following anterior/posterior colpotomy and transecting the sacro-uterine ligaments, a keyhole instrument port with transvaginal indication is then inserted to improve access and visibility. The abdominal cavity is accessed through the colpotomy and then insufflated. Laparoscopic instruments are inserted and the surgery is done in a Trendelenburg position. Then the uterus, fallopian tubes or ovaries are removed vaginally (depending on the procedure type). Then the instrument port is removed, the abdomen is deflated, and the vaginal incision is closed with absorbable sutures.

Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia (IPG773)

Recommendations

Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia in people with limited treatment options should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wanting to do percutaneous deep venous arterialisation for chronic limb-threatening ischaemia should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Further research should report:

- details of patient selection (including number of patients dependent on dialysis)
- details of the procedure technique
- duration of anticoagulation
- patient outcomes (including planned and unplanned reintervention rate, major amputation rate, and quality of life).

The Condition

Chronic limb-threatening ischaemia of the lower extremities is caused by severely narrowed or blocked arteries. It is an advanced stage of peripheral arterial disease. The severely reduced blood supply causes ischaemic pain, ulceration, tissue loss and gangrene. It is associated with high amputation and mortality rates and poor quality of life.

Chronic limb-threatening ischaemia usually needs treatment to re-establish blood flow to the affected area and to prevent major amputation. Treatment options include medications, endovascular interventions and surgical treatments. Management of chronic limb-threatening ischaemia is described in NICE's clinical guideline on peripheral arterial disease (CG147).

The Procedure

The procedure uses an endovascular, minimally invasive approach. An arteriovenous fistula is created to allow venous arterialisation in the below-the-knee vasculature. The aim is to restore blood flow to the ischaemic foot.

Preoperative investigation is needed to confirm adequate pedal venous anatomy and identify a suitable crossover point between the vessels.

The procedure is usually done using general anaesthesia and with ultrasound guidance. Antegrade arterial access is established through the common femoral artery and retrograde venous access is established through the tibial vein. Arterial and venous catheters are inserted and advanced to the target artery and vein. Once both catheters are positioned with a crossover point, a needle is used to create an arteriovenous fistula. Valvulotomy of the vein is then done, usually from the crossover point to the midfoot. Multiple stents are placed in the vein from the level of the calcaneus to the arteriovenous crossover point, and a crossing stent is inserted to maintain the arteriovenous fistula. This establishes retrograde blood flow down the veins, which become arterialised.

Arteriography is done at the end of the procedure to visualise blood flow into the deep venous arch.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

Health Technology Evaluations (HTE)

Digital technologies for delivering specialist weight-management services to manage weight-management medicine HTE14

Recommendations

Can be used in the NHS with evidence generation

Five digital weight-management technologies **can be used** in the NHS while more evidence is generated, to deliver specialist weight-management services for adults who are eligible for weight-management medicine. The technologies are:

- Gro Health W8Buddy (DDM Health), for prescribing and monitoring weight-management medicine
- Liva (Liva), for tracking weight-management medicine
- Oviva (Oviva), for prescribing and monitoring weight-management medicine
- Roczen (Reset Health), for prescribing and monitoring weight-management medicine
- Second Nature (Second Nature), for prescribing and monitoring weight-management medicine.

These technologies can only be used once they have appropriate 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 (4 years), 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.

Can only be used in research

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

- CheqUp (CheqUp Health)
- Juniper (Juniper Technologies UK)
- Wellbeing Way (Xyla Health and Wellbeing).

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 and cost of the medicine.

More information will be included in the evidence generation plan.

The Technology

Digital weight-management technologies can be used to deliver specialist weight-management services. They can be accessed online or through an app and provide a multidisciplinary programme and support from the service's multidisciplinary team (MDT) of healthcare professionals.

Some technologies offer weight-management medicine prescribing and medicine reviews with a prescribing clinician, alongside regular reviews with other members of the service's MDT. Other technologies collect and share medicine adherence data with the person's NHS team, to support the NHS team with prescribing weight-management medicine. The frequency of reviews may vary depending on the technology, user preference and stage of the programme.

Semaglutide for weight management must be used within a specialist weight-management service that provides multidisciplinary management of overweight or obesity, including but not limited to tier 3 and tier 4 services (see TA875). Liraglutide for managing overweight and obesity must be prescribed in secondary care by a specialist multidisciplinary tier 3 weight-management service (see TA664).

Tier 3 and 4 specialist weight-management services for people with overweight and obesity are defined in NHS England's guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery (2016) and CG189. A typical MDT should include an obesity doctor, specialist nurse, specialist dietitian, psychologist and physiotherapist. It should also have access to healthcare professionals with expertise in surgical assessments. The intensity, frequency and variety of support from an MDT of healthcare professionals varies between NHS specialist weight-management services. It may be offered in person, remotely by telephone or video call, or as a combination of in-person and remote support. Most programmes offered by these services take between 12 and 24 months to complete, but some may only take

6 months. The criteria for accessing these services may also vary depending on the geographical area and local funding.

Financial Factors

These technologies are commissioned by ICBS.

Given that a potential benefit of this technology is that it may improve access to weight-management services, it should be acknowledged that overall costs may increase as a direct result of expanding weight-management services. The recommended technologies deliver specialist weight-management services, but it may be determined locally to retain some elements of face-to-face care. Where this is the case, the expansion of the service through the implementation of these technologies may also require additional resources to support the face-to-face interventions that are retained. Where the technology costs do not include the costs of prescribing the weight loss medicine, provision for the increase in these costs will also need to be made.

Virtual ward platform technologies for acute respiratory infections HTE13

Recommendations

Virtual ward platform technologies **can be used** in the NHS while more evidence is generated to monitor people over 16 with acute respiratory infection in their usual place of residence. They can be used for people who have been:

- referred for hospital admission or
- admitted to hospital and their condition is stable or improving but needs ongoing monitoring.

  These technologies can only be used once they have appropriate regulatory approval, including CE mark, and Digital Technology Assessment Criteria (DTAC) approval.

Virtual ward platform technologies should have these key features:

- interoperability with electronic patient record systems and associated medical devices
- appropriate regulatory approval for associated medical devices (devices must also meet local testing standards and be validated for use in a place of residence)
- validated accuracy in people with black or brown skin for devices that measure oxygen saturation
- risk-stratified alerts (for example, red, amber or green) for healthcare professionals for when readings go outside of the agreed range (alerts can be based on device-measured vital signs or questionnaire responses)

- trend-based alerts (to increase specificity) if they are using continuous-monitoring wearable devices
- patient interface with an easy to use, user-centred design.

Further evidence should be generated on the following key clinical and cost outcomes:

- length of virtual ward or hospital stay
- hospital admission and readmission rates
- number of alerts when using a virtual ward (including false-positive and false-negative alerts)
- costs and resource use (including virtual ward service delivery costs)
- patient and carer experience and acceptability (including carer burden)
- demographics of the people admitted to a virtual ward (including information relating to health inequalities)
- healthcare professional experience and acceptability
- number of contacts with other healthcare providers, such as GP visits, home visits and calls to 111.

The Technology

Virtual ward platform technologies would be used as an alternative to inpatient secondary care, care in the community or care in the person's usual place of residence without the use of a virtual ward platform technology.

A virtual ward platform technology comprises a patient-facing app or website, medical devices for measuring vital signs and a digital platform for healthcare professionals. The aim of these technologies is to expand the capacity of the acute care sector by monitoring people, who would otherwise be in hospital, remotely in their home or usual place of residence. Several virtual ward platform technologies are available in the NHS.

Virtual wards are designed to provide an alternative to admission into hospital or support early discharge out of hospital. A virtual ward is not intended to be a mechanism for enhanced primary care programmes; chronic disease management; home intravenous or infusion services; intermediate or day care; safety netting; or proactive deterioration prevention.

Financial Factors

These technologies are commissioned by ICBs.

Depending on current local practice, recommendations/areas which may require additional resources and result in additional costs include:

- the virtual ward technology including specific hardware/software and upgrades to support the technology
- time required for training and support
- any costs associated with a lack of interoperability of the virtual ward technology with electronic patient record systems and associated medical devices
- costs associated with the delivery, collection and repurposing of the virtual ward equipment.

Implementing the guidance may:

- be cost saving because people are having their healthcare managed at home or in their usual place of residence instead of in hospital
- reduce pressures on hospital in-patient care
- improve patient flow.

These benefits may provide savings to offset against technology and implementation costs.

NICE Quality Standards

Acute respiratory infection in over 16s: initial assessment and management including virtual wards (hospital at home) QS210

This quality standard covers the initial assessment and management of suspected acute respiratory infection in over 16s, including acute respiratory infection virtual wards. It covers people with comorbidities that may affect their risk, such as chronic obstructive pulmonary disease and asthma, but does not cover long-term management of those conditions. It does not cover aspiration pneumonia or respiratory infection acquired while an inpatient in hospital or during end-of-life care.

Current NICE Consultations

Title/link	End date of consultation
Kurin Lock for blood culture collection	13 November 2023
Harmful gambling: identification, assessment and management	15 November 2023
Olipudase alfa for treating acid sphingomyelinase deficiency (Niemann Pick disease type B and AB) [ID3913]	16 November 2023
Overweight and obesity management	28 November 2023