NICE Update Bulletin November 2017

Hyperlinks to the relevant NICE web page are included.

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

Type	Guidance title and reference number
Technology Appraisals (TAs)	**Ibrutinib for treating Waldenstrom's macroglobulinaemia TA491** **Recommendations** 1.1 Ibrutinib is recommended **for use in the Cancer Drugs Fund** as an option for treating Waldenstrom's macroglobulinaemia in adults who have had at least 1 prior therapy, only if the conditions in the managed access agreement for ibrutinib are followed. 1.2 This guidance is not intended to affect the position of patients whose treatment with ibrutinib was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. **The technology** Ibrutinib has a marketing authorisation in the UK for treating adults with Waldenstrom's macroglobulinaemia: • who have had at least 1 prior therapy, or • as first-line treatment in patients for whom chemo-immunotherapy is unsuitable. **Financial factors** This technology is commissioned by NHS England. The resource impact of ibrutinib will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed by the date the managed access agreement expires (anticipated September 2020) or when the results of the managed access agreement data collection are available, whichever is sooner. The aim of the review is to decide whether or not the drug can be recommended for routine use. It is estimated that 335 people with Waldenstrom's macroglobulinaemia will be eligible for treatment with ibrutinib over the course of the managed access agreement. **Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy TA490** **Recommendations** 1.1 Nivolumab is recommended **for use within the Cancer Drugs Fund** as an option for treating squamous cell carcinoma of the head and neck in adults whose disease has progressed on platinum-based chemotherapy, only if: • the disease has progressed within 6 months of having chemotherapy • nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression and • the conditions in the managed access agreement are followed.

1.2 This recommendation is not intended to affect treatment with nivolumab 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

Nivolumab has a marketing authorisation in the UK as monotherapy for 'the treatment of squamous cell cancer of the head and neck in adults progressing on or after platinum-based therapy'.

Financial factors

This technology is commissioned by NHS England.

The resource impact of nivolumab will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed when the results of the managed access agreement data collection are available, which is expected to end in September 2019. As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed.

It is estimated that 240 people per year with squamous cell carcinoma of the head and neck are eligible for treatment with nivolumab.

Vismodegib for treating basal cell carcinoma TA489

Recommendations

1.1 Vismodegib is **not recommended** within its marketing authorisation for treating symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that is inappropriate for surgery or radiotherapy, in adults.

1.2 This recommendation is not intended to affect treatment with vismodegib 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

Vismodegib is indicated for the treatment of 'adult patients with:

- symptomatic metastatic basal cell carcinoma
- locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy'.

Financial factors

Vismodegib is not recommended because of the uncertainty in the evidence and because it is not cost effective.

Regorafenib for previously treated unresectable or metastatic gastro-intestinal stromal tumours TA488

Recommendations

1.1 Regorafenib is recommended as an option for treating unresectable or metastatic gastrointestinal stromal tumours in adults whose disease has progressed on, or who are intolerant to, prior treatment with imatinib and sunitinib, only if:

- their Eastern Cooperative Oncology Group (ECOG) performance status is 0 to 1 and
- the company provides regorafenib with the discount agreed in the patient access scheme.

1.2 When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate.

1.3 These recommendations are not intended to affect treatment with regorafenib 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

Regorafenib is indicated 'for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib'.

Financial factors

This technology is commissioned by NHS England.

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 population size is small.

Venetoclax for treating chronic lymphocytic leukaemia TA487

Recommendations

1.1 Venetoclax is recommended **for use within the Cancer Drugs Fund**, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia, that is, in adults:

- with a 17p deletion or TP53 mutation and when a B-cell receptor pathway inhibitor is unsuitable, or whose disease has progressed after a B‑cell receptor pathway inhibitor or
- without a 17p deletion or TP53 mutation, and whose disease has progressed after both chemo‑immunotherapy and a B-cell receptor pathway inhibitor and
- only if the conditions in the managed access agreement are followed.

1.2 This recommendation is not intended to affect treatment with venetoclax 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

Venetoclax has a conditional marketing authorisation for 'the treatment of chronic lymphocytic leukaemia (CLL) in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B‑cell receptor pathway inhibitor' and for 'the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemo‑immunotherapy and a B‑cell receptor pathway inhibitor'.

Before the marketing authorisation was granted, venetoclax was designated a promising innovative medicine and was available to patients in the NHS through the early access to medicines scheme.

Financial factors

This technology is commissioned by NHS England.

The resource impact of venetoclax will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed when the results of the managed access agreement data collection are available, which is expected to end in December

2020. As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed.

It is estimated that 240 people per year with chronic lymphocytic leukaemia are eligible for treatment with venetoclax.

Aflibercept for treating choroidal neovascularisation TA486

Recommendations

1.1 Aflibercept is recommended, within its marketing authorisation, as an option for treating visual impairment because of myopic choroidal neovascularisation in adults, only if the company provides aflibercept with the discount agreed in the patient access scheme.

1.2 If patients and their clinicians consider both aflibercept and ranibizumab to be suitable treatments, the least costly should be used, taking into account anticipated administration costs, dosage and price per dose.

The technology

Aflibercept has a UK marketing authorisation for 'treating visual impairment due to myopic choroidal neovascularisation in adults'.

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 an option alongside current standard treatment options.

Because aflibercept has been recommended through the fast track appraisal process, NHS England and commissioning groups have committed to providing funding to implement this guidance 30 days after publication.

Sarilumab for moderate to severe rheumatoid arthritis TA485

Recommendations

1.1 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if:

- disease is severe (a disease activity score [DAS28] of more than 5.1) and
- the company provides sarilumab with the discount agreed in the patient access scheme.

1.2 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if:

- disease is severe (a DAS28 of more than 5.1) and
- they cannot have rituximab and
- the company provides sarilumab with the discount agreed in the patient access scheme.

1.3 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if:

- disease is severe (a DAS28 of more than 5.1) and
- the company provides sarilumab with the discount agreed in the patient

access scheme.

1.4 Sarilumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met.

1.5 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

1.6 These recommendations are not intended to affect treatment with sarilumab 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

Sarilumab has a marketing authorisation in the UK for the 'treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs.' Sarilumab can be given as monotherapy or in combination with methotrexate.

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 an option alongside current standard treatment options.

Nivolumab for previously treated non-squamous non-small-cell lung cancer TA484

Recommendations

1.1 Nivolumab is recommended **for use within the Cancer Drugs Fund** as an option for treating locally advanced or metastatic non-squamous non-small-cell lung cancer in adults after chemotherapy, only if:

- their tumours are PD-L1 positive and
- nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression, and
- the conditions in the managed access agreement are followed.

1.2 This recommendation is not intended to affect treatment with nivolumab 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

Nivolumab has a marketing authorisation for treating 'locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy in adults'. Before the marketing authorisation was granted, nivolumab was available in the NHS through the early access to medicines scheme.

Financial factors

This technology is commissioned by NHS England.

The resource impact of nivolumab will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed when the results of the managed access agreement data collection are available. The data collection is anticipated to

conclude June 2019, when it is expected that 5-year follow-up data will be available from the CheckMate 057 clinical trial. The aim of the review is to decide whether or not the drug can be recommended for routine use.

It is estimated that 350 people with locally advanced or metastatic non-squamous non-small-cell lung cancer are eligible for treatment with nivolumab, over the course of the managed access agreement.

Nivolumab for previously treated squamous non-small-cell lung cancer TA483

Recommendations

1.1 Nivolumab is recommended **for use within the Cancer Drugs Fund** as an option for treating locally advanced or metastatic squamous non-small-cell lung cancer in adults after chemotherapy, only if:

- nivolumab is stopped at 2 years of uninterrupted treatment, or earlier in the event of disease progression, and
- the conditions in the managed access agreement are followed.

1.2 This recommendation is not intended to affect treatment with nivolumab 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

Nivolumab has a marketing authorisation for treating 'locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy in adults'. Before the marketing authorisation was granted, nivolumab was available in the NHS through the early access to medicines scheme.

Financial factors

This technology is commissioned by NHS England.

The resource impact of nivolumab will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed when the results of the managed access agreement data collection are available. The data collection is anticipated to conclude June 2019, when it is expected that 5-year follow-up data will be available from the CheckMate 017 clinical trial. The aim of the review is to decide whether or not the drug can be recommended for routine use.

It is estimated that 950 people with metastatic, squamous, non-small-cell lung cancer are eligible for treatment with nivolumab, over the course of the managed access agreement.

Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma TA462 (update)

November 2017: This guidance has been amended after a change to the commercial arrangements in September 2017. This change does not affect the cost effectiveness of nivolumab. Reference to a patient access scheme in recommendation 1.1 has been replaced with details of a commercial access agreement. Sections 2 and 5.4 have been updated with the same information.

Recommendations

1.1 Nivolumab is recommended, within its marketing authorisation, as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin, when the company provides nivolumab in line with the commercial access agreement with NHS England.

The technology

Nivolumab has a marketing authorisation in the UK for 'the treatment of adult

patients with relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant and treatment with brentuximab vedotin'.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £5m per year in England (or £9,100 per 100,000 population). This is because the population size is small (less than 50 people per year in England).

Nivolumab for previously treated advanced renal cell carcinoma TA417 (update)

November 2017: This guidance has been amended after a change to the commercial arrangements in September 2017. This change does not affect the cost effectiveness of nivolumab. Reference to a patient access scheme in recommendation 1.1 has been replaced with details of a commercial access agreement. Sections 2 and 5.4 have been updated with the same information.

Recommendations

1.1 Nivolumab is recommended, within its marketing authorisation, as an option for previously treated advanced renal cell carcinoma in adults, when the company provides nivolumab in line with the commercial access agreement with NHS England.

The technology

Nivolumab 'as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults'.

Before the marketing authorisation was granted (April 2016), nivolumab was available in the NHS through the early access to medicines scheme.

Financial factors

This technology is commissioned by NHS England.

Across England, it is estimated that around 800 people with previously treated advanced renal cell carcinoma are eligible for treatment with nivolumab. From 2020/21, it is estimated that around 330 people will have second line treatment with nivolumab and around 30 people will have third line treatment with nivolumab, after treatment with axitinib or everolimus at second line.

Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane TA458 (update)

November 2017: This guidance was amended after a change to the commercial arrangements in October 2017. This change does not affect the cost effectiveness of trastuzumab emtansine. Reference to a commercial access agreement in recommendation 1.1 has been replaced with details of a patient access scheme. Sections 2 and 5.4 have been updated with the same information.

Recommendations

1.1 Trastuzumab emtansine is recommended, within its marketing authorisation, as an option for treating human epidermal growth factor receptor 2 (HER2)‑positive, unresectable, locally advanced or metastatic breast cancer in adults who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy. Trastuzumab emtansine is recommended only if the company provides it with the discount agreed in the patient access scheme.

The technology

	Trastuzumab emtansine, as a single agent, has a UK marketing authorisation 'for the treatment of adult patients with HER2‑positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • received prior therapy for locally advanced or metastatic disease or • developed disease recurrence during or within 6 months of completing adjuvant therapy'. **Financial factors** This technology is commissioned by NHS England. NICE estimated that around 820 people with HER2 positive advanced breast cancer who previously received trastuzumab and a taxane are eligible for treatment with trastuzumab emtansine. Based on Cancer Drugs Fund (CDF) records, around 720 people had trastuzumab emtansine treatment. Uptake was not expected to change as a result of trastuzumab emtansine moving into routine commissioning.
Highly specialised technology guidance (HSTs)	None published so far this month.
NICE Guidelines (NGs)	**Asthma: diagnosis, monitoring and chronic asthma management NG80** 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. The investment and training required to implement the guideline will take time. In the meantime, primary care services should implement what they can of the recommendations, using currently available approaches to diagnosis until the infrastructure for objective testing is in place. This guideline includes recommendations on: • Initial clinical assessment • Diagnosing asthma in young children • Objective tests for diagnosing asthma (including diagnostic algorithms) • Pharmacological treatment • Adherence, self-management and decreasing treatment • Monitoring asthma control **Glaucoma: diagnosis and management NG81** 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. This guideline includes recommendations on: • case-finding • diagnosis • standard practice for all assessments • reassessment • treatment • organisation of care • providing information

	Fractures (complex): assessment and management NG37 (update) This guideline covers assessing and managing pelvic fractures, open fractures and severe ankle fractures (known as pilon fractures and intra-articular distal tibia fractures) in pre-hospital settings (including ambulance services), emergency departments and major trauma centres. It aims to reduce deaths and long-term health problems by improving the quality of emergency and urgent care. **November 2017:** NICE amended recommendation 1.1.10 to change the wording from 'administer prophylactic antibiotics' to 'consider administering prophylactic antibiotics'. **Familial hypercholesterolaemia: identification and management CG71 (update)** This guideline covers identifying and managing familial hypercholesterolaemia (FH), a specific type of high cholesterol that runs in the family, in children, young people and adults. It aims to help identify people at increased risk of coronary heart disease as a result of having FH. **November 2017:** The evidence on case finding, diagnosis and statin monotherapy was reviewed. Some new recommendations were added and some recommendations were updated. Nicotinic acid has been removed from the recommendations. A new recommendation cross-referring to the technology appraisal guidance on alirocumab and evolocumab has been added.
NICE Public Health Guidelines	None published so far this month.
NICE Medicines Practice Guidelines (MPGs)	None published so far this month.
Interventional Procedures Guidance (IPGs)	**Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea IPG598** **Recommendations** 1.1 Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea is limited 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 hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients 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 hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. 1.3 Patient selection and the procedure should be done by clinicians with special expertise in the management of obstructive sleep apnoea. 1.4 Further research including the use of observational data from registries should provide information on patient selection, safety outcomes, quality of life, long-term outcomes and the position of the procedure in the treatment pathway. NICE may update the guidance on publication of further evidence.

The procedure

Hypoglossal nerve stimulation aims to treat obstructive sleep apnoea by preventing the tongue prolapsing backwards and causing upper airway obstruction during sleep. It works by delivering an electrical current to the hypoglossal nerve. This contracts the genioglossus muscle, the major muscle responsible for tongue protrusion, and all other intrinsic muscles of the tongue. Using general anaesthesia, a neurostimulator is implanted in an infraclavicular subcutaneous pocket and a stimulating lead is placed on the main trunk of the hypoglossal nerve. The neurostimulator delivers electrical pulses to the hypoglossal nerve. With some devices, stimulation can be synchronised with respiration using sensing leads that measure changes in breathing. The respiratory-sensing leads are positioned between the external and internal intercostal muscle. The stimulator is programmed and controlled wirelessly to adapt to specific patient needs.

Processed nerve allografts to repair peripheral nerve discontinuities IPG597

Recommendations

1.1 Current evidence on the safety and efficacy of processed nerve allografts to repair peripheral nerve discontinuities is adequate to support the use of this procedure for digital nerves provided that **standard arrangements** are in place for clinical governance, consent and audit.

1.2 The evidence on the safety of processed nerve allografts to repair peripheral nerve discontinuities in other sites raises no major safety concerns. However, current evidence on its efficacy in these sites is limited in quantity. Therefore, for indications other than digital nerve repair, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

1.3 Clinicians wishing to do processed nerve allografts to repair peripheral nerve discontinuities in sites other than the digital nerves should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy on mixed nerve repair and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having processed nerve allografts to repair peripheral nerve discontinuities.

1.4 This procedure should only be done by surgeons with training and experience in peripheral nerve repair.

1.5 Patient selection should take into consideration the site, type of nerve (motor, sensory, mixed) and the size of the defect.

1.6 NICE encourages further research into processed nerve allografts to repair peripheral nerve discontinuities. This should include information on the type of nerve repaired, the anatomical site, the size of the defect, patient reported outcome measures, functional outcomes, time to recovery and long-term outcomes (12 months to 18 months).

The procedure

Acellular processed nerve allografts are nerves from deceased human donors that have had their immunogenic components removed using tissue processing techniques. They are stored frozen until implantation and are available in different sizes. Immunosuppressive treatment is not needed.

The procedure is done under general anaesthesia. The injured nerve is exposed, and the nerve ends are cleared of necrotic tissues and resected to allow for tension-free alignment with the graft. The graft is sutured to the exposed nerve ends. After grafting, limb splinting may be needed for several weeks to allow

optimal nerve regeneration. The typical length of an allograft implant is 1cm to 3cm.

The aim of the procedure is to bridge the peripheral nerve discontinuity to allow axonal regeneration and growth through the allograft towards the distal nerve.

Extracranial to intracranial bypass for intracranial atherosclerosis IPG596

This guidance replaces NICE interventional procedures guidance on extracranial to intracranial bypass for intracranial atherosclerosis (IPG348).

Recommendations

1.1 Current evidence on the safety and efficacy of extracranial to intracranial bypass for intracranial atherosclerosis shows that there is no benefit to the patient from the intervention. There are major concerns around its safety, therefore this procedure **should not be used** to treat this condition.

The procedure

The aim of extracranial to intracranial bypass for intracranial atherosclerosis is to increase blood flow in intracranial arteries to relieve symptoms of cerebral hypoperfusion or reduce the risk of stroke. Under general anaesthesia, the extracranial donor artery (usually the superficial temporal artery) is anastomosed to a superficial cerebral artery (usually a subpial middle cerebral artery branch) through a mini-craniotomy. Typically, an end-to-side anastomosis is used. A graft (for example a radial artery or a saphenous vein graft) may be needed to allow higher flow.

Careful pre-operative planning involving ultrasound, angiography, computed tomography (CT), single-photon emission CT scanning or brain reserve testing is needed.

Total distal radioulnar joint replacement for symptomatic joint instability or arthritis IPG595

Recommendations

1.1 Current evidence on the safety and efficacy of total distal radioulnar joint replacement for symptomatic joint instability or arthritis is limited 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 total distal radioulnar joint replacement for symptomatic joint instability or arthritis should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having total distal radioulnar joint replacement for symptomatic joint instability or arthritis.

1.3 Patient selection and the procedure should only be done by clinicians with special expertise in hand and wrist surgery.

1.4 Further research should provide information on patient selection, and continue to collect long-term outcomes. NICE may update the guidance on publication of further evidence.

The procedure

Total distal radioulnar replacement differs from conventional treatment because it involves replacing all 3 components of the distal radioulnar joint. The aim of the procedure is to increase stability of the joint and improve pain-free movement.

The procedure is done with the patient under general or regional anaesthesia, and with a tourniquet applied to the upper arm. Radiological screening is used during the procedure to check the position of the joint. An incision is made along the ulnar border and the ulnar head is removed, taking care to avoid damage to the ulnar

	nerve, tendons and artery. A plate bearing a socket is fixed to the radius, and the ulna component of the prosthesis is then inserted and attached to the radial component, using a ball to allow pronation and supination. The range of motion of the joint is checked and the wound is closed. Patients are usually encouraged to start full range-of-motion exercises about 2 weeks after the procedure.
Medical Technologies Guidance	None published so far this month.
Diagnostics Guidance	**Tests in secondary care to identify people at high risk of ovarian cancer DG31** **Recommendations** 1.1 There is currently **not enough evidence** to recommend the routine adoption of the IOTA ADNEX model, Overa (MIA2G), RMI I (at thresholds other than 200 or 250), ROMA or IOTA Simple Rules in secondary care in the NHS to help decide whether to refer people with suspected ovarian cancer to a specialist multidisciplinary team (MDT). 1.2 The NICE guideline on ovarian cancer recommends that people with an RMI I of 250 or more are referred to a specialist MDT. Evidence suggests that there is no substantial change in accuracy if the threshold for RMI I is lowered to 200. 1.3 The IOTA ADNEX model, Overa (MIA2G), RMI I (at thresholds other than 250), ROMA and IOTA Simple Rules show promise. Further research is recommended on test accuracy and the impact of the test results on clinical decision-making (see section 6 for detailed research recommendations). **The diagnostic tests** The ADNEX model was developed by the International Ovarian Tumor Analysis (IOTA) group to assess people with an adnexal mass who are considered to need surgery. The model uses 3 clinical predictors and 6 ultrasound-derived predictors to estimate the probability that a pelvic tumour is benign or malignant Also, the model estimates probabilities that a tumour is borderline, stage I cancer, stage II to IV cancer or secondary metastatic cancer. The Overa (MIA2G) is a CE-marked qualitative serum test that combines the results of 5 immunoassays into a single numeric result (the Overa Risk Score). The 5 biomarkers included in the test are: follicle-stimulating hormone (FSH), human epididymis protein 4 (HE4), apolipoprotein A‑1 (Apo A‑1), transferrin (TRF), and cancer antigen 125 (CA125). The assay is for use in people over 18 years with a pelvic mass for whom surgery may be considered. It is intended to be part of preoperative assessment to help decide if a person presenting with a pelvic mass has a high or low risk of ovarian malignancy. The RMI I tool combines 3 pre-surgical features (measured serum CA125 levels [CA125], ultrasound imaging [U] and menopausal status [M]) to create an index score: RMI I score = U×M×CA125. The ROMA combines serum CA125 and HE4 levels with a person's menopausal status to estimate the probability that they have epithelial ovarian cancer. The ROMA has not been validated in people under 18 years old, people being treated with chemotherapy and people who have previously been treated for a malignancy. Simple Rules was developed by the IOTA group to assess people with a pelvic mass who are considered to need surgery. It is a scoring system based on the presence of ultrasound features, to characterise an ovarian tumour before surgery as benign or malignant. A transvaginal probe is needed and image quality must be of sufficient quality to allow the ultrasound features specified by the Simple Rules system to be seen.

NICE Quality Standards	**Asthma QS25 (update)** This quality standard covers diagnosing and managing asthma in adults, young people and children. It describes high-quality care in priority areas for improvement. **November 2017:** Statement 1 was amended to reflect the NICE guideline on asthma: diagnosis, monitoring and chronic asthma management. **Glaucoma in adults QS7 (update)** This quality standard covers care for people with suspected or diagnosed chronic open angle glaucoma (COAG) or with ocular hypertension (OHT). It includes diagnosis, monitoring and treatment. It describes high-quality care in priority areas for improvement. **November 2017:** Statements 6, 10 and 12 were amended to reflect changes to the updated NICE guideline on glaucoma: diagnosis and management.

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

Title / link	End date of consultation
Emergency and acute medical care	01/12/2017
Short bowel syndrome - teduglutide [ID885]	04/12/2017
Senza for delivering high frequency spinal cord stimulation to treat chronic neuropathic pain	04/12/2017
Trauma	05/12/2017
Perioperative care	13/12/2017
Peripheral arterial disease: diagnosis and management (standing committee update)	14/12/2017
Care and support of older people with learning disabilities	15/12/2017
Avelumab for merkel cell carcinoma [ID1102]	18/12/2017
Eribulin for treating locally advanced or metastatic breast cancer after one prior chemotherapy regimen [ID1072]	18/12/2017
Neuropad for detecting early diabetic peripheral neuropathy	20/12/2017
Tinnitus	21/12/2017
Mosaicplasty for symptomatic articular cartilage defects of the knee	22/12/2017
Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina	22/12/2017
Eating disorders	08/01/2018
Black, Asian and other minority ethnic groups: promoting health and preventing premature mortality	08/01/2018
Hearing loss in adults: assessment and management	12/01/2018

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