

NICE Update Bulletin March 2017

(issued Wednesday 22 March 2017)

Hyperlinks to the relevant NICE web page are included, to activate link left click on your mouse.

Details are also available from the NICE website (<http://www.nice.org.uk>)

| <u>Type</u> | <u>Guidance title and reference number</u> |
|-----------------------------|--|
| Technology Appraisals (TAs) | <p data-bbox="395 510 1270 544"><u>Ustekinumab for treating active psoriatic arthritis TA340 (update)</u></p> <p data-bbox="395 562 1437 734">March 2017: Under the original patient access scheme the company provided 2x45-mg pre-filled syringes, for patients who needed the higher dose of 90-mg, at the same total cost to the NHS as for a single 45-mg pre-filled syringe. The patient access scheme has been withdrawn because the company now provides a 90-mg vial at the same cost as the 45-mg vial.</p> <p data-bbox="395 770 1437 831"><u>Ustekinumab for the treatment of adults with moderate to severe psoriasis TA180 (update)</u></p> <p data-bbox="395 848 1437 1021">March 2017: Under the original patient access scheme the company provided 2x45-mg pre-filled syringes, for patients who needed the higher dose of 90-mg, at the same total cost to the NHS as for a single 45-mg pre-filled syringe. The patient access scheme has been withdrawn because the company now provides a 90-mg vial at the same cost as the 45-mg vial.</p> <p data-bbox="395 1057 1437 1151"><u>Ibrutinib with bendamustine and rituximab for treating relapsed or refractory chronic lymphocytic leukaemia after systemic therapy TA437 (terminated appraisal)</u></p> <p data-bbox="395 1169 1437 1323">NICE was unable to make a recommendation about the use in the NHS of ibrutinib with bendamustine and rituximab for treating relapsed or refractory chronic lymphocytic leukaemia after systemic therapy because no evidence submission was received from Janssen-Cilag, but will review this decision if the company decides to make a submission.</p> <p data-bbox="395 1359 1437 1420"><u>Bevacizumab for treating EGFR mutation-positive non-small-cell lung cancer TA436 (terminated appraisal)</u></p> <p data-bbox="395 1438 1437 1570">NICE was unable to make a recommendation about the use in the NHS of bevacizumab for treating epidermal growth factor receptor mutation-positive non-small-cell lung cancer because no evidence submission was received from Roche, but will review this decision if the company decides to make a submission.</p> <p data-bbox="395 1606 1437 1666"><u>Tenofovir alafenamide for treating chronic hepatitis B TA435 (terminated appraisal)</u></p> <p data-bbox="395 1684 1437 1809">NICE was unable to make a recommendation about the use in the NHS of tenofovir alafenamide for treating chronic hepatitis B because no evidence submission was received from Gilead, but will review this decision if the company decides to make a submission.</p> <p data-bbox="395 1845 1437 1906"><u>Elotuzumab for previously treated multiple myeloma TA434 (terminated appraisal)</u></p> <p data-bbox="395 1924 1437 2049">NICE was unable to make a recommendation about the use in the NHS of elotuzumab for previously treated multiple myeloma because no evidence submission was received from Bristol-Myers Squibb, but will review this decision if the company decides to make a submission.</p> |

| | |
|---|--|
| <p>Highly specialised technology guidance (HSTs)</p> | <p>None published so far this month.</p> |
| <p>NICE Guidelines (NGs)</p> | <p><u>Mental health of adults in contact with the criminal justice system NG66</u></p> <p>This guideline covers assessing, diagnosing and managing mental health problems in adults (aged 18 and over) who are in contact with the criminal justice system. It aims to improve mental health and wellbeing in this population by establishing principles for assessment and management, and promoting more coordinated care planning and service organisation across the criminal justice system.</p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> • assessing and managing a person’s mental health problems, including assessing risk to themselves and others • planning their care • psychological and pharmacological interventions • how services should be organised • staff training <p><u>Stroke and transient ischaemic attack in over 16s: diagnosis and initial management CG68 (update)</u></p> <p>This guideline covers interventions in the acute stage of a stroke or transient ischaemic attack (TIA). It offers the best clinical advice on the diagnosis and acute management of stroke and TIA in the 48 hours after onset of symptoms, although some interventions of up to 2 weeks are covered as well.</p> <p>March 2017: Recommendation 1.4.1.1 was updated as the source guidance for this recommendation had been superseded by new advice. The footnote to recommendation 1.4.2.3 was amended to give a definition of aspirin intolerance, rather than a link to a definition.</p> <p><u>Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer CG164 (update)</u></p> <p>This guideline covers care for people with a family history of breast, ovarian or another related (prostate or pancreatic) cancer. It aims to improve the long-term health of these families by describing strategies to reduce the risk of and promote early detection of breast cancer (including genetic testing and mammography). It also includes advice on treatments (tamoxifen, raloxifene) and surgery (mastectomy).</p> <p>March 2017: NICE has reviewed the evidence for chemoprevention for women with no personal history of breast cancer and changed some recommendations in section 1.7.</p> <p><u>Early and locally advanced breast cancer: diagnosis and treatment CG80 (update)</u></p> <p>This guideline covers diagnosis and surgical and pharmacological treatment of women and men with early and locally advanced breast cancer. It aims to improve early identification and treatment of breast cancer to prevent disease progression and reduce deaths.</p> <p>March 2017: A new recommendation was added to section 1.6 (recommendation 1.6.9, dated 2017) after the evidence for genetic testing in women with triple negative breast cancer was reviewed.</p> |

**Interventional
Procedures
Guidance (IPGs)**

[Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse IPG577](#)

This guidance replaces NICE interventional procedures guidance on sacrocolpopexy with hysterectomy for uterine prolapse repair (IPG284).

Recommendations

1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is inadequate in quantity and quality. Therefore this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse should:

- Inform the clinical governance leads in their trusts.
- During the consent process, ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Patient selection and treatment should only be done by specialists with experience in managing pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training in the procedure.

1.3 Clinicians should enter details about all patients having sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical device used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

1.4 NICE may update the guidance on publication of further evidence.

The procedure

Uterine prolapse is when the womb (uterus) slips down from its normal position, into, and sometimes through, the vagina. It can affect quality of life, and cause problems with bowel and bladder function, and sex. A minor prolapse can be treated with pelvic floor exercises and pessaries, without the need for surgery. If the prolapse is severe, surgery may be needed. There are different types of surgery, some include using mesh for additional support.

NICE has looked at using sacrocolpopexy with hysterectomy using mesh as another treatment option. Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is usually done under general anaesthetic. It can be done as open abdominal surgery or by keyhole surgery using small cuts in the abdomen.

The aim is to support the pelvic organs in their usual place, after removal of the womb (hysterectomy). This is done by attaching a piece of mesh usually from the top, and sometimes from the front or back of the vagina, to a ligament in the pelvis at the base of the spine, or to a bone at the bottom of the spine. The mesh is similar to a fine net, and is usually made of polypropylene. The procedure can be done with surgery for other conditions, for example, for stress incontinence. Different types of meshes or tissue grafts have been used and these may have different risks.

[Extraurethral \(non-circumferential\) retropubic adjustable compression devices for stress urinary incontinence in women IPG576](#)

This guidance replaces NICE interventional procedures guidance on extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women (IPG133).

| | |
|---|---|
| | <p><u>Recommendations</u></p> <p>1.1 Current evidence on the safety and efficacy of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>1.2 Clinicians wishing to insert extraurethral retropubic adjustable compression devices for stress urinary incontinence in women should:</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having extraurethral retropubic adjustable compression devices for stress urinary incontinence. <p>1.3 All adverse events involving any medical devices used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.</p> <p>1.4 Further research into this procedure should include detailed safety outcomes, long-term results and patient-reported outcome measures. NICE may update the guidance on publication of further evidence.</p> <p><u>The procedure</u></p> <p>Stress urinary incontinence is when urine leaks out at times when your bladder is under pressure, for example, when you cough or laugh, or during exercise. It usually happens because the muscles (such as the pelvic floor muscles) that stop urination are weakened or damaged. Treatment includes lifestyle changes such as weight loss and pelvic floor muscle training. If these don't work, surgery can be considered such as inserting special tapes (mesh) or slings, or colposuspension by open surgery.</p> <p>NICE has looked at using extraurethral (non-circumferential) retropubic adjustable compression devices as another treatment option. Extraurethral (non-circumferential) retropubic adjustable compression devices aim to reduce the risk of urinary leakage in women with stress urinary incontinence. The procedure can be done with local, regional or general anaesthetic. It involves placing 2 small silicone balloons under the bladder, through a cut in the skin behind the vagina. The balloons are placed on either side of the urethra (the tube that carries urine from the bladder). The balloons are filled with fluid and they support the bladder, reducing leaks but allowing the normal passage of urine.</p> <p>Each balloon is attached to a soft, plastic tube with a rubber disc (port) on the end. The port is implanted below the skin near the vaginal opening. After the procedure, fluid can be added or removed from the balloons through these ports to get the best effect for the individual person. The balloons are meant to be permanent.</p> |
| <p>Medical Technologies Guidance</p> | <p><u>ENDURALIFE powered CRT-D devices for treating heart failure MTG33</u></p> <p><u>Recommendations</u></p> <p>1.1 The case for adopting ENDURALIFE-powered cardiac resynchronisation therapy-defibrillator (CRT-D) devices for treating heart failure is supported by the published evidence. Extended battery life is of clinical and patient benefit and associated with fewer replacement procedures.</p> <p>1.2 ENDURALIFE-powered CRT-Ds should be considered as an option in people offered CRT-D devices in line with NICE technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy.</p> |

| | |
|--------------------------------------|--|
| | <p>1.3 Cost modelling was based on published data using predecessor devices, and showed that the price and lifespan of the CRT-D have the greatest effect on overall treatment costs. Assuming an average selling price of £12,404 across different devices, using ENDURALIFE-powered CRT-Ds may save between £2,120 and £5,627 per patient over 15 years through a reduction in the need for replacement procedures. This could save the NHS in England around £6 million in the first 5 years.</p> <p><u>The technology</u></p> <p>A CRT-D is a type of implantable device used to treat heart failure. It sends small electrical signals to both lower chambers of the heart, helping the chambers to beat more in sync. ENDURALIFE is a battery technology for these devices.</p> <p>ENDURALIFE-powered CRT-Ds have longer battery life than non-ENDURALIFE-powered CRT-Ds. A device that lasts longer may need to be replaced less often.</p> |
| <p>Diagnostics Guidance</p> | <p>None published so far this month.</p> |
| <p>NICE Quality Standards</p> | <p><u>Community engagement: improving health and wellbeing QS148</u></p> <p>This quality standard covers community engagement approaches to improve health and wellbeing and reduce health inequalities, and initiatives to change behaviours that harm people’s health. This includes building on the strengths and capabilities of communities, helping them to identify their needs and working with them to design and deliver initiatives and improve equity.</p> <p><u>Healthy workplaces: improving employee mental and physical health and wellbeing QS147</u></p> <p>This quality standard covers the health and wellbeing of all employees, including their mental health. It describes high-quality care in priority areas for improvement. It does not cover managing long-term sickness absence.</p> <p><u>Head and neck cancer QS146</u></p> <p>This quality standard covers assessing, diagnosing and managing head and neck cancer, including cancer of the upper aerodigestive tract, in young people (aged 16 and 17) and adults (aged 18 and over). It describes high-quality care in priority areas for improvement.</p> <p><u>Vaccine update in under 19s QS145</u></p> <p>This quality standard covers increasing vaccine uptake among children and young people aged under 19 in groups and settings that have low immunisation coverage. It describes high-quality care in priority areas for improvement.</p> <p><u>Care of dying adults in the last days of life QS144</u></p> <p>This quality standard covers the clinical care of adults (aged 18 and over) who are dying, during the last 2 to 3 days of life. It describes high-quality care in priority areas for improvement.</p> <p>It does not cover care before the last few days of life, such as palliative care or ‘end of life care’ (often defined as care during the last year or so of a progressive disease), or care after death. These are included in NICE’s quality standard for end of life care for adults.</p> <p><u>End of life care for adults QS13 (update)</u></p> <p>This quality standard covers care for adults (aged 18 and over) who are approaching the end of their life.</p> |

This includes people who are likely to die within 12 months, people with advanced, progressive, incurable conditions and people with life-threatening acute conditions. It also includes support for their families and carers. Care provided by health and social care staff in all settings is covered. It describes high-quality care in priority areas for improvement. It does not include the care of people in the last days of life, which is covered by NICE's quality standard for [care of dying adults in the last days of life](#).

March 2017: This quality standard was updated and statement 11 on care in the last days of life was removed and replaced by NICE's quality standard for care of dying adults in the last days of life.

Current NICE consultations with links and end dates for stakeholders to contribute

| Title / link | End date of consultation |
|--|---------------------------------|
| Chronic kidney disease (QS update) | 28/03/2017 |
| Nutrition support in adults | 31/03/2017 |
| Developmental follow-up of children and young people born preterm | 03/04/2017 |
| Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma [ID972] | 03/04/2017 |
| Gaucher disease (type 1) - eliglustat [ID709] | 04/04/2017 |
| Uveitis (non-infectious) - adalimumab and dexamethasone [ID763] | 04/04/2017 |
| Sepsis | 07/04/2017 |
| Transition between inpatient mental health settings and community and care homes | 07/04/2017 |
| Low back pain | 07/04/2017 |
| Psoriasis (plaque, chronic, severe, children, young people) - adalimumab, etanercept and ustekinumab [ID854] | 07/04/2017 |
| Daratumumab for multiple myeloma [ID933] | 07/04/2017 |
| Child abuse and neglect | 19/04/2017 |
| Endometriosis: diagnosis and management | 20/04/2017 |

Produced by
Rebecca Heayn (Clinical Effectiveness Governance Manager),
NEW Devon CCG Clinical Effectiveness and Medicines Optimisation Team
County Hall, Topsham Road, Exeter, EX2 4QL
For distribution Northern, Eastern and Western Devon CCG
& South Devon and Torbay CCG