NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: January 2022

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NICE Rapid COVID-19 Guidelines

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

This guideline covers the management of COVID-19 for children, young people and adults in all care settings. It brings together NICE's existing recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily.

January 2022: NICE added recommendations on neutralising monoclonal antibodies for people with COVID-19 who are not in hospital.

Technology Appraisals (TAs)

Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection TA761

Recommendations

Osimertinib is **recommended** for use within the **Cancer Drugs Fund** as adjuvant treatment after complete tumour resection in adults with stage 1b to 3a non-small-cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. It is recommended only if:

- osimertinib is stopped at 3 years, or earlier if there is disease recurrence or unacceptable toxicity and
- the company provides osimertinib according to the managed access agreement.

This recommendation is not intended to affect treatment with osimertinib 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

Lung cancer is the third most common cancer and the most common cause of cancer death in the UK. Lung cancer falls into two main histological categories: around 85-90% are NSCLC and the remainder are small-cell lung cancers. NSCLC can be further classified into squamous cell carcinoma and non-squamous cell carcinoma.

An estimated 10% to 15% of people with NSCLC have mutations to the protein EGFR. EGFR inhibition may induce cell death and inhibit tumour growth in EGFR-mutated tumour cells. There are currently no EGFR-targeted therapies for resectable NSCLC available in the NHS in England.

Osimertinib is a selective, small molecule tyrosine kinase inhibitor that targets the sensitising (exon 19 deletions and exon 21 L858R point mutations) and T790M mutant forms of the EGFR-TK, while having minimal activity against wild-type EGFR. Osimertinib is administered orally.

Financial Factors

This technology is commissioned by NHS England.

There are currently no targeted adjuvant treatments (including those specific to EGFR mutations) available in England for NSCLC after complete tumour resection. Current clinical trial evidence shows that compared with active monitoring, treatment with osimertinib reduces the risk of the disease coming back. It may also lower the risk of death. However, this evidence is uncertain because information from the trial was released early and the data is still immature.

The cost-effectiveness estimates for osimertinib are therefore uncertain. Osimertinib has the potential to be cost effective, but more evidence is needed to address these uncertainties. In the meantime, the resource impact of osimertinib will be covered by the Cancer Drugs Fund budget. Following the final results of the ADAURA trial being available, NICE will then decide whether or not to recommend it for use on the NHS and update the guidance. It will be available through the Cancer Drugs Fund until then.

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

Selpercatinib for previously treated RET fusion-positive advanced non-small-cell lung cancer TA760

Recommendations

Selpercatinib is **recommended** for use within the **Cancer Drugs Fund** as an option for treating RET fusion-positive advanced non-small-cell lung cancer (NSCLC) in adults who need systemic therapy after immunotherapy, platinum-based chemotherapy or both. It is recommended only if the conditions in the managed access agreement are followed.

This recommendation is not intended to affect treatment with selpercatinib 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

Lung cancer falls into two main histological categories: around 85-90% are NSCLC and the remainder are small-cell lung cancers. NSCLC can be further classified into squamous cell carcinoma and non-squamous cell carcinoma.

Most lung cancers are diagnosed at an advanced stage when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage III) or to other parts of the body (metastatic disease; stage IV).

At advanced stage (III and IV) NSCLC treatment aims to control the cancer for as long as possible and help with symptoms. Treatment generally includes chemotherapy, targeted drugs, radiotherapy and symptom control treatment. Treatment choices are influenced by the presence of biological markers (such as mutations in epidermal growth factor receptor-tyrosine kinase [EGFR-TK], anaplastic-lymphoma-kinase [ALK] or PD-L1 status), histology (squamous or non-squamous) and previous treatment experience.

Selpercatinib is a small molecule inhibitor of the rearranged during transfection (RET) receptor tyrosine kinase. Chromosomal rearrangements involving fusions of RET with various partners can result in the growth of cancer cells. Point mutations in RET can also result in irregular RET proteins that can promote the growth of cancer cells. Administration of selpercatinib can target RET cancers and inhibit growth of tumour cells. It is administered orally as a capsule.

Financial Factors

This technology is commissioned by NHS England.

NICE has recommended selpercatinib for use within the Cancer Drugs Fund and selpercatinib will be available to the NHS in line with the managed access agreement with NHS England. As part of this, NHS England and the company have a commercial access agreement that makes selpercatinib available to the NHS at a reduced cost. The financial terms of the agreement are commercial in confidence.

The resource impact of selpercatinib will be covered by the Cancer Drugs Fund budget. More evidence on selpercatinib is being collected to address uncertainties. After this, NICE will decide whether or not to recommend it for use on the NHS and update the guidance.

Fostamatinib for treating refractory chronic immune thrombocytopenia TA759

Recommendations

Fostamatinib is **not recommended**, within its marketing authorisation, for treating refractory chronic immune thrombocytopenia in adults.

This recommendation is not intended to affect treatment with fostamatinib 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

Immune thrombocytopenia (ITP, also called immune thrombocytopenic purpura) is an autoimmune condition characterised by increased platelet destruction and, in some cases, inadequate platelet production. The condition can result in low platelet counts and bleeding. ITP is defined as persistent 3 to 12 months after diagnosis, and chronic when it lasts longer than 12 months.

The UK incidence of adult ITP is estimated to be between 1.6 to 3.9 per 100,000 adults per year. People with ITP may be asymptomatic or have symptoms including fatigue, anxiety, spontaneous bruising, mucosal bleeding and, in severe cases, gastrointestinal or intracranial bleeding. Diagnosis is based on excluding other possible causes of the symptoms

Treatment is typically initiated with 'rescue therapies', such as corticosteroids and intravenous immunoglobulins and then with 'active treatments' including rituximab, other immunosuppressive agents and thrombopoietin receptor agonists (TPO-RAs) (romiplostim and eltrombopag). Splenectomy is an option, but its use is rare in the UK.

NICE technology appraisals TA221 and TA293 recommend TPO-Ras (romiplostim and eltrombopag) for adults with chronic ITP whose condition is refractory to standard active treatments and rescue therapies or those who are at high risk of bleeding and require frequent courses of rescue therapies.

Fostamatinib is a spleen tyrosine kinase (SYK) inhibitor that blocks the IgG antibody receptor signalling in white blood cells to stop the immune destruction of platelets. It is administered orally.

Financial Factors

This technology is commissioned by NHS England.

The cost-effectiveness estimates for fostamatinib compared with rituximab are higher than what NICE normally considers cost effective. Therefore, fostamatinib is not recommended. The company has a commercial arrangement, which would have applied if the technology had been recommended.

Solriamfetol for treating excessive daytime sleepiness caused by narcolepsy TA758

Recommendations

Solriamfetol is **recommended** as an option for treating excessive daytime sleepiness in adults with narcolepsy with or without cataplexy. This is only if modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable.

This recommendation is not intended to affect treatment with solriamfetol 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

Excessive waketime sleepiness (also known as hypersomnia) means people struggle to stay awake and alert during the day (or equivalent waking hours), leading to an irrepressible need to sleep or unintended lapses into drowsiness or sleep. People with excessive sleepiness are likely to fall asleep during the day (often while eating or talking), regularly nap during the day but wake up feeling unrefreshed, and still sleep for long hours at night. One cause of excessive sleepiness is narcolepsy.

Narcolepsy is a rare, disabling long-term brain disorder that causes a person to fall asleep at inappropriate times. In people with narcolepsy, the brain is unable to regulate sleep and waking patterns normally, which can result in excessive daytime sleepiness, sleep paralysis, excessive dreaming, disturbed nocturnal sleep, sleep attacks (falling asleep suddenly and without warning) and cataplexy (temporary loss of muscle control resulting in weakness and possible collapse).

Medicines used to treat the symptoms of narcolepsy include stimulants such as modafinil, dexamfetamine or methylphenidate, and sodium oxybate. Pitolisant is another treatment option for people with narcolepsy. Solriamfetol is a phenylalanine-derived, second-generation wake-promoting agent. Solriamfetol prevents the reuptake of dopamine and noradrenaline, and indirectly enhances dopaminergic and noradrenergic neurotransmission. It is administered orally.

Financial Factors

This technology is commissioned by CCGs.

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.

The cost-effectiveness estimates for solriamfetol compared with dexamfetamine or methylphenidate are highly uncertain, because they were based only on assumptions. They are also likely to be higher than what NICE normally considers acceptable. However, solriamfetol is cost effective compared with pitolisant and sodium oxybate.

Cabotegravir with rilpivirine for treating HIV-1 TA757

Recommendations

Cabotegravir with rilpivirine is **recommended**, within its marketing authorisation, as an option for treating HIV-1 infection in adults:

- with virological suppression (HIV-1 RNA fewer than 50 copies/ml) on a stable antiretroviral regimen and
- without any evidence of viral resistance to, and no previous virological failure with, any non-nucleoside reverse transcriptase inhibitors or integrase inhibitors.

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

The Technology

HIV is a virus that causes AIDS. HIV attacks the immune system destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital for fighting infections. The destruction of these cells leaves people living with HIV with a suppressed immune system and vulnerable to infections and some other diseases.

There are two main types of HIV. Most cases within the UK are from the HIV-1 type and it is considered more transmissible than HIV-2.

Current clinical management involves life-long antiretroviral treatment (ART), which stops the virus replicating in the body and destroying CD4+ T cells. There is no cure for HIV, but ART enables most people to live a long and healthy life with an undetectable viral load, which eliminates the risk of passing on the infection. ARTs are usually used as triple- or dual-combination to avoid the disease adapting and becoming resistant. Choice of ART combinations is complex and individualised, often including consideration of; contraindications, drug-drug interactions, tolerability, treatment history, drug resistance profile, adherence and future salvage regimens.

Cabotegravir is a HIV-1 integrase strand transfer inhibitor (INSTI) which prevents viral DNA integration and inhibits HIV replication. Rilpivirine is a diarylpyrimidine non-nucleoside reverse-transcriptase inhibitor (NNRTI) of HIV-1. Cabotegravir and rilpivirine are administered as an oral lead-in therapy for 4 weeks followed by separate intramuscular injections once every month until the fifth month and then once every 2 months.

Financial Factors

This technology is commissioned by NHS England.

Cabotegravir with rilpivirine is the first long-acting antiretroviral injection available for HIV-1. Clinical trial results show that cabotegravir with rilpivirine is as effective as oral antiretrovirals at keeping the viral load lower than 50 copies/ml of blood. The most likely cost-effectiveness estimate is likely to be within what NICE normally considers an acceptable use of NHS resources.

NICE estimate that in Devon, the eligible population for treatment is 405. Of these 405 people, 142 people will receive cabotegravir with rilpivirine for treating HIV-1 after 5 years.

Sodium zirconium cyclosilicate for treating hyperkalaemia TA599 (UPDATE)

January 2022: NICE made changes to recommendations 1.1 and 1.2 because sodium zirconium cyclosilicate is now available in both primary and secondary care.

Recommendations

Sodium zirconium cyclosilicate is **recommended** as an option for treating hyperkalaemia in adults only if used:

- in emergency care for acute life-threatening hyperkalaemia alongside standard care or
- for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they:
    - have a confirmed serum potassium level of at least 6.0 mmol/litre and
    - because of hyperkalaemia, are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor and
    - are not on dialysis. **[amended 2022]**

Stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable. **[amended 2022]**

These recommendations are not intended to affect treatment with sodium zirconium cyclosilicate 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

Hyperkalaemia is an abnormally high level of potassium in the blood. Many people with hyperkalaemia may not have any symptoms, whilst other people have muscle weakness, muscle stiffness or fatigue. Severe hyperkalaemia can cause irregular heartbeat (arrhythmia) leading to cardiac arrest and death.

Hyperkalaemia usually occurs in people with impaired kidney function which may be caused by acute kidney injury (AKI) or chronic kidney disease (CKD). CKD is prevalent among people with diabetes or chronic heart failure. Hyperkalaemia is common among people with end-stage renal disease and in older people.

Treatment options for mild and moderate hyperkalaemia include a low-potassium diet and stopping medicines that cause hyperkalaemia. Further options include sodium polystyrene sulphonate or calcium polystyrene sulphonate, which reduce the levels of potassium in the body.

CG108 recommends closely monitoring potassium, creatinine levels, and estimated glomerular filtration rate (eGFR) in people with heart failure. It also recommends specialist advice if the patient develops hyperkalaemia or renal function deteriorates. CG169 recommends that people with AKI who have hyperkalaemia that is not responding to medical management should be

referred for renal replacement therapy immediately. To prevent hyperkalaemia, CG182 recommends the cautious use of renin–angiotensin system antagonists (ACE inhibitors and ARBs) in people with CKD.

Sodium zirconium cyclosilicate is a potassium binder. It contains an insoluble, non-absorbed zirconium silicate with a structure designed to trap potassium ions. This lowers the amount of potassium available for absorption into the blood stream and increases the amount that is excreted in faeces. It is administered orally as a suspension in water.

Financial Factors

This technology is commissioned by CCGs.

NICE has not produced an updated resource impact report in respect of this updated guidance.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Rehabilitation after traumatic injury NG211

This guideline covers complex rehabilitation needs after traumatic injury, including assessment and goal setting, rehabilitation plans and programmes, physical, psychological and cognitive rehabilitation, rehabilitation for specific injuries, coordination of rehabilitation in hospital, at discharge and in the community, and commissioning and organising rehabilitation services.

Note: Traumatic injury is any major or minor injury that requires admission to hospital at the time of injury, including musculoskeletal, visceral and nerve injuries, soft tissue damage, spinal injury, limb reconstruction and limb loss.

Glaucoma: diagnosis and management NG81 (UPDATE)

This guideline covers diagnosing and managing glaucoma in people aged 18 and over. It includes recommendations on testing and referral (case-finding) for chronic open-angle glaucoma and ocular hypertension and on effective diagnosis, treatment and reassessment to stop these conditions progressing.

January 2022: NICE have reviewed the evidence and made new recommendations on treatment and organisation of care for people with ocular hypertension and chronic open angle glaucoma (COAG).

NICE have made the following changes to recommendations without an evidence review:

- **Wording was added throughout to clarify that surgery refers to glaucoma surgery and to reflect the new recommendations on 360° selective laser trabeculoplasty.**
- **Wording was added to recommendation 1.4.11 to clarify that people with suspected COAG should be offered treatment if they are at risk of visual impairment within their lifetime.**

NICE have also made minor changes have been made to the wording of other recommendations to bring the language and style up to date, without changing the meaning.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

None published this month.

Medical Technologies Guidance (MTGs)

Sedaconda ACD-S for sedation with volatile anaesthetics in intensive care MTG65

Recommendations

Sedaconda anaesthetic conserving device-S (Sedaconda ACD-S) is **recommended** as a cost-saving option for delivering inhaled sedation in an intensive care setting when the volatile anaesthetics isoflurane or sevoflurane are being considered.

Further research is recommended to identify any health conditions or groups of patients that would benefit more from inhaled sedation with Sedaconda ACD-S than from standard care.

The Technology

Adults who need sedation in intensive care have sedation with intravenous sedatives and analgesics, primarily propofol or midazolam with alfentanil, fentanyl or morphine. Children in intensive care usually have sedation with intravenous midazolam and morphine or fentanyl. Most mechanically ventilated people receive sedatives to keep them comfortable and to facilitate

treatment when in intensive care. A systematic review reported that there was a substantial incidence of sub-optimal sedation in people in intensive care unit (ICU) with a greater tendency toward oversedation.

Volatile anaesthetics are not licensed for sedation in ICUs but are licensed for inducting and maintaining anaesthesia in operating theatres. However, clinical experts reported that sedation is a continuum to anaesthesia. The off-label use of volatile anaesthetics in sedation is widely accepted and is not considered to be harmful.

The Sedaconda anaesthetic conserving device-S (Sedaconda ACD-S; Sedana Medical) is a volatile anaesthetic delivery system to give isoflurane or sevoflurane to people who are mechanically ventilated, usually in an intensive care setting. The technology conserves inhaled anaesthetics within the delivery system and any waste gas is captured by a passive or active gas scavenging system. It is a single use device and can be used with almost any kind of ventilator, except high-frequency ventilators.

Delivery devices, such as Sedaconda ACD-S, as well as scavenging systems, make using isoflurane and sevoflurane in intensive care safer for staff. Isoflurane has shown safe, effective sedation for up to 96 hours in small studies, with faster awakening than midazolam. Isoflurane has shown improved awakening to propofol. Sedaconda ACD-S is for use by healthcare professionals, trained to use inhalational anaesthetic drugs and recognise and manage any adverse effects, in an intensive care setting.

Volatile anaesthetics are halogenated chlorofluorocarbons or fluorinated hydrocarbons and are therefore potentially damaging to the Earth's ozone layer. They also contribute to global warming if not properly captured and disposed of. It is anticipated that use of Sedaconda ACD-S will help improve safe capture of volatile anaesthetics.

Financial Factors

This technology is commissioned by CCGs.

NICE do not expect this guidance to have a significant impact on resources. This is because Sedaconda ACD-S is a further treatment option and the population size is small and any cost is likely to be offset by savings and benefits. There may be efficiency savings as a result of a reduced length of stay in intensive care units when using inhaled sedation with Sedaconda ACD-S.

Cost modelling shows that, over 30 days, Sedaconda ACD-S is cost saving compared with intravenous propofol sedation by £3,833.76 per adult. In children, Sedaconda ACD-S is also cost saving compared with intravenous midazolam sedation, by £2,837.41 per child. These savings are from reduced time on mechanical ventilation, which may shorten the length of time in intensive care for the patient.

KardiaMobile for detecting atrial fibrillation MTG64

Recommendations

KardiaMobile is **recommended** as an option for detecting atrial fibrillation (AF) for people with suspected paroxysmal AF, who present with symptoms such as palpitations and are referred for ambulatory electrocardiogram (ECG) monitoring by a clinician.

The Technology

Cardiac arrythmias are experienced by more than 2 million people a year in the UK. The term covers a number of conditions in which the heartbeat is irregular, too fast or too slow. Common types of arrhythmia are atrial fibrillation, supraventricular tachycardia, bradycardia, heart block and ventricular fibrillation.

Atrial fibrillation is the most common sustained cardiac arrhythmia.. People with atrial fibrillation may present with breathlessness, heart palpitations and dizziness or temporary loss of consciousness. The frequency and severity of symptoms varies from person to person and symptoms of a person can also fluctuate widely over time. These changes can be monitored via ECG. Atrial fibrillation can also be asymptomatic.

Atrial fibrillation is associated with an increased risk of thrombo-embolic complications including stroke as well as the need for hospitalisation and death. Untreated atrial fibrillation is associated with a 5-fold increased risk of stroke and a 3-fold increased risk of heart failure

An ECG is commonly used to diagnose an arrhythmia. An ECG records heart rhythm over a short period of time. If the ECG does not reveal an abnormality at that moment in time, the person's heart rhythm may need monitoring for a longer period of time. This may involve wearing a small portable ECG recording device for 24 hours or longer. This is often known as a Holter monitor or ambulatory ECG monitoring. Alternatively, cardiac event recorders may be used in patients with occasional symptoms. These are either a portable device to record the heart rhythm at the time of symptoms using a device that is worn strapped to a person's body and may require electrodes to be stuck to the skin, or a device that is implanted under the skin.

NICE's guidelines CG180 and CG109 provide recommendations on current methods of arrhythmia detection.

KardiaMobile is a portable ECG recorder for detecting AF. KardiaMobile works with a compatible smart mobile device to run the Kardia app. While taking a reading, the ECG recording is sent wirelessly to the mobile device where it can be viewed in the app. The app shows the ECG trace and the classification as either normal, possible AF, tachycardia, bradycardia or unclassified. Traces may also be classified as unreadable if the ECG data cannot be interpreted because of possible interference. KardiaMobile is easy to use. It is compact and can be used anywhere, at any time of the day. ECG recordings can be made available to healthcare professionals as soon as they are taken rather than at the end of a specified monitoring period.

Financial Factors

This technology is commissioned by CCGs.

Cost modelling shows that KardiaMobile is cost saving compared with Holter monitoring over 2 years in people presenting with symptoms such as palpitations. KardiaMobile is cost saving because of a reduction in repeat diagnostic assessments and the associated cardiology appointments.

The financial impact for providers and commissioners resulting from any capacity benefit will be determined by the contract in place, but the capacity benefit may assist in reducing waiting lists.

NICE estimate that in Devon, 1,007 people will be eligible to use KardiaMobile as an option for AF detection. Of these 1,007 people, 503 will use KardiaMobile and 503 people will use Holter ECG to detect AF. NICE estimate that the introduction of KardiaMobile will have an overall cost saving of approximately £2,600 in Devon. This takes into account, cardiologist appointment and device costs, treatment costs and adverse events costs. Further, NICE estimate that use of KardiaMobile will reduce cardiology technologist appointment slots by 294 appointments.

Diagnostic Guidance (DGs)

None published this month.

NICE Quality Standards

None published this month.

Current NICE Consultations

Title / link	End date of consultation
Gout: diagnosis and management	02/02/2022
Postnatal care (QS update)	04/02/2022
Cardiovascular disease: risk assessment and reduction, including lipid modification	08/02/2022
Daratumumab in combination for untreated systemic amyloid light-chain amyloidosis [ID3748]	10/02/2022
Ibrutinib for treating Waldenstrom's macroglobulinaemia (CDF Review of TA491) [ID3778]	11/02/2022
Diabetic retinopathy	15/02/2022
Roxadustat for treating anaemia in people with chronic kidney disease [ID1483]	16/02/2022
Social, emotional and mental wellbeing in primary and secondary education	25/02/2022

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