NHS Devon

NICE Update Bulletin: February 2024

This bulletin includes details of the following new and updated NICE guidance – click on the titles below for further details:

1. **Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations TA952**
2. **Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer TA951**
3. **Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over TA950**
4. **Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over TA949**
5. **Tuberculosis NG33 (UPDATE)**
6. **Endoscopic sleeve gastroplasty for obesity IPG783**
7. **Digitally enabled therapies for adults with depression: early value assessment HTE8 (UPDATE)**
8. **Current NICE Consultations**

Technology Appraisals (TAs)

Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations TA952

Recommendations

Talazoparib is **recommended**, within its marketing authorisation, for treating HER2-negative, locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations in adults who have had:

- an anthracycline or a taxane, or both, unless these treatments are not suitable, and
- endocrine therapy if they have hormone receptor (HR)-positive breast cancer, unless this is not suitable.

  Talazoparib is only recommended if the company provides it according to the commercial arrangement

The Technology

Breast cancer arises from the tissues of the ducts or lobules of the breast. The cancer is said to be 'advanced' if it has spread to other parts of the body such as the bones, liver, and lungs (metastatic cancer), or if it has grown directly into nearby tissues and cannot be completely removed by surgery (locally advanced).

Current treatments for advanced breast cancer aim to relieve symptoms, prolong survival and maintain a good quality of life with minimal adverse events. Treatment depends on whether the cancer cells have HER2 and hormone positive receptors, the extent of the disease and previous treatments.

CG81 recommends systemic sequential therapy for most patients with advanced breast cancer having chemotherapy. Where anthracyclines are not suitable (because they are contraindicated or because of prior anthracycline treatment) the sequencing should follow: single-agent docetaxel (taxane) as a first line treatment, single-agent vinorelbine or capecitabine as second line treatment and single-agent capecitabine or vinorelbine (whichever was not used as second line treatment) as third line treatment. In addition, TA423 recommends eribulin as an option for treating locally advanced or metastatic breast cancer when it has progressed after at least two chemotherapy regimens.

Financial Factors

This technology is commissioned by NHS England.

This technology is a new treatment option and is not expected to displace existing therapies but delay their use. NICE estimate that in Devon, 7 people will receive talazoparib each year.

Talazoparib is orally administered by the patient. It is anticipated that around 50 % of talazoparib will be dispensed in secondary care and 50 % via homecare.

The company has a commercial arrangement. This makes talazoparib available to the NHS with a discount.

Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer TA951

Recommendations

Olaparib with abiraterone and prednisone or prednisolone is **recommended**, within its marketing authorisation, as an option for untreated hormone-relapsed metastatic prostate cancer in adults who cannot have or do not want chemotherapy. It is only recommended if the company provides it according to the commercial arrangements.

The Technology

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer.

Prostate cancer is the most common cancer in men and the incidence increases with age. It is more common in those who have a family history of prostate cancer, in black African men compared to white men and is least common in Asian men.

NG131 recommends radical treatment (surgery and radiotherapy) and androgen deprivation therapy (ADT) for the treatment of local and locally advanced prostate cancer. The aim of ADT is to suppress androgen levels and cause prostate cancer cell death. This can be achieved by orchidectomy or by hormonal treatments such as luteinising hormone-releasing hormone agonist and antagonist and androgen receptor inhibitor.

For newly diagnosed metastatic prostate cancer cases, docetaxel (chemotherapy) can be offered within 12 weeks of starting ADT. In other metastatic cases, ADT is recommended initially.

Prostate cancer may initially be responsive to hormone therapy but eventually become resistant to it. This is known as hormone-relapsed prostate cancer and refers to prostate cancer which has progressed following ADT.

Hormone-relapsed prostate cancer is characterised by a rise in prostate-specific antigen (PSA) despite ADT.

NICE has published a number of technology appraisals with recommendations for the treatment of prostate cancer: TA377, TA387, TA101, TA259, TA316, TA391, TA412

Financial Factors

This technology is commissioned by NHS England.

Clinical trial evidence shows that olaparib with abiraterone and prednisone or prednisolone increases how long people live and how long they have before their cancer gets worse compared with abiraterone alone.

The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. Therefore, olaparib with abiraterone and prednisone or prednisolone is recommended.

NICE estimate that in Devon, 58 people will be eligible for treatment and that 23 of these people will receive olaparib with abiraterone and prednisolone each year.

The company has a commercial arrangement. This makes olaparib with abiraterone available to the NHS with a discount.

Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over TA950

Recommendations

Nivolumab–relatlimab is **recommended** as an option for untreated advanced (unresectable or metastatic) melanoma in people 12 years and over, only if:

- nivolumab–relatlimab is stopped after 2 years of treatment, or earlier if the cancer progresses, and
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with nivolumab–relatlimab that was started in the NHS before this guidance was published. Anyone 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. For children or young people, this decision should be made jointly by the clinician, the child or young person, and their parents or carers.

The Technology

Cutaneous melanoma is a cancer of the skin. In its early stages, melanoma is normally asymptomatic and can often be cured by surgery. However, it can spread to nearby skin and/or lymph nodes (stage 3) or other parts of the body (stage 4). Most melanomas occur in people with pale skin. The risk factors are skin that tends to burn in the sun, having many moles, intermittent sun exposure and sunburn.

Approximately 50% of melanomas harbour activating BRAF mutations. **TA319** recommends ipilimumab as an option for previously untreated unresectable or metastatic melanoma. In addition, **TA366**, **TA384** and **TA400** recommend pembrolizumab (for melanoma that has not previously been treated with ipilimumab), nivolumab, and nivolumab with ipilimumab as treatment options, respectively. NG14 recommends immunotherapy with nivolumab plus ipilimumab.

Pembrolizumab or nivolumab are suitable only when nivolumab plus ipilimumab is unsuitable or unacceptable, for example due to potential toxicity. For people with BRAF mutation positive melanoma, targeted therapies are recommended when immunotherapy is contraindicated or unsuitable. Single agents dabrafenib or vemurafenib are suitable only when combination therapy with binimetinib and trametinib is contraindicated. When targeted therapies and immunotherapy treatment are contraindicated, dacarbazine chemotherapy or best supportive care is recommended.

Financial Factors

This technology is commissioned by NHS England.

NICE do not expect this guidance to have significant impact on resources. This is because the technology is a further treatment option and the overall cost of treatment for this patient group will be similar.

The company has a commercial arrangement. This makes nivolumab–relatlimab available to the NHS with a discount.

Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over TA949

Recommendations

Belumosudil is **recommended**, within its marketing authorisation, for treating chronic graft-versus-host disease in people 12 years and over after 2 or more systemic treatments. It is recommended only if the company provides it according to the commercial arrangement.

The Technology

Graft versus host disease (GVHD) usually occurs after an allogeneic haematopoietic stem cell transplant (HSCT) when donated white T-cells attack the body's own cells. Chronic GVHD (cGVHD) results in fibrotic skin disease, bronchiolitis, salivary and lacrimal gland disease and eosinophilic fasciitis and typically occurs later after a HSCT (whereas acute GVHD usually occurs much sooner after a HSCT).

Manifestations typically appear within the first year after HCT, when immunosuppressive medications are reduced.

cGVHD causes severe morbidity and mortality mainly because of infections resulting from immunodeficiency, as well as damage to organs such as the lungs and liver. People who receive a transplant from a mismatched unrelated donor are more at risk of developing cGVHD. People from a non-white family background are less likely to find a related donor match which results in people from ethnic minority family background being at increased risk of cGVHD. Between 5 and 11% of allograft recipients are expected to develop extensive cGVHD that may require second or subsequent lines of therapy.

In clinical practice, systemic corticosteroids, with or without a calcineurin inhibitor, are used as first line treatment of cGVHD. Second line treatment could be any one treatment from: extracorporeal photophoresis (ECP), imatinib, rituximab, sirolimus, mycophenolate mofetil and if not used at first line, a calcineurin inhibitor.

For those whose disease does not respond adequately to a second line treatment, a third line treatment would be used. This could be any of the treatments that were available but not used at second line. Topical treatments and organ-specific supportive agents, including antibiotics and vaccinations, also have an important role in the effective management of cGVHD.

Bulumosudil is administered orally.

Financial Factors

This technology is commissioned by NHS England.

NICE do not expect this guidance to have a significant impact on resources. This is because the population size is small, with around 65 people eligible each year in England.

The company has a commercial arrangement, (simple discount patient access scheme). This makes belumosudil available to the NHS with a discount.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Tuberculosis NG33 (UPDATE)

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.

February 2024: NICE removed the final bullet of recommendation 1.1.3.10, which said 'have a family history of TB in the past 5 years', to align it with the chapter on tuberculosis in the Green Book.

NICE Rapid COVID-19 Guidelines

None published this month.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Endoscopic sleeve gastroplasty for obesity IPG783

Recommendations

Use endoscopic sleeve gastroplasty as an option to treat obesity in adults with **standard arrangements** in place for clinical governance, consent and audit.

Patient selection, assessment, and monitoring should be done by a multidisciplinary team within a specialist weight management service experienced in managing obesity (see the section on initial assessment and discussions with the multidisciplinary team in the NICE guideline on obesity [**CG189**]).

This procedure should only be done in specialist weight management centres by clinicians with specific training and experience in the procedure.

Details about everyone having endoscopic sleeve gastroplasty for obesity should be submitted into the National Bariatric Surgery Registry.

Evidence on safety shows this procedure is safe in the short and long term. Evidence on efficacy shows that, when combined with lifestyle changes, people with a body mass index (BMI) over 30 kg/m^2 who have the procedure lose weight. Therefore, it can be used with standard arrangements.

The Condition

Obesity is defined as body mass index (BMI) of 30 kg/m^2 or over. The degree of obesity is classified as:

- Obesity class 1 (BMI 30 kg/m^2 to 34.9 kg/m^2
- Obesity class 2 (BMI 35 kg/m^2 to 39.9 kg/m^2) and
- Obesity class 3 (BMI 40 kg/m^2 or more).

CG189 recognises the people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnicity are prone to central adiposity and their cardiometabolic risk occurs as a lower BMI. So, a lower BMI of 27.5 kg/m^2 or above is recommended as the threshold for people in these groups.

Obesity is directly linked to a number of other illnesses including type 2 diabetes, hypertension, gallstones and gastro-oesophageal reflux disease, as well as psychological and psychiatric morbidities. Weight loss reduces the risk of comorbidities and improves long term survival.

CG189 recommends a multicomponent approach involving dietary advice, exercise, lifestyle changes and medication. Bariatric surgery is recommended as an option in some people who have class 3 obesity, or class 2 obesity and other significant disease and have not lost enough weight using other methods. It is also considered at a lower BMI threshold than in other populations in people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnicity.

Surgical procedures for obesity aim to help people to lose weight and to maintain weight loss by restricting the size of the stomach, decreasing he capacity to absorb food, or both. Procedures that reduce the size of the stomach limit the capacity for food intake by producing a feeling of satiety with a smaller ingested volume of food. They include laparoscopic gastric banding and sleeve gastrectomy. Procedures that aim to decrease the capacity to absorb food include biliopancreatic diversion and duodenal switch. People are also advised to modify their eating behaviour by adhering to an explicit postoperative diet advised by specialist dieticians.

The Procedure

Endoscopic sleeve gastroplasty is a minimally invasive transoral endoscopic procedure that reduces the volume of the stomach and may delay gastric emptying. It creates a sensation of fullness and reduces the amount of food that can be eaten at one time.

The procedure is done under general anaesthesia. It may be done as a day case, but most people are kept under observation overnight and discharged the next day. A single or a double channel scope with a procedure-specific endoscopic device attached is passed through the mouth. A series of endoluminal full-thickness suture plications are done along the greater curvature of the stomach (through the gastric wall, extending from the pre-pyloric antrum to the fundus). This involves folding the stomach in on itself and stitching it together, creating a restrictive endoscopic sleeve to reduce the stomach volume by about 70 % to 80 %. There is no resection of the stomach and the procedure may be reversible in the early stages.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

Health Technology Evaluations (HTE)

Digitally enabled therapies for adults with depression: early value assessment HTE8 (UPDATE)

February 2024: The technology Beating the Blues has been removed because it is no longer available to the NHS. This is because the company for the technology, 365 Health Solutions, is no longer trading.

Two digitally enabled therapies **can be used** as treatment options for adults with depression while further evidence is generated on their clinical and cost effectiveness. The therapies should be used with support from a trained practitioner or therapist in NHS Talking Therapies for anxiety and depression services. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval and an NHS Talking Therapies for anxiety and depression digitally enabled therapies assessment from NHS England. The technologies are:

- Deprexis (Ethypharm Digital Therapy)
- Space from Depression (SilverCloud).

NICE Quality Standards

None published this month.

Current NICE Consultations

Title/link	End date of consultation
Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma [Review of TA658] [ID4067]	01/03/2024
Minimally invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus	07/03/2024
Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome [ID3947]	14/03/2024
Methods and processes for including NICE technology appraisal recommendations in guidelines	15/03/2024
Tafamidis for treating transthyretin amyloidosis with cardiomyopathy [ID6327]	19/03/2024
Voxelotor for treating sickle cell disease [ID1403]	19/03/2024
Ivosidenib with azacytidine for untreated acute myeloid leukaemia with an IDH1 R132 mutation [ID6198]	20/03/2024
Working alongside people and communities at NICE: a strategy	27/03/2024