NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: July 2019

Hyperlinks to the relevant NICE web page are included below.

Technology Appraisals (TAs)

Letermovir for preventing cytomegalovirus disease after a stem cell transplant TA591

Recommendations

Letermovir is **recommended**, within its marketing authorisation, as an option for preventing cytomegalovirus (CMV) reactivation and disease after an allogeneic haematopoietic stem cell transplant (HSCT) in adults who are seropositive for CMV. It is recommended only if the company provides it according to the commercial arrangement.

The technology

Letermovir is indicated for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive [R+] recipients of an allogeneic haematopoietic stem cell transplant.

The recommended dose of letermovir is 480 mg once daily (oral tablets and solution for intravenous infusion), decreasing to 240 mg once daily if co-administered with cyclosporin A. Treatment with letermovir may be started on the day of transplant or on any day up to 28 days afterwards and should continue for 100 days after transplant; longer treatment may be considered in some patients at high risk for late CMV reactivation.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources because the population size is small. It is estimated that around 600 people per year in England are eligible for treatment with letermovir for preventing cytomegalovirus disease after a stem cell transplant.

The company has a commercial arrangement (simple discount patient access scheme). This makes letermovir available to the NHS with a discount. The size of the discount is commercial in confidence.

Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis TA590

Recommendations

Fluocinolone acetonide intravitreal implant is **recommended**, within its marketing authorisation, as an option for preventing relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye. It is recommended only if the company provides it according to the commercial arrangement.

The technology

Fluocinolone acetonide intravitreal implant is indicated for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

Fluocinolone acetonide intravitreal implant is administered through intravitreal injection. Each implant contains 0.19 mg of fluocinolone acetonide and releases fluocinolone acetonide for up to 36 months.

Financial factors

This technology is commissioned by NHS England.

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

The company has a commercial arrangement (simple discount patient access scheme). This makes fluocinolone acetonide intravitreal implant available to the NHS with a discount.

Blinatumomab for treating acute lymphoblastic leukaemia in remission with minimal residual disease activity TA589

Recommendations

Blinatumomab is **recommended** as an option for treating Philadelphia-chromosome-negative CD19-positive B-precursor acute lymphoblastic leukaemia in adults with minimal residual disease (MRD) of at least 0.1%, only if:

- the disease is in first complete remission and
- the company provides blinatumomab according to the commercial arrangement.

This recommendation is not intended to affect treatment with blinatumomab 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

Blinatumomab is indicated as monotherapy for the treatment of adults with Philadelphia-chromosome-negative CD19 positive B-precursor acute lymphoblastic leukaemia in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.

Blinatumomab is administered by continuous intravenous infusion delivered at a constant rate using an infusion pump. A single cycle of blinatumomab treatment comprises continuous intravenous infusion at a dose of 28 micrograms/day for 28 days, followed by a 14-day treatment-free interval.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that around 55 people with acute lymphoblastic leukaemia with MRD in England are eligible for treatment with blinatumomab and around 50 people will have blinatumomab from year 2020/21 onwards once uptake has reached 90%.

Nusinersen for treating spinal muscular atrophy TA588

Recommendations

Nusinersen is **recommended** as an option for treating 5q spinal muscular atrophy (SMA) only if:

- people have pre-symptomatic SMA, or SMA types 1, 2 or 3 and
- the conditions in the managed access agreement are followed.

The technology

Nusinersen has a marketing authorisation for the treatment of 5q spinal muscular atrophy. The dosage in the marketing authorisation is 12 mg, by intrathecal infusion, on days 0, 14, 28 and 63, then every 4 months.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that between 600 and 1,200 children and adults are currently living with SMA, in the UK.

Nusinersen will be available through the NHS in line with the managed access agreement with NHS England. The managed access agreement details various risk management strategies, including patient selection, starting and stopping rules, data collection, patient consent, exit strategy and commercial offer. Taking these into account, nusinersen is recommended for people with pre-symptomatic SMA, or SMA types 1, 2 or 3 if the conditions in the managed access agreement are followed, including the collection of more data to address the uncertainties. The guidance will be reviewed based on data collected in the managed access arrangement. The review of the guidance will be published by the end of the fifth year.

NICE Guidelines (NGs)

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.

In July 2019, following user feedback NICE changed the timing of referral from urgent to immediate for adults with sudden-onset speech or language disturbance and children under 4 years with a change in head circumference and signs or symptoms of raised intracranial pressure.

Chronic obstructive pulmonary disease in over 16s: diagnosis and management NG115 (update)

This guideline covers diagnosing and managing chronic obstructive pulmonary disease or COPD (which includes emphysema and chronic bronchitis) in people aged 16 and older. It aims to help people with COPD to receive a diagnosis earlier so that they can benefit from treatments to reduce symptoms, improve quality of life and keep them healthy for longer.

In July 2019, NICE reviewed the evidence and made new recommendations on inhaled triple therapy for stable COPD and systemic corticosteroids for managing exacerbations.

End of life care for infants, children and young people with life-limiting conditions: planning and management NG61 (update)

This guideline covers the planning and management of end of life and palliative care in for infants, children and young people (aged 0–17 years) with life-limiting conditions. It aims to involve children, young people and their families in decisions about their care, and improve the support that is available to them throughout their lives.

In July 2019, NICE added a footnote to this guideline to reflect a change in the law relating to gabapentin. As of 1 April 2019, because of a risk of abuse and dependence gabapentin is controlled under the Misuse of Drugs Act 1971 as a class C substance and is scheduled under the Misuse of Drugs Regulations 2001 as schedule 3.

Motor neurone disease: assessment and management NG42 (update)

This guideline covers assessing and managing motor neurone disease (MND). It aims to improve care from the time of diagnosis, and covers information and support, organisation of care, managing symptoms and preparing for end of life care.

In July 2019, NICE added a footnote to this guideline to reflect a change in the law relating to gabapentin. As of 1 April 2019, because of a risk of abuse and dependence gabapentin is controlled under the Misuse of Drugs Act 1971 as a class C substance and is scheduled under the Misuse of Drugs Regulations 2001 as schedule 3.

Multiple sclerosis in adults: management CG186 (update)

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

In July 2019, NICE updated a footnote in this guideline to reflect a change in the law relating to gabapentin. As of 1 April 2019, because of a risk of abuse and dependence gabapentin is controlled under the Misuse of Drugs Act 1971 as a class C substance and scheduled under the Misuse of Drugs Regulations 2001 as schedule 3.

Neuropathic pain in adults: pharmacological management in non-specialist settings CG173 (update)

This guideline covers managing neuropathic pain (nerve pain) with pharmacological treatments (drugs) in adults in non-specialist settings. It aims to improve quality of life for people with conditions such as neuralgia, shingles and diabetic neuropathy by reducing pain and promoting increased participation in all aspects of daily living. The guideline sets out how drug treatments for neuropathic pain differ from traditional pain management.

In July 2019, NICE updated footnotes in this guideline to reflect a change in the law relating to pregabalin and gabapentin. As of 1 April 2019, because of a risk of abuse and dependence pregabalin and gabapentin are controlled under the Misuse of Drugs Act 1971 as class C substances and scheduled under the Misuse of Drugs Regulations 2001 as schedule 3.

Generalised anxiety disorder and panic disorder in adults: management CG113 (update)

This guideline covers the care and treatment of people aged 18 and over with generalised anxiety disorder (chronic anxiety) or panic disorder (with or without agoraphobia or panic attacks). It aims to help people achieve complete relief of symptoms (remission), which is associated with better functioning and a lower likelihood of relapse.

In July 2019, NICE updated footnotes and tables in this guideline to reflect a change in the law relating to pregabalin and gabapentin. As of 1 April 2019, because of a risk of abuse and dependence pregabalin and gabapentin are controlled under the Misuse of Drugs Act 1971 as class C substances and scheduled under the Misuse of Drugs Regulations 2001 as schedule 3.

Long-acting reversible contraception CG30 (update)

This guideline covers long-acting reversible contraception. It aims to increase the use of long-action reversible contraception by improving the information given to women about their contraceptive choices.

In July 2019, NICE updated the guideline. They note that in March 2019 they revised their decision on how to implement the recommendations of their October 2017 review. Although no new evidence was identified, they noted significant changes in how they commission and provide contraceptive services in England. They have removed the recommendations in this guideline that no longer fit with current practice. There are also many new LARC products now available. See the Long-acting reversible contraception: implementation resource summary for links to the latest information.

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)

Ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids IPG657

Recommendations

Current evidence on the safety of ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids shows there are well-recognised complications including skin burns. The evidence on efficacy is limited in quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these and provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having ultrasound-guided high intensity transcutaneous focused ultrasound for symptomatic uterine fibroids. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

During the consent process clinicians should tell patients that their symptoms may not be fully relieved and may return, and that further procedures may be needed. They should also tell patients about the risk of skin burns. Patients considering pregnancy should be told that the effects of the procedure on fertility and future pregnancy are uncertain.

Patient selection should be done by a multidisciplinary team including a gynaecologist and an appropriate imaging specialist.

The procedure should only be done in specialised centres by clinicians with specific training in this technique.

NICE encourages further research and prospective data collection. Studies comparing ultrasound-guided high-intensity focused ultrasound with other therapies such as uterine artery embolisation and MRI-guided high-intensity transcutaneous focused ultrasound would be useful. Studies should report patient selection (including size, location and number of fibroids), patient-reported outcome measures, long-term outcomes and subsequent pregnancy rates.

The condition

Uterine fibroids are benign tumours of the uterine wall. They can be asymptomatic or cause symptoms including menorrhagia, intermenstrual bleeding, pelvic pressure or pain, and urinary incontinence. They can be associated with fertility problems and miscarriage.

Treatment depends on whether the fibroids cause symptoms, and if the person would like to have children in the future. For symptomatic fibroids, treatment options include medications, interventional radiology and surgery. Interventional radiology treatments include uterine artery embolisation and MRI-guided focused ultrasound. Surgery includes hysterectomy, myomectomy, endometrial ablation techniques and myolysis.

The procedure

Ultrasound-guided high-intensity transcutaneous focused ultrasound (HIFU) for symptomatic uterine fibroids is done with the patient lying face down, with the abdominal wall immersed in degassed water. Intravenous sedation may be used to help minimise body movement. A urinary catheter is inserted to keep the bladder empty during the procedure. Continuous sonographic imaging is used to identify the fibroid(s) with a real-time diagnostic ultrasound scanner integrated into the centre of a therapeutic ultrasound transducer. After the target fibroid has been confirmed, it is ablated by high-intensity ultrasound energy. The patient may have to lie still for up to 3 hours.

Ultrasound-guided HIFU uses grayscale or echogenicity changes to determine the adequacy of ablation. After treatment, imaging (by ultrasound or MRI scan) is used to evaluate the volume of the fibroid ablated.

Transurethral laser ablation for recurrent non-muscle-invasive bladder cancer IPG656

Recommendations

The evidence on the safety of transurethral laser ablation for recurrent non-muscle-invasive bladder cancer shows that there are no major safety concerns. However, current evidence on its efficacy is limited in quality and quantity. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do transurethral laser ablation for recurrent non-muscle-invasive bladder cancer should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having transurethral laser ablation for recurrent non-muscle-invasive bladder cancer. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Patient selection should be done by a specialist bladder cancer multidisciplinary team.

NICE encourages further research and prospective data collection into transurethral laser ablation for recurrent non-muscle-invasive bladder cancer. Studies should investigate patient selection, types of laser used, tumour recurrence and long-term follow up.

The condition

The most common form of bladder cancer is transitional cell carcinoma. Non-muscle-invasive transitional cell carcinoma is classified as stage Ta when it is confined to the uroepithelium and stage T1 when it has spread into the connective tissue layer between the urothelium and the muscle wall. Non-muscle-invasive transitional cell carcinomas usually appear as small growths from the bladder lining. They can be graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Carcinoma in situ consists of aggressive cancer cells that spread within the surface lining of the bladder and appear flat. It is more likely to recur after treatment.

NICE's guideline on bladder cancer describes its diagnosis and management. Surgical interventions for non-muscle-invasive transitional cell carcinoma include transurethral resection, in which malignant tissue is removed with an electrocautery device during cystoscopy. Bacillus Calmette-Guérin (BCG) vaccine or chemotherapy drugs may be put directly into the bladder, either as treatments in themselves or as adjuvant therapy after transurethral resection. Cystectomy may also be necessary in some patients.

The procedure

This procedure is most often used for very small, recurrent bladder tumours. It is usually done as day surgery using local anaesthesia. A flexible cystoscope is passed through the urethra into the bladder. The tumours are then ablated using a laser fibre contained in the cystoscope. If there is a lot of bleeding after the procedure, a urinary catheter may be inserted to allow bladder irrigation. Adjuvant intravesical chemotherapy may be offered after the procedure.

The aim is to destroy the tumour with less morbidity than is seen with conventional treatments. The suggested benefits over cystodiathermy include less bleeding and reduced pain.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

Therapeutic monitoring of TNF-alpha inhibitors in rheumatoid arthritis (DG36)

Recommendations

Enzyme-linked immunosorbent assay (ELISA) tests for therapeutic monitoring of tumour necrosis factor (TNF)-alpha inhibitors (drug serum levels and antidrug antibodies) show promise but there is currently **insufficient evidence to recommend** their routine adoption in rheumatoid arthritis. The ELISA tests covered by this guidance are Promonitor, IDKmonitor, LISA-TRACKER, RIDASCREEN, MabTrack, and tests used by Sanquin Diagnostic Services.

Laboratories currently using ELISA tests for therapeutic monitoring of TNF-alpha inhibitors in rheumatoid arthritis should do so as part of research and further data collection.

Further research is recommended on the clinical effectiveness of using ELISA tests for therapeutic monitoring of TNF-alpha inhibitors in rheumatoid arthritis.

The technologies

The assessment compared 6 intervention tests (enzyme-linked immunosorbent assay [ELISA] tests: Promonitor, IDKmonitor, LISA-TRACKER, RIDASCREEN, MabTrack, and in-house tests used by Sanquin Diagnostic Services) with 1 comparator (standard care). These ELISA tests are intended to be used for measuring the levels of tumour necrosis factor (TNF)-alpha inhibitors and antibodies to TNF-alpha inhibitors in the blood of people having TNF-alpha inhibitor treatment for rheumatoid arthritis.

Single or duplicate ELISA tests may be done. Testing can be concurrent or reflex, and can include testing of free or total antibody levels:

- Concurrent testing: tests for TNF-alpha inhibitor drug levels and antibodies to TNF-alpha inhibitors are done at the same time.
- Reflex testing: the test for TNF-alpha inhibitor drug levels is done first. If the drug is undetectable, testing for antibodies to the TNF-alpha inhibitor would be done without a further request from the treating clinician. If TNF-alpha inhibitor is present in the sample, then testing for antibodies would not be done.
- Testing of free antibody levels: the test measures the levels of antidrug antibodies that are unbound to drug.
- Testing of total antidrug antibody levels: the test measures levels of both unbound (free) antidrug antibodies and those bound to TNF-alpha inhibitor.

NICE Quality Standards

Learning disability: care and support of people growing older QS187

This quality standard covers identifying, assessing and regularly reviewing the care and support needs of people with a learning disability as they grow older. People with a learning disability have many of the same age-related health and social care needs as other people, but this quality standard focuses on the specific challenges associated with their learning disability. It describes high-quality care in priority areas for improvement.

Lyme disease QS186

This quality standard covers diagnosing and managing Lyme disease in people of all ages. It also includes raising public awareness about prevention. It describes high-quality care in priority areas for improvement.

Hearing loss in adults QS185

This quality standard covers assessing and managing hearing loss in adults (aged 18 and over). It includes people presenting with hearing loss for the first time in adulthood

whether it started in adulthood or earlier. It describes high-quality care in priority areas for improvement.

Learning disability: behaviour that challenges QS101 (update)

This quality standard covers care and support and services for children, young people and adults with a learning disability (or a learning disability and autism) and behaviour that challenges, and their families and carers. It describes high quality care in priority areas for improvement.

In July 2019, NICE updated this quality standard. Four new statements were added to the 2015 version, one statement from 2015 was updated and one was amended.

Statement 2 (statement 1 in the 2015 version) has been amended to align with a statement on annual health checks in NICE's quality standard on learning disability: care and support of people growing older.

Statement 4 (statement 3 in the 2015 version) has been updated.

A definition of behaviour that challenges has been added to the 2015 statements, in line with NICE's guideline on learning disabilities and behaviour that challenges: service design and delivery.

Hypertension in pregnancy QS35 (update)

This quality standard covers diagnosing and managing hypertension (high blood pressure) and pre-eclampsia during pregnancy, labour and birth. It also covers advice for women with hypertension who may become pregnant and postnatal care for women who have had hypertension or pre-eclampsia. It describes high-quality care in priority areas for improvement.

In July 2019, NICE updated this quality standard to reflect changes to the updated NICE guideline on hypertension in pregnancy. Statements 2, 3, 5 and 6 were amended and links and references to source guidance have been updated.

Patient experience in adult NHS services QS15 (update)

This quality standard covers improving the quality of the patient experience for people who use adult NHS services. It describes high-quality care in priority areas for improvement.

In July 2019, this quality standard was updated to ensure that it remains current. It will be reviewed again when the NICE guideline on shared decision making is published in 2021. Statements from the 2012 version have been retained with amendments or merged with statements covering similar topics.

Service user experience in adult mental health services QS14 (update)

This quality standard covers improving the experience of people using adult NHS mental health services. It describes high-quality care in priority areas for improvement.

In July 2019, this quality standard was updated to ensure that it remains current. It will be reviewed again when the NICE guideline on shared decision making is published in 2021. Statements from the 2011 version have been retained or merged with statements covering similar topics.

Current NICE consultations

Title / link	End date of consultation
Pentosan polysulfate sodium for treating bladder pain syndrome [ID1364]	01/08/2019
gammaCore for cluster headache	02/08/2019
Vaccine uptake in the general population	05/08/2019
Lower urinary tract symptoms in men: assessment and management	07/08/2019
Rapid tests for Group A Streptococcal infections in people with a sore throat	07/08/2019
Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke	08/08/2019
Diverticular disease: diagnosis and management	09/08/2019
Indoor air quality at home	09/08/2019
Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema (part review of TA301) [ID1421]	21/08/2019
Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues	22/08/2019
Pressurised intraperitoneal aerosol chemotherapy for peritoneal carcinomatosis	22/08/2019
Selective internal radiation therapy for non-resectable colorectal metastases in the liver	22/08/2019
Lung cancer (update)	23/08/2019