NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: February 2020

Hyperlinks to the relevant NICE web page are included below.

Technology Appraisals (TAs)

Peginterferon beta-1a for treating relapsing–remitting multiple sclerosis TA624

Recommendations

Peginterferon beta-1a is **recommended**, within its marketing authorisation, as an option for treating relapsing–remitting multiple sclerosis in adults.

The technology

Peginterferon beta-1a has been licensed since 2014 in adult patients for the treatment of relapsing remitting multiple sclerosis.

Peginterferon beta-1a is given by subcutaneous injection every 2 weeks at a dose of 125 micrograms.

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 has been commissioned by NHS England since 2015 for people with relapsing–remitting multiple sclerosis as a first-line treatment or as an alternative when other first-line treatments are not tolerated. Therefore, it is not thought that practice will change substantially as a result of this guidance.

Peginterferon beta-1a involves less frequent injections than other beta interferons, so improves choice for people with relapsing–remitting multiple sclerosis.

Patiromer for treating hyperkalaemia TA623

Recommendations

Patiromer 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 stages 3b to 5 chronic kidney disease or heart failure, if they:

- have a confirmed serum potassium level of at least 6.0 mmol/litre and
- are not taking, or are taking a reduced dosage of, a renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and
- are not on dialysis.

Stop patiromer if RAAS inhibitors are no longer suitable.

This recommendation is not intended to affect treatment with patiromer 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

Patiromer has a marketing authorisation in the UK for the treatment of hyperkalaemia in adults.

Patiromer is administered orally. The recommended starting dose is 8.4 g once a day and the maximum dose is 25.2 g. The dose can be increased or decreased after a minimum interval of 1 week based on serum potassium levels. The dose should be reduced or stopped if serum potassium is below the desired range. Patiromer should be taken with or without food and separated by 3 hours from other oral medication. The onset of action for patiromer is 4 to 7 hours and patiromer should not replace emergency treatment for life-threatening hyperkalaemia.

Financial factors

This technology is commissioned by CCGs.

NICE estimates that 13,600 people in England with acute life-threatening hyperkalaemia or with persistent hyperkalaemia are eligible for treatment with patiromer. This equates to 295 people in the Devon population.

NICE estimates that 88 people will have patiromer in Devon (53 in emergency care and 35 with persistent hyperkalaemia when treatment is started in hospital from 2023/24 onwards once uptake has reached 30% (18% emergency care and 12% for people with persistent hyperkalaemia when treatment is started in hospital). Ongoing treatment for people with persistent hyperkalaemia could be in either secondary care or in a primary care setting.

Dapagliflozin with insulin for treating type 1 diabetes TA597 (update)

Recommendations

In February 2020, NICE changed the measures of assessing haemoglobin A1c (HbA1c) in the recommendations to reflect those commonly used in the NHS. Other minor changes have been made to the recommendations to align them with dapagliflozin's expected clinical use.

Dapagliflozin with insulin is **recommended** as an option for treating type 1 diabetes in adults with a body mass index (BMI) of at least 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, only if:

- they are on insulin doses of 0.5 units/kg of body weight/day or more and
- they have completed a structured education programme that is evidence based, quality assured, delivered by trained educators and includes information about diabetic ketoacidosis, such as:
  - how to recognise its risk factors, signs and symptoms
  - how and when to monitor blood ketone levels
  - what actions to take for elevated blood ketones and
- treatment is started and supervised by a consultant physician specialising in endocrinology and diabetes treatment, and haemoglobin A1c (HbA1c) levels are assessed after 6 months and regularly after this.

Stop dapagliflozin if there has not been a sustained improvement in glycaemic control (that is, a fall in HbA1c level of about 0.3% or 3 mmol/mol).

These recommendations are not intended to affect treatment with dapagliflozin 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

Dapagliflozin is indicated for the treatment of type 1 diabetes mellitus as an adjunct to insulin in patients with a BMI ≥27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy. It is administered orally at a dosage of 5 mg once daily.

Dapagliflozin should not be started in people with type 1 diabetes with a low insulin need. It should not be started in people with a glomerular filtration rate [GFR] of less than 60 ml/min and should be stopped at a GFR persistently below 45 ml/min. During treatment with dapagliflozin, insulin therapy should be continuously optimised to prevent ketosis and diabetic ketoacidosis, and the insulin dose should only be reduced to avoid hypoglycaemia. This treatment should only be started and supervised by specialist doctors. Patients should be able and committed to control ketone levels in their body. They should be educated about risk factors for diabetic ketoacidosis and how to recognise its signs and symptoms.

Financial factors

This technology is commissioned by CCGs.

NICE estimates that around 90,100 people with type 1 diabetes in England with a BMI of at least 27 kg/m^2 are eligible for treatment with dapagliflozin. Around 40% may discontinue treatment at 6 months in line with the guidance recommendations. After discontinuation, around 5,400 people in England will have dapagliflozin by year 2023-24 once uptake has reached 10%.

Sotagliflozin with insulin for treating type 1 diabetes TA622

Recommendations

Sotagliflozin with insulin is **recommended** as an option for treating type 1 diabetes in adults with a body mass index (BMI) of at least 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, only if:

- sotagliflozin is given as one 200 mg tablet daily
- they are on insulin doses of 0.5 units/kg of body weight/day or more and
- they have completed a structured education programme that is evidence based, quality assured, delivered by trained educators and includes information about diabetic ketoacidosis, such as:
  - how to recognise its risk factors, signs and symptoms
  - how and when to monitor blood ketone levels
  - what actions to take for elevated blood ketones and
- treatment is started and supervised by a consultant physician specialising in endocrinology and diabetes treatment, and haemoglobin A1c (HbA1c) levels are assessed after 6 months and regularly after this.

Stop sotagliflozin if there has not been a sustained improvement in glycaemic control (that is, a fall in HbA1c level of about 0.3% or 3 mmol/mol).

These recommendations are not intended to affect treatment with sotagliflozin 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

Sotagliflozin is indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus with a body mass index (BMI) 27 kg/m^2 or more, who have failed to achieve adequate glycaemic control despite optimal insulin therapy.

Sotagliflozin should not be started in people with type 1 diabetes with a low insulin need. It should not be started in people with a glomerular filtration rate of less than 60 ml/min and should be stopped at a glomerular filtration rate persistently below 45 ml/min. Sotagliflozin should be initiated and supervised by a physician experienced in the management of type 1 diabetes mellitus. During treatment with sotagliflozin, insulin therapy should be continuously optimised to prevent ketosis and diabetic ketoacidosis, and the insulin dose should only be reduced to avoid hypoglycaemia.

It is administered orally as a 200 mg tablet once daily before the first meal of the day. After at least 3 months, if additional glycaemic control is needed, in patients tolerating sotagliflozin 200 mg, the dose may be increased to 400 mg once daily.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources; the technology is a further treatment option and is available at a similar price to the current treatment options.

Sotagliflozin is not yet available in the NHS, but the company anticipates that it will be available to the NHS in England and Wales within 12 months of guidance publication. Therefore, the period of time the NHS has to comply with these recommendations has been extended to within 3 months of the commercial launch of sotagliflozin in England.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Neonatal parenteral nutrition NG154

This guideline covers parenteral nutrition (intravenous feeding) for babies born preterm, up to 28 days after their due birth date and babies born at term, up to 28 days after their birth. Parenteral nutrition is often needed by preterm babies, critically ill babies, and babies who need surgery.

This guideline includes recommendations on:

- indications for, and timing of, neonatal parenteral nutrition
- administration of neonatal parenteral nutrition
- energy needs of babies on neonatal parenteral nutrition
- neonatal parenteral nutrition volume
- constituents of neonatal parenteral nutrition
- standardised neonatal parenteral nutrition formulations (‘standardised bags’)
- monitoring neonatal parenteral nutrition
- stopping neonatal parenteral nutrition
- service design
- information and support for parents and carers

Asthma: diagnosis, monitoring and chronic asthma management NG80 (update)

This guideline covers diagnosing, monitoring and managing asthma in adults, young people and children. It aims to improve the accuracy of diagnosis, help people to control their asthma and reduce the risk of asthma attacks. It does not cover managing severe asthma or acute asthma attacks.

In February 2020, NICE reviewed the evidence for increasing the dose of inhaled corticosteroids within a self-management programme in children and young people with asthma. They updated the advice on self-management for children and young people with deteriorating asthma control.

Epilepsies: diagnosis and management CG137 (update)

The guideline covers diagnosing, treating and managing epilepsy and seizures in children, young people and adults in primary and secondary care. It offers best practice advice on managing epilepsy to improve health outcomes so that people with epilepsy can fully participate in daily life.

In February 2020, NICE amended recommendations in line with the MHRA guidance on valproate use by women and girls. The MHRA states that valproate must not be used in women and girls of childbearing potential (including young girls who are likely to need treatment into their childbearing years), unless other options are unsuitable and the pregnancy prevention programme is in place. This is because of the risk of malformations and developmental abnormalities in the baby.

Bipolar disorder: assessment and management CG185 (update)

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

In February 2020, NICE amended recommendations in line with the MHRA guidance on valproate use by women and girls. The MHRA states that valproate must not be used in women and girls of childbearing potential (including young girls who are likely to need treatment into their childbearing years), unless other options are unsuitable and the pregnancy prevention programme is in place. This is because of the risk of malformations and developmental abnormalities in the baby.

Antenatal and postnatal mental health: clinical management and service guidance CG192 (update)

This guideline covers recognising, assessing and treating mental health problems in women who are planning to have a baby, are pregnant, or have had a baby or been pregnant in the past year. It covers depression, anxiety disorders, eating disorders, drug- and alcohol-use disorders and severe mental illness (such as psychosis, bipolar disorder and schizophrenia). It promotes early detection and good management of mental health problems to improve women's quality of life during pregnancy and in the year after giving birth.

In February 2020, NICE amended recommendations on anticonvulsants for mental health problems in line with the MHRA guidance on valproate use by women and girls. The MHRA states that valproate must not be used in women and girls of childbearing potential (including young girls who are likely to need treatment into their childbearing years), unless other options are unsuitable and the pregnancy prevention programme is in place. This is because of the risk of malformations and developmental abnormalities in the baby.

Public Health Guidelines

None published this month.

Antimicrobial prescribing guidelines

Impetigo NG153

This guideline sets out an antimicrobial prescribing strategy for adults, young people and children aged 72 hours and over with impetigo. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline includes recommendations on:

- advice to reduce the spread of impetigo
- initial treatment
- reassessment and further treatment
- referral and seeking specialist advice
- choice of antimicrobial

Leg ulcer infection NG152

This guideline sets out an antimicrobial prescribing strategy for adults with leg ulcer infection. It aims to optimise antibiotic use and reduce antibiotic resistance.

This guideline includes recommendations on:

- treatment
- advice
- reassessment
- referral and seeking specialist advice
- choice of antibiotic

Social Care guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

None published this month.

Medical Technologies Guidance (MTGs)

Episcissors-60 for mediolateral episiotomy MTG47

Recommendations

Episcissors-60 show promise for mediolateral episiotomy. But there is currently **not enough evidence to support** the case for routine adoption in the NHS.

Research is recommended to address uncertainties about the efficacy and safety of using Episcissors-60. This research should:

- determine if using Episcissors-60 in addition to other care bundle measures is more effective in achieving an optimal episiotomy angle and in preventing episiotomy-related obstetric anal sphincter injuries (OASI) than standard episiotomy scissors
- include patient-reported outcome measures
- address potential equality considerations by ensuring patients at greatest risk of OASI are recruited
- determine the relative cost of using Episcissors-60 compared with standard episiotomy scissors.

The technology

Episcissors-60 are adapted surgical scissors used to perform an incision for mediolateral episiotomies. The scissors have 5 cm long blades with a guide limb mounted at the blade pivot point and angled at 60 degrees from the blades. A cutting angle of 60 degrees is ensured by pointing the guide limb towards the anus in the vertical perineal midline.

Episcissors-60 are available in reusable and single-use disposable versions. They are intended for use in women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise. They are intended to be used by obstetricians or midwives. The use of Episcissors-60 does not need any special training measures.

Diagnostics Guidance (DGs)

SepsiTest assay for rapidly identifying bloodstream bacteria and fungi DG20 (update)

In February 2020, NICE removed the LightCycler SeptiFast Test MGRADE assay and the IRIDICA BAC BSI assay from the recommendation in this guidance because they are no longer available to the NHS.

Recommendations

There is currently **insufficient evidence to recommend** the routine adoption in the NHS of the SepsiTest assay for rapidly identifying bloodstream bacteria and fungi. The test shows promise and further research to provide robust evidence is encouraged, particularly to demonstrate the value of using the test results in clinical decision-making.

The test

SepsiTest is a CE-marked PCR in vitro test for detecting bacterial and fungal DNA in 1 ml of k-EDTA- or citrate-treated whole blood. The test is able to identify species from more than 200 genera of bacteria and 65 genera of fungi.

The SepsiTest involves 3 distinct processes: extracting and purifying microbial DNA using centrifugation, universal PCR and sequencing. The PCR result, which is available after 4 hours, indicates whether bacteria or fungi are present in the sample. Amplicons from positive samples are then sequenced to confirm the PCR result and to determine which bacteria or fungi species are present. If readable sequences are available from sequence analysis, bacteria and fungi can be identified using the SepsiTest-BLAST online tool. Sequencing results may be available in 3 to 4 hours depending on the analyser used.

The analytical sensitivity of SepsiTest ranges from 10 to 80 colony-forming units/ml, depending on the target species.

NICE Quality Standards

Intrapartum care: existing medical conditions and obstetric complications QS192

This quality standard covers care during labour and birth for women who need extra support because they have a medical condition or complications in their current or previous pregnancy. It also covers women who have had no antenatal care. It describes high-quality care in priority areas for improvement. It does not cover the antenatal and postnatal care of pregnant women with mental health conditions, hypertension in pregnancy, diabetes in pregnancy or the organisation of care for pregnant women with complex social factors.

Current NICE consultations

Title / link	End date of consultation
Pembrolizumab with axitinib for untreated advanced renal cell carcinoma [ID1426]	04/03/2020
Electrical stimulation to improve muscle strength in non-neurological chronic conditions	05/03/2020
Behaviour change: digital and mobile health interventions	06/03/2020
Suspected neurological conditions	11/03/2020
Axonics sacral neuromodulation system for bladder control in people with symptoms of overactive bladder	13/03/2020
Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma [ID1576]	18/03/2020
Transcranial magnetic stimulation for auditory hallucinations	25/03/2020
Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention	25/03/2020
Swallowable gastric balloon capsule for weight loss	25/03/2020
Low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer	25/03/2020
Acute coronary syndromes	27/03/2020
Joint replacement (primary): hip, knee and shoulder	03/04/2020

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