NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: April 2019

Hyperlinks to the relevant NICE web page are included below.

Technology Appraisals (TAs)

Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma TA577

Recommendations

Brentuximab vedotin is recommended as an option for treating CD30-positive cutaneous T-cell lymphoma (CTCL) after at least 1 systemic therapy in adults, only if:

- they have mycosis fungoides stage IIB or over, primary cutaneous anaplastic large cell lymphoma or Sézary syndrome and
- the company provides brentuximab vedotin according to the commercial arrangement.

These recommendations are not intended to affect treatment with brentuximab vedotin 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

Brentuximab vedotin is indicated for the treatment of adult patients with CD30-positive cutaneous T-cell lymphoma after at least 1 prior systemic therapy.

The recommended dose is 1.8 mg/kg given as an intravenous infusion over 30 minutes every 3 weeks. People with CTCL should have up to 16 cycles.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that 90 people in England with CD30-positive cutaneous T-cell lymphoma (CTCL) are eligible for treatment with brentuximab vedotin and 80 people with have brentuximab vedotin from year 2020-21 onwards once uptake has reached 90%.

Bosutinib for untreated chronic myeloid leukaemia (terminated appraisal) TA576

NICE is unable to make a recommendation about the use in the NHS of bosutinib for untreated chronic myeloid leukaemia in adults because no evidence submission was received from Pfizer. NICE will review this decision if the company decides to make a submission.

Tildrakizumab for treating moderate to severe plaque psoriasis TA575

Recommendations

Tildrakizumab is recommended as an option for treating plaque psoriasis in adults, only if:

- the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
- the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
- the company provides the drug according to the commercial arrangement.

Consider stopping tildrakizumab between 12 weeks and 28 weeks if there has not been at least a 50% reduction in the PASI score from when treatment started.

Stop tildrakizumab at 28 weeks if the psoriasis has not responded adequately. An adequate response is defined as:

- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

If patients and their clinicians consider tildrakizumab to be one of a range of suitable treatments, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements).

When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any adjustments they consider appropriate.

These recommendations are not intended to affect treatment with tildrakizumab 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

Tildrakizumab has a marketing authorisation for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Tildrakizumab is administered by subcutaneous injection at a dose of 100 mg at weeks 0 and 4 and every 12 weeks thereafter. In patients with certain characteristics (for example, high disease burden, body weight of 90 kg or more), a 200 mg dose may provide greater efficacy.

Consideration should be given to stopping treatment in patients whose psoriasis has shown no response after 28 weeks of treatment. An initial partial response may subsequently improve with continued treatment beyond 28 weeks.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because the technology is a further treatment option and is available at a similar price.

Certolizumab pegol for treating moderate to severe plaque psoriasis TA574

Recommendations

Certolizumab pegol is recommended as an option for treating plaque psoriasis in adults, only if:

- the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
- the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
- the lowest maintenance dosage of certolizumab pegol is used (200 mg every 2 weeks) after the loading dosage and
- the company provides the drug according to the commercial arrangement.

Stop certolizumab pegol at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:

- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

If patients and their clinicians consider certolizumab pegol to be one of a range of suitable treatments, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements).

When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any adjustments they consider appropriate.

These recommendations are not intended to affect treatment with certolizumab pegol 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

Certolizumab pegol is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

The recommended starting dosage of certolizumab pegol for adults is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. The maintenance dosage of certolizumab pegol for adults is 200 mg every 2 weeks. A dosage of 400 mg every 2 weeks can be considered when there is an insufficient response.

Financial factors

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because the technology is a further treatment option and is available at a similar price.

Daratumumab with bortezomib and dexamethasone for previously treated multiple myeloma TA573

Recommendations

Daratumumab plus bortezomib plus dexamethasone is recommended for use within the Cancer Drugs Fund as an option for treating relapsed multiple myeloma in people who have had 1 previous treatment. It is recommended only if the conditions in the managed access agreement for daratumumab plus bortezomib plus dexamethasone are followed.

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

The technology

Daratumumab has a marketing authorisation in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Daratumumab 16 mg/kg body weight is administered by intravenous infusion every week for weeks 1 to 9, every 3 weeks for weeks 10 to 24 and every 4 weeks from week 25 onwards.

Bortezomib is administered by subcutaneous injection at a dose of 1.3 mg/m^2 twice weekly on days 1, 4, 8 and 11 for 8×21-day cycles.

Dexamethasone is administered orally at a dose of 80 mg weekly.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that around 2,700 people per year in England with multiple myeloma who have received at least one prior therapy are eligible for treatment with daratumumab with bortezomib and dexamethasone.

Daratumumab will be available to the NHS in line with the managed access agreement with NHS England. The resource impact will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed by the date the managed access agreement expires or when the results of the data collection are available, whichever is sooner, to decide whether the drug can be recommended for routine use.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Ectopic pregnancy and miscarriage: diagnosis and initial management NG126

This guideline covers diagnosing and managing ectopic pregnancy and miscarriage in women with complications, such as pain and bleeding, in early pregnancy (that is, up to 13 completed weeks of pregnancy). It aims to improve how early pregnancy loss is diagnosed, and the support women are given, to limit the psychological impact of their loss.

This guideline includes new and updated recommendations on:

- using ultrasound scans for diagnosis of tubal ectopic pregnancy
- expectant management

It also includes recommendations on:

- support and information giving
- early pregnancy assessment services

- symptoms and signs of ectopic pregnancy
- diagnosis of viable intrauterine pregnancy and ectopic pregnancy
- management of miscarriage
- management of ectopic pregnancy

Surgical site infections: prevention and treatment NG125

This guideline covers preventing and treating surgical site infections in adults, young people and children who are having a surgical procedure involving a cut through the skin. It focuses on methods used before, during and after surgery to minimise the risk of infection.

This guideline includes new and updated recommendations on:

- nasal decolonisation before surgery
- antiseptic skin preparation during surgery
- antiseptics and antibiotics before wound closure
- methods of wound closure

It also includes recommendations on:

- information for patients and carers
- what happens before surgery
- what happens during surgery
- what happens after surgery
- treating surgical site infection and specialist wound care services

Specialist neonatal respiratory care for babies born preterm NG124

This guideline covers specific aspects of respiratory support (for example, oxygen supplementation, assisted ventilation, treatment of some respiratory disorders, and aspects of monitoring) for preterm babies in hospital.

This guideline includes recommendations on:

- risk factors for bronchopulmonary dysplasia
- respiratory support for preterm babies
- managing respiratory disorders
- monitoring
- sedation and analgesia
- involving, supporting and informing parents and carers
- discharge planning

Urinary incontinence and pelvic organ prolapse in women: management NG123

This guideline covers assessing and managing urinary incontinence and pelvic organ prolapse in women aged 18 and over. It also covers complications associated with mesh surgery for these conditions.

⚠ In July 2018, the Government announced a period of 'high vigilance restriction' on the use of a group of procedures, including vaginally inserted mesh and tape to treat stress urinary incontinence and pelvic organ prolapse, in England. For details, see the letter from NHS England and NHS Improvement to trust medical directors. At the time of publication of this updated NICE guideline, the high vigilance restriction period had been extended and, until it ends, professionals should continue to follow its requirements.

This guideline includes new and updated recommendations on:

- organisation of specialist services
- collecting data on surgery and surgical complications
- urodynamic testing to assess urinary incontinence
- pelvic floor muscle training and absorbent containment products for urinary incontinence
- medicines and botulinum toxin type A injections for overactive bladder
- surgical management of stress urinary incontinence
- assessing pelvic organ prolapse
- non-surgical and surgical management of pelvic organ prolapse
- surgery for women with both stress urinary incontinence and pelvic organ prolapse
- assessing and managing complications associated with mesh surgery

These supplement the existing recommendations on:

- assessing urinary incontinence
- non-surgical management of stress urinary incontinence

Caesarean section CG132 (update)

This guideline covers when to offer caesarean section, procedural aspects of the operation and care after caesarean section. It aims to improve the consistency and quality of care for women who are considering a caesarean section or have had a caesarean section in the past and are now pregnant again.

This guideline includes recommendations on:

- when to offer planned caesarean section
- when a caesarean section may be required during birth
- procedural aspects of caesarean section
- care of the baby and mother after caesarean section
- recovery after caesarean section
- subsequent pregnancy and childbirth after caesarean section

April 2019: NICE withdrew a recommendation on wound closure methods and replaced it with a link to the updated NICE guideline on surgical site infections: prevention and treatment.

Intrapartum care for women with existing medical conditions or obstetric complications and their babies NG121 (update)

This guideline 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. The guideline also covers women who have had no antenatal care. It aims to improve experiences and outcomes for women and their babies.

This guideline includes recommendations on:

- heart disease, bleeding disorders and subarachnoid haemorrhage
- asthma, long-term systemic steroids and obesity
- acute kidney injury and chronic kidney disease
- sepsis and intrapartum haemorrhage
- previous caesarean section and labour after 42 weeks
- small-for-gestational-age baby and large-for-gestational-age baby
- no antenatal care

April 2019: NICE replaced recommendations on continuous cardiotocography for women with a previous caesarean section with links to our guideline on caesarean section.

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)

Endoscopic ablation for a pilonidal sinus IPG646

Recommendations

Current evidence on endoscopic ablation for a pilonidal sinus raises no major safety concerns and the evidence on efficacy is adequate in quality and quantity. Therefore, this procedure can be used provided that **standard arrangements** are in place for clinical governance, consent and audit.

The condition

A pilonidal sinus is a small infected tract or a network of interlinking tracts under the skin between the buttocks. The exact cause is unknown but it may be from loose hairs pushing into the skin, combined with friction from clothes. The risk of developing a pilonidal sinus is increased by spending long periods of time sitting down, being overweight, a persistent irritation or injury to the affected area, having a hairy buttock cleft or a family history of the condition.

A pilonidal sinus does not usually cause symptoms unless it is infected and an abscess develops causing pain, redness, swelling under the skin and leakage of blood and pus.

Treatments include conservative management with regular bathing and keeping the area dry, and antibiotics if the sinus is infected. However this does not close the sinus tract. Procedures to close the sinus include injecting fibrin glue and surgical excision.

The procedure

Endoscopic ablation of a pilonidal sinus is less invasive than surgery and is usually done as a day case, using spinal or local anaesthesia. With the patient in the prone position, the external opening of the sinus is incised and a fistuloscope is inserted into the sinus tract. A continuous jet of irrigation solution is used, allowing optimal visualisation and assessment of the inside of the sinus. Under direct vision, forceps are used to remove hairs, infected tissue and any debris. Then an electrode is passed through the fistuloscope to cauterise the main sinus tract and any secondary tracts or abscess cavities. Necrotic material is removed using an endobrush and the sinus tract is cleaned using irrigation solution.

Endoscopic ablation for an anal fistula IPG645

Recommendations

Current evidence on endoscopic ablation for an anal fistula raises no major safety concerns and the evidence on efficacy is adequate in quality and quantity. Therefore, this procedure can be used provided that **standard arrangements** are in place for clinical governance, consent and audit.

The condition

An anal fistula is an abnormal tract between the anal canal and the skin around the anus. It may cause symptoms such as pain or discomfort, and leak blood or pus. It usually results from previous anal abscesses (cryptoglandular), and can be associated with other conditions including inflammatory bowel disease (such as Crohn's disease) and cancer.

Anal fistulas can be classified according to their relationship with the external sphincter. A fistula may be complex, with several openings onto the perianal skin. Intersphincteric fistulas are the most common type and cross only the internal anal sphincter. Trans-sphincteric fistulas pass through both the internal and external sphincters.

Treatment of an anal fistula commonly involves surgery. The type of surgery depends on the medical history, extent, location and complexity of the fistula in relation to

surrounding muscles. The aim is to drain infected material and encourage healing. If the fistula does not heal completely, another surgical procedure may be needed. For simple intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula tract (involving muscle division that may affect continence). For high and complex (deeper) fistulas that involve more muscle, with a high risk of faecal incontinence or recurrence, surgery aims to treat the fistula and preserve sphincter-muscle function.

The procedure

Endoscopic ablation of an anal fistula is a less invasive procedure than surgery. It aims to preserve sphincter-muscle function and faecal continence. It may be done in combination with surgical techniques such as creating a mucosal advancement flap.

The procedure is usually done as a day case using spinal or general anaesthesia. With the patient in the lithotomy position, a fistuloscope is inserted into the fistula tract from the external opening. A continuous jet of irrigation solution is used, which allows optimal visualisation of the fistula tract, the internal opening and any secondary tracts or abscess cavities. When the fistuloscope exits through the internal opening to the rectal mucosa, 2 or 3 stitches are inserted to isolate the internal opening. Under direct vision, an electrode is passed through the fistuloscope and the material in the fistula tract is cauterised from the external to the internal opening. All necrotic material is removed using a fistula brush and a continuous jet of irrigation solution. The fistuloscope is removed and the internal opening closed by suturing, stapling or by creating a cutaneous mucosal flap.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

None published this month.

Current NICE consultations

Title / link	End date of consultation
Alcohol-use disorders: prevention	08/05/2019
Type 1 diabetes in adults: diagnosis and management	08/05/2019
Diabetes (type 1 and type 2) in children and young people: diagnosis and management	08/05/2019
Diabetic foot problems: prevention and management	08/05/2019
Type 2 diabetes in adults: management	08/05/2019
Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence	08/05/2019
Twin and triplet pregnancy (update)	09/05/2019
Ribociclib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer [ID1318]	09/05/2019
Dacomitinib for untreated EGFR-positive non-small-cell lung cancer (ID1346)	09/05/2019
Osimertinib for untreated EGFR-positive non-small-cell lung cancer [ID1302]	09/05/2019
Cellulitis and erysipelas: antimicrobial prescribing	10/05/2019
Diabetic foot infection: antimicrobial prescribing	16/05/2019
Dapagliflozin, in combination with insulin, for treating type 1 diabetes [ID1478]	17/05/2019
Sodium zirconium cyclosilicate for treating hyperkalaemia [ID1293]	20/05/2019
Suicide prevention	23/05/2019
Low energy contact x-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer	23/05/2019
Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm	23/05/2019
Bioprosthetic plug insertion for anal fistula	23/05/2019
Social and emotional wellbeing in primary and secondary education	28/05/2019
Termination of pregnancy	31/05/2019
Osteoarthritis: care and management (update)	31/05/2019
End of life care – service delivery	07/06/2019