

NICE Update Bulletin February 2016 issued Wednesday February 24th 2016

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<u>Type</u>	<u>Guidance title and reference number</u>
Technology Appraisals (TAs)	<p><u>TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis TA383</u></p> <p><u>1 Recommendations</u></p> <p>1.1 Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop.</p> <p>1.2 Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs.</p> <p>1.3 The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen.</p> <p>1.4 The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as:</p> <ul style="list-style-type: none"> • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. <p>1.5 Treatment with another tumour necrosis factor (TNF) -alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.</p> <p>1.6 When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate.</p> <p><u>The technology</u></p> <p>Adalimumab (Humira), certolizumab pegol (Cimzia), etanercept (Enbrel), golimumab (Simponi), and infliximab (Remicade, Merck Sharp & Dohme; Inflectra, Hospira; Remsima, Napp) inhibit the pro-inflammatory cytokine, tumour necrosis factor (TNF) -alpha. TNF-alpha inhibitors may modify the inflammatory process of the disease. Adalimumab, certolizumab pegol, golimumab and infliximab are monoclonal antibodies, and etanercept is a recombinant human TNF-receptor fusion protein.</p> <p><u>Financial factors</u></p> <p>Populating the resource impact template with the default values gives a net increase in spend of £1,005K for NEW Devon CCG and £316K for SDT CCG without discounts applied.</p>

[Nivolumab for treating advanced \(unresectable or metastatic\) melanoma TA384](#)

1 Recommendations

1.1 Nivolumab as monotherapy **is recommended**, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults.

The technology

Nivolumab (Opdivo) is a human monoclonal antibody (immunoglobulin G4) that blocks the programmed cell death-1 receptor (PD-1). This receptor is part of the immune checkpoint pathway, and blocking its activity may promote an anti-tumour immune response. Nivolumab has a marketing authorisation as monotherapy 'for treating advanced (unresectable or metastatic) melanoma in adults'. It is administered intravenously over 60 minutes at a dose of 3 mg/kg every 2 weeks. The summary of product characteristics recommends that 'treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated'.

Financial factors

The acquisition cost of nivolumab is £439 per 4 ml (40 mg) vial and £1,097 per 10 ml (100 mg) vial (excluding VAT; company's submission). Costs may vary in different settings because of negotiated procurement discounts.

No resource impact report or costing template was available on the NICE website at the time of writing.

[Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia TA385](#)

1 Recommendations

1.1 This guidance should be used with NICE's guidelines on cardiovascular disease: risk assessment and reduction, including lipid modification and familial hypercholesterolaemia: identification and management.

1.2 **Ezetimibe monotherapy is recommended as an option** for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults in whom initial statin therapy is contraindicated.

1.3 Ezetimibe monotherapy is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults who cannot tolerate statin therapy (as defined in section 1.6).

1.4 Ezetimibe, co-administered with initial statin therapy, is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults who have started statin therapy when:

- serum total or low-density lipoprotein (LDL) cholesterol concentration is not appropriately controlled (as defined in section 1.7) either after appropriate dose titration of initial statin therapy or because dose titration is limited by intolerance to the initial statin therapy (as defined in section 1.6) and
- a change from initial statin therapy to an alternative statin is being considered.

1.5 When prescribing ezetimibe co-administered with a statin, ezetimibe should be prescribed on the basis of lowest acquisition cost.

1.6 For the purposes of this guidance, intolerance to initial statin therapy is defined as the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy.

1.7 For the purposes of this guidance, appropriate control of cholesterol concentrations should be based on individual risk assessment according to national guidance on managing cardiovascular disease in the relevant populations.

The technology

Ezetimibe (Ezetrol) is a cholesterol-absorption inhibitor that blocks the intestinal absorption of dietary and biliary cholesterol and related plant sterols, without affecting the

	<p>uptake of triglycerides or fat-soluble vitamins. Because of this mechanism of action, ezetimibe can be combined with a statin to provide either a complementary or an alternative mode of cholesterol reduction.</p> <p><u>Financial factors</u></p> <p>The NICE resource impact report states that no resource impact is anticipated because the recommendations have not significantly changed from the previous NICE guidance.</p>
<p>Highly specialized technology guidance (HSTs)</p>	<p>None published so far this month</p>
<p>NICE Guidelines (NGs)</p>	<p><u>Epilepsies: diagnosis and management CG137 (updated)</u></p> <p>In February 2016, NICE updated this guideline to link to the Medicines and Healthcare Products Regulatory Agency's (MHRA) toolkit to ensure female patients are better informed about the risks of taking valproate during pregnancy</p> <p><u>Bipolar disorder: assessment and management CG185 (updated)</u></p> <p>In February 2016, NICE updated this guideline to link to the Medicines and Healthcare Products Regulatory Agency's (MHRA) toolkit to ensure female patients are better informed about the risks of taking valproate during pregnancy.</p> <p><u>Skin cancer prevention PH32 (Updated)</u></p> <p>This guidance was partially updated in February 2016 by the NICE guideline on sun exposure: risks and benefits.</p> <p><u>Attention deficit hyperactivity disorder: diagnosis and management CG72 (updated)</u></p> <p>In February 2016, recommendations about dietary advice were updated.</p> <p><u>Tuberculosis NG33 (Update)</u></p> <p>This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It aims to improve ways of finding people who have TB in the community and recommends that everyone under 65 with latent TB should be treated. It describes how TB services should be organised, including the role of the TB control board. Populating the NICE resource impact template with default values gives an increase in expenditure of £29K for NEW Devon CCG and £9K for SDT CCG</p> <p><u>Sunlight exposure: risks and benefits NG34</u></p> <p><u>Background</u></p> <p>Communicating the risks and benefits of sunlight exposure is challenging. On the one hand, people have been advised to protect their skin from the sun to avoid skin cancer. On the other hand, they have been advised to expose themselves to sunlight to ensure that they get enough vitamin D. Unless carefully interpreted, the evidence on the role of sunlight in preventing low vitamin D status can conflict with sun protection messages.</p> <p>Between October and March in the UK, sunlight contains very little of the ultraviolet B (UVB) wavelength the skin needs to make vitamin D. So people rely on body stores from sunlight exposure in the summer and dietary sources to maintain vitamin D levels. Low vitamin D status has been associated with musculoskeletal conditions – rickets, osteomalacia, falls and lack of muscle strength and function (SACN update on vitamin D – 2007).</p> <p><u>Recommendations</u></p> <p>This guideline includes recommendations on:</p> <ul style="list-style-type: none"> • At-risk groups • Message content

- Mass media campaigns
- Local strategic approach

Financial factors

Implementing NICE's guideline may result in the following benefits and savings. Fewer people with skin cancer caused by ultraviolet exposure. Treating someone with malignant melanoma skin cancer costs the NHS on average £2,600, however around 10% of people diagnosed progress to unresectable melanoma and therefore may receive chemotherapy. Treatment with chemotherapy at this stage of their disease may cost up to £38,000 per patient per year.

[Myeloma: diagnosis and management NG35](#)

Background

Myeloma is a malignancy of the plasma cells that normally produce immunoglobulin. It affects multiple organs and systems, including the bones, kidneys, blood and immune systems. Myeloma is the seventeenth most common cancer in the UK. It occurs more frequently in men and in people of African–Caribbean family origin. Diagnosis is often delayed because the symptoms are not specific to myeloma, and this leads to significant early morbidity and mortality. Myeloma management is complex and challenging. Effective treatments have been developed over the past 15 years, and although myeloma is still incurable these treatments have led to improvements in overall survival and quality of life. However, myeloma treatment increasingly involves expensive drugs and frequent hospital visits.

Recommendations

The recommendations cover:

- 1.1 Communication and support
- 1.2 Laboratory investigations
- 1.3 Imaging investigations
- 1.4 Service organisation
- 1.5 Managing newly diagnosed myeloma
- 1.6 Managing acute renal disease caused by myeloma
- 1.7 Preventing and managing bone disease
- 1.8 Preventing and managing complications
- 1.9 Monitoring
- 1.10 Managing relapsed myeloma

Financial factors

Myeloma services are commissioned by clinical commissioning groups and NHS England. Providers are NHS hospital trusts.

The NICE resource impact report focuses on the recommendations that will consider to have the greatest resource impact nationally, and therefore need the most additional resources to implement or that can potentially generate the biggest savings. They are:

- Consider whole-body MRI as first-line imaging.
- Consider whole-body low-dose CT if MRI is unsuitable.
- Only consider skeletal survey if both MRI and CT are unsuitable.

[Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over NG36](#)

Background

Upper aerodigestive tract cancers are found at various sites in the airways of the head and neck: the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx and nasal

sinuses. The majority are squamous cell cancers. The major risk factors for upper aerodigestive tract squamous cell cancer in the UK are tobacco smoking and alcohol consumption.

Recommendations

1.1 Information and support

1.2 Investigation

1.3 Treatment of early stage disease

1.4 Treatment of advanced disease

1.5 HPV-related disease

1.6 Less common upper aerodigestive tract cancers

1.7 Optimising rehabilitation and function

1.8 Follow-up of people with cancer of the upper aerodigestive tract and management of osteoradionecrosis

Financial factors

Cancer of the upper aerodigestive tract services are commissioned by NHS England, and provided by secondary and tertiary care providers. The NICE resource impact report states that there are no significant costs anticipated from this guideline. However the patient pathway may change because of the recommendations and some savings may be achieved.

[Fractures \(complex\): assessment and management NG37](#)

Background

Complex fractures make up the minority of the 1.8 million fractures that occur in England each year, but are associated with considerable morbidity and are a large burden on healthcare resources. The treatment of complex fractures is often complicated and usually involves multiple healthcare professionals and specialists. This guideline covers the triage, initial and acute stage assessment and management, imaging, referral to specialist care and treatment of complex fractures in children (under 16s) and adults (16 or over).

Recommendations

This guideline includes recommendations on:

- managing pelvic fractures and open fractures in pre-hospital settings
- destination for people with suspected fractures
- assessing and managing vascular injury in hospital settings
- managing pelvic fractures and open fractures in hospital settings
- management of pilon and intra-articular distal tibia fractures in hospital settings
- documentation, and information and support for patients, family members and carers

Financial factors

The NICE resource impact report identified the following as areas of potential cost

- providing airway management in pre-hospital settings
- additional use of CT or MRI for first-line imaging for spinal injury assessment and non-complex fracture
- providing a definitive written report of emergency department X-rays of suspected fractures before the person is discharged from the emergency department.

Multiple areas of potential savings were also identified.

[Fractures \(non-complex\): assessment and management NG38](#)

Background

The annual incidence of fractures in Britain is about 3.6% and the lifetime prevalence nearly 40%. Most of the 1.8 million fractures that occur in England each year are non-complex, and include a wide range of injuries over the complete age range from infancy to old age. Many different bones can be involved and the mechanisms of injury are many and varied. The range of treatment options is also wide. Because of this, non-complex fractures present an enormous challenge to the NHS. There is a need to achieve a balance between making sure that injuries needing treatment are not missed and treatment is avoided for injuries that are likely to get better on their own.

Recommendations

This guideline includes recommendations on:

- 1.1 Initial pain management and immobilisation
- 1.2 Acute stage assessment and diagnostic imaging
- 1.3 Management in the emergency department
- 1.4 Ongoing orthopaedic management
- 1.5 Documentation
- 1.6 Information and support for patients, family members and carers
- 1.7 Non-accidental injury
- 1.8 Training and skills

[Major trauma: assessment and initial management NG39](#)

Background

In its 2010 report Major trauma care in England the National Audit Office estimated that there are 20,000 cases of major trauma per year in England. Each year 5,400 people die of their injuries and many others sustain permanent disability. Regional trauma networks were developed across England from April 2012. Within these networks major trauma centres provide specialised care for patients with multiple, complex and serious major trauma injuries, working closely with local trauma units.

Recommendations

This guideline includes recommendations on:

- 1.1 Immediate destination after injury
- 1.2 Airway management in pre-hospital and hospital settings
- 1.3 Management of chest trauma in pre-hospital settings
- 1.4 Management of chest trauma in hospital settings
- 1.5 Management of haemorrhage in pre-hospital and hospital settings
- 1.6 Reducing heat loss in pre-hospital and hospital settings
- 1.7 Pain management in pre-hospital and hospital settings
- 1.8 Documentation in pre-hospital and hospital settings
- 1.9 Information and support for patients, family members and carers
- 1.10 Training and skills

Financial factors

For each patient with an ISS (injury severity score) higher than 8, there is an extra payment of £1,500 for major trauma centres registered with TARN (Trauma Audit and Research Network).

[Major trauma: service delivery NG40](#)

Background

According to the National Audit Office's 2010 report Major trauma care in England, 'There is unacceptable variation in major trauma care in England depending upon where

and when people are treated. Care for patients who have suffered major trauma, for example following a road accident or a fall, has not significantly improved in the past 20 years despite numerous reports identifying poor practice, and services are not being delivered efficiently or effectively.' Since then regional trauma networks have been developed across England. Within these networks major trauma centres provide specialised care for patients with multiple, complex and serious major trauma injuries, working closely with local trauma units. This guideline, together with the NICE guidelines on non-complex fractures, complex fractures, major trauma and spinal injury, aims to address areas of uncertainty in the delivery of trauma services.

Recommendations

This guideline includes recommendations on:

- 1.1 Pre-hospital triage
- 1.2 Transferring patients with major trauma
- 1.3 Pre-alert procedures
- 1.4 Procedures for receiving patients in trauma units and major trauma centres
- 1.5 Transfer between emergency departments
- 1.6 Organisation of hospital major trauma services
- 1.7 Documentation
- 1.8 Monitoring and audit
- 1.9 Information and support for patients, family members and carers
- 1.10 Training and skills
- 1.11 Access to major trauma services

[Spinal injury: assessment and initial management NG41](#)

Background

Spinal injury usually involves a fracture of the spinal column, which sometimes leads to spinal cord injury. The main causes of spinal injury are road traffic collisions, falls, violent attacks, sporting injuries and domestic incidents. Although spinal injury affects all ages, young and middle-aged men and older women tend to be the populations at highest risk. Approximately 1,000 people sustain a new spinal cord injury each year in the UK. These injuries are associated with serious neurological damage and can result in paraplegia, tetraplegia or death. Currently there are no 'cures' for spinal cord injury and in the UK there are 40,000 people living with long-term disabilities as a result of such injuries.

Recommendations

This guideline includes recommendations on:

- 1.1 Assessment and management in pre-hospital settings
- 1.2 Pain management in pre-hospital and hospital settings
- 1.3 Immediate destination after injury
- 1.4 Emergency department assessment and management
- 1.5 Diagnostic imaging
- 1.6 Communication with tertiary services
- 1.7 Early management in the emergency department after traumatic spinal cord injury
- 1.8 Information and support for patients, family members and carers
- 1.9 Documentation in pre-hospital and hospital settings
- 1.10 Training and skills

[Motor neurone disease: assessment and management NG42](#)

Background

Motor neurone disease (MND) is a neurodegenerative condition that affects the brain

and spinal cord. MND is characterised by the degeneration of primarily motor neurones, leading to muscle weakness. The presentation of the disease varies and can be as muscle weakness, wasting, cramps and stiffness of arms and/or legs; problems with speech and/or swallowing or, more rarely, with breathing problems. As the disease progresses, the pattern of symptoms and signs becomes similar, with increasing muscle weakness in the person's arms and legs, problems swallowing and communicating and weakness of the muscles used for breathing, which ultimately leads to death. Most people die within 2–3 years of developing symptoms, but 25% are alive at 5 years and 5–10% at 10 years.

Recommendations

This guideline includes recommendations on:

- 1.1 Recognition and referral
- 1.2 Information and support at diagnosis
- 1.3 Cognitive assessments
- 1.4 Prognostic factors
- 1.5 Organisation of care
- 1.6 Psychological and social care support
- 1.7 Planning for end of life
- 1.8 Managing symptoms
- 1.9 Equipment and adaptations to aid activities of daily living and mobility
- 1.10 Nutrition and gastrostomy
- 1.11 Communication
- 1.12 Respiratory function and respiratory symptoms
- 1.13 Cough effectiveness
- 1.14 Non-invasive ventilation

Financial factors

The NICE resource impact report states that implementation of this guideline may increase costs depending on current services however this should enable people with MND to be better supported and may reduce unplanned admissions for people with MND.

[Transition from children's to adults' services for young people using health or social care services NG43](#)

This guideline covers both health and social care services. It aims to improve the planning and delivery of care, and young people's experience as they move from children's to adults' services. It focuses on all young people aged up to 25 who are going through a planned transition, including those who have mental health problems, are disabled or who are looked after. There is a wealth of policy and guidance on agreed principles in respect of good transitional care, but there is also evidence that these principles are often not reflected in practice.

This guideline includes recommendations on:

- 1.1 Overarching principles
- 1.2 Transition planning
- 1.3 Support before transfer
- 1.4 Support after transfer
- 1.5 Supporting infrastructure

Financial factors

The NICE resource impact report states that it is anticipated that implementing the recommendations in the guidance will be cost saving, over the long term, to the NHS and Local Authorities. As young people should not fall between services, there is a

<p>Interventional Procedures Guidance (IPGs)</p>	<p>reduced risk that they will have a crisis and require significant interventions in later life.</p> <p><u>Angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction IPG546</u></p> <p><u>Recommendations</u></p> <p>1.1 Current evidence on the safety and efficacy of angioplasty and stenting to treat peripheral arterial disease causing refractory erectile dysfunction is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.</p> <p>1.2 Further research should provide clear details of patient selection. Efficacy outcomes should include procedural success (as measured by arterial imaging and blood-flow measurement), validated scoring systems of erectile dysfunction, and the duration of treatment effect. All complications should be reported. NICE may update the guidance on publication of further evidence.</p> <p><u>The procedure</u></p> <p>Angioplasty and stenting of atherosclerosis in the small arteries distal to the internal iliac arteries aim to offer a less invasive alternative to open surgical revascularisation to patients with arteriogenic erectile dysfunction (ED) that is refractory to standard treatments.</p> <p><u>Endovascular aneurysm sealing for abdominal aortic aneurysm IPG547</u></p> <p><u>Recommendations</u></p> <p>1.1 Current evidence on the safety and efficacy of endovascular aneurysm sealing for abdominal aortic aneurysm is adequate in the short term but there are uncertainties about safety and efficacy in the longer term. 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 do endovascular aneurysm sealing for abdominal aortic aneurysm should:</p> <ul style="list-style-type: none"> •Inform the clinical governance leads in their NHS trusts. •Ensure that patients understand the uncertainties about the procedure's long-term safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. <p>1.3 Clinicians should enter details about all patients having endovascular aneurysm sealing for abdominal aortic aneurysm onto the National Vascular Registry.</p> <p>1.4 NICE encourages further research on this procedure in the form of controlled clinical trials, observational studies and analysis of registry data. Details about patient selection, including anatomical details, should be clearly documented. Research should compare the procedure with conventional stent graft endovascular aneurysm repair. All complications should be reported. Long-term outcomes should be described as data become available. NICE may update the guidance on publication of further evidence</p> <p><u>The procedure</u></p> <p>Endovascular aneurysm sealing is a new approach to standard endovascular aneurysm repair (EVAR). It uses a polymer filling to form a rubbery cast within the aneurysm sac, which excludes it from the circulation. The aim is to stabilise the stent graft position and reduce the rate of endoleaks and repeat interventions.</p> <p><u>Mechanical clot retrieval for treating acute ischaemic stroke IPG548</u></p> <p><u>1 Recommendations</u></p> <p>1.1 Current evidence on the safety and efficacy of mechanical clot retrieval for treating acute ischaemic stroke is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.</p> <p>1.2 Selection of patients for mechanical clot retrieval for treating acute ischaemic stroke</p>
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	<p>should be done by clinicians experienced in the use of thrombolysis for stroke and in interpretation of relevant imaging. The procedure should only be carried out by appropriately trained specialists with regular experience in intracranial endovascular interventions, with appropriate facilities and neuroscience support.</p> <p><u>The procedure</u></p> <p>Several types of device and different techniques have been used for clot retrieval. Most recent clinical trial evidence is based on the use of stent retrievers, which are currently the most commonly used type of device. The stent retriever is a self-expanding metal mesh tube that is introduced through a catheter and partially deployed within the clot. The stent retriever traps the clot within its mesh and is then withdrawn through the catheter.</p> <p><u>Normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death IPG549</u></p> <p><u>1 Recommendations</u></p> <p>1.1 Current evidence on the efficacy of normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death shows that the procedure extends preservation times compared with conventional cold storage. The evidence on safety is adequate in the short term. Therefore, this procedure may be used with standard arrangements for clinical governance and audit. The usual consent procedures for organ donation and implantation must also be followed.</p> <p>1.2 NICE encourages further research into normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death. Outcomes should include primary graft function, graft function in the long term and device-related complications.</p> <p><u>The procedure</u></p> <p>Normothermic extracorporeal preservation aims to keep the donor's heart beating outside the body, using a perfusion machine that delivers warm oxygenated blood supplemented with catecholamine, nutrients and electrolytes. This technique aims to decrease the amount of damage that occurs to the heart after removal, by reducing the rate of tissue deterioration compared with conventional cold ischaemic storage.</p>
<p>Medical Technologies Guidance</p>	<p>None published so far this month</p>
<p>Diagnostics Guidance</p>	<p><u>Tests for rapidly identifying bloodstream bacteria and fungi (LightCycler SeptiFast Test MGRADE, SepsiTest and IRIDICA BAC BSI assay) DG20</u></p> <p><u>Recommendation</u></p> <p>There is currently insufficient evidence to recommend the routine adoption in the NHS of the LightCycler SeptiFast Test MGRADE, SepsiTest and IRIDICA BAC BSI assay for rapidly identifying bloodstream bacteria and fungi. The tests show promise and further research to provide robust evidence is encouraged, particularly to demonstrate the value of using the test results in clinical decision-making</p> <p><u>Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system) DG21</u></p> <p><u>1 Recommendations</u></p> <p>1.1 The MiniMed Paradigm Veo system is recommended as an option for managing blood glucose levels in people with type 1 diabetes only if:</p> <ul style="list-style-type: none"> •they have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion and •the company arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system. <p>1.2 The MiniMed Paradigm Veo system should be used under the supervision of a trained multidisciplinary team who are experienced in continuous subcutaneous insulin</p>

infusion and continuous glucose monitoring for managing type 1 diabetes only if the person or their carer:

- agrees to use the sensors for at least 70% of the time
- understands how to use it and is physically able to use the system and
- agrees to use the system while having a structured education programme on diet and lifestyle, and counselling.

1.3 People who start to use the MiniMed Paradigm Veo system should only continue to use it if they have a decrease in the number of hypoglycaemic episodes that is sustained. Appropriate targets for such improvements should be set.

1.4 The Vibe and G4 PLATINUM CGM system shows promise but there is currently insufficient evidence to support its routine adoption in the NHS for managing blood glucose levels in people with type 1 diabetes. Robust evidence is needed to show the clinical effectiveness of using the technology in practice.

1.5 People with type 1 diabetes who are currently provided with the MiniMed Paradigm Veo system or the Vibe and G4 PLATINUM CGM system by the NHS for clinical indications that are not recommended in this NICE guidance should be able to continue using them until they and their NHS clinician consider it appropriate to stop.

The Technology

The integrated sensor-augmented pump therapy systems, which combine continuous glucose monitoring with continuous subcutaneous insulin infusion, are intended to help people with type 1 diabetes manage their blood glucose levels. The systems are designed to continuously measure interstitial glucose levels (every few minutes) and allow immediate real-time adjustment of insulin therapy. The systems produce alerts if the glucose levels become too high or too low. The MiniMed Paradigm Veo system can also automatically suspend insulin delivery if there is no response to a low-glucose warning.

Financial factors

The NICE resource impact report states that the guidance might have resource implications at a local level as a result of variation in clinical practice across the country. Therefore, NICE encourage organisations to evaluate their own practice against the recommendations in the NICE guidance and assess costs locally.

[Therapeutic monitoring of TNF-alpha inhibitors in Crohn's disease \(LISA-TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits\) DG22](#)

Recommendations

1.1 The LISA-TRACKER, IDKmonitor and Promonitor enzyme-linked immunosorbent assay (ELISA) kits show promise for therapeutic monitoring of tumour necrosis factor (TNF)-alpha inhibitors in people with Crohn's disease but **there is insufficient evidence to recommend their routine adoption across the NHS.**

1.2 Laboratories currently using LISA-TRACKER, IDKmonitor and Promonitor ELISA kits for therapeutic monitoring of TNF-alpha inhibitors in people with Crohn's disease whose disease loses response to TNF-alpha inhibitors should:

- have specialist expertise in immunoassay analysis, including an understanding of the technical factors that may affect the results of the ELISA kits
- work closely with the treating or referring clinician, in a network, to ensure appropriate use of the tests and interpretation of the results
- work with clinicians to collect data through a prospective study, for local audit, or for submission to an existing registry. (The IBD Registry is being adapted to receive data on TNF-alpha inhibitor levels and antibodies against TNF-alpha inhibitors. When this facility is available, all data should be entered onto the database.

1.3 Further research is recommended on the clinical and cost effectiveness of using LISA-TRACKER, IDKmonitor and Promonitor ELISA kits for therapeutic monitoring of TNF-alpha inhibitors in people with Crohn's disease whose disease responds to

	<p>treatment with TNF-alpha inhibitors.</p> <p><u>The Technology</u></p> <p>The LISA-TRACKER, IDKmonitor, and Promonitor enzyme-linked immunosorbent assay (ELISA) kits are intended to be used for measuring the levels of tumour necrosis factor (TNF)-alpha inhibitors and antibodies against TNF-alpha inhibitors in the blood of people having TNF-alpha-inhibitor treatment for Crohn's disease.</p>
<p>NICE Quality Standards</p>	<p><u>Chronic heart failure in adults QS9 (updated)</u></p> <p>This quality standard covers the assessment, diagnosis and management of chronic heart failure in adults (18 and older). The diagnosis and management of acute heart failure is covered by NICE's quality standard on acute heart failure in adults.</p> <p><u>Chronic obstructive pulmonary disease in adults QS10 (updated)</u></p> <p>This quality standard covers the assessment, diagnosis and management of chronic obstructive pulmonary disease (COPD). It does not cover prevention, screening or case finding.</p> <p><u>Healthcare-associated infections QS113</u></p> <p>This quality standard covers organisational factors in preventing and controlling healthcare-associated infections in secondary care settings. Organisational factors include management arrangements, policies, procedures, monitoring, evaluation, audit and accountability.</p> <p><u>Irritable bowel syndrome in adults QS114</u></p> <p>This quality standard covers the diagnosis and management of irritable bowel syndrome in adults. It does not cover other gastrointestinal disorders such as non-ulcer dyspepsia, coeliac disease and inflammatory bowel disease.</p> <p><u>Antenatal and postnatal mental health QS115</u></p> <p>This quality standard covers the recognition, assessment, care and treatment of mental health problems in women during pregnancy and the postnatal period (up to 1 year after childbirth). It also includes providing pre-conception support and advice for women with an existing mental health problem who might become pregnant, and the organisation of mental health services needed in pregnancy and the postnatal period.</p>
<p>Commissioning Guides</p>	<p>None published so far this month</p>
<p>Public health briefings for local government</p>	<p>None published so far this month</p>

Current NICE consultations with links and start and finish dates for stakeholders to make contribution

Title / link	Start date of consultation	End date of consultation
Mental wellbeing and independence for older people : Topic engagement	10/02/2016	24/02/2016
Psychosis and schizophrenia in children and young people (standing committee update) : Addendum consultation	28/04/2016	25/02/2016
Hypercholesterolaemia (primary), dyslipidaemia (mixed) - evolocumab [ID765] : Appraisal consultation : 2	05/02/2016	26/02/2016
Crohn's disease (standing committee update) : Addendum consultation	01/02/2016	29/02/2016
Hypercholesterolaemia (primary) and dyslipidaemia (mixed) - alirocumab [ID779] : Appraisal consultation	08/02/2016	29/02/2016
Blood transfusion : Topic engagement	17/02/2016	02/03/2016
Oral health promotion in the community : Topic engagement	17/02/2016	02/03/2016
Dementia - assessment, management and support for people living with dementia and their carers : Addendum consultation	08/02/2016	07/03/2016
Lysosomal acid lipase deficiency - sebelipase alfa [ID737] : Evaluation consultation : 1	11/02/2016	10/03/2016
Non-Hodgkin's lymphoma : Draft guidance consultation	29/01/2016	11/03/2016
Hidradenitis suppurativa (moderate, severe) - adalimumab [ID812] : Appraisal consultation : 1	12/02/2016	11/03/2016
Diabetes in children and young people : Quality Standard consultation	15/02/2016	14/03/2016
Microstructural scaffold (patch) insertion without autologous cell implantation for repairing symptomatic chondral knee defects : Interventional procedure consultation	19/02/2016	18/03/2016
Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting : Interventional procedure consultation	19/02/2016	18/03/2016
Ultrasound-guided percutaneous radiofrequency ablation for benign or inoperable thyroid nodules : Interventional procedure consultation	19/02/2016	18/03/2016
Harmful sexual behaviour among children and young people : Draft guidance consultation	24/02/2016	06/04/2016

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