

# NICE Update Bulletin: September 2024

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

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2. [Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer TA1007](#)
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## Technology Appraisals (TAs)

### Trifluridine-tipiracil with bevacizumab for treating metastatic colorectal cancer after 2 systemic treatments TA1008

#### Recommendations

Trifluridine-tipiracil with bevacizumab is **recommended**, within its marketing authorisation, for treating metastatic colorectal cancer in adults who have had 2 lines of treatment (including fluoropyrimidine-, oxaliplatin- and irinotecan- based chemotherapies, antivascular endothelial growth factor or anti-epidermal growth factor receptor treatments). Trifluridine-tipiracil with bevacizumab is only recommended if the company provides trifluridine-tipiracil according to the commercial arrangement.

#### The Technology

Colorectal cancer is a malignant tumour arising from the lining of the large intestine (colon and rectum). Metastatic colorectal cancer refers to disease that has spread beyond the large intestine and nearby lymph nodes. This type of cancer often first spreads to the liver, but metastases may also occur in other parts of the body, including the lungs, brain and bones. Most colorectal cancers are adenocarcinomas, these start in glands that line the insides of the colon and rectum.

Metastatic colorectal cancer treatment aims to prolong survival and improve quality of life. Treatment can involve a combination of surgery, chemotherapy, biological therapy and radiotherapy.

NICE has published the following related guidance:

- [NG151](#) Colorectal cancer
- [TA61](#) guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer
- [TA709](#) Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency.
- [TA405](#) Trifluridine-tipiracil for previously treated metastatic colorectal cancer
- [TA866](#) Regorafenib for previously treated metastatic colorectal cancer
- [TA716](#) Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency
- [TA668](#) Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer

## Financial Factors

This technology is commissioned by NHS England.

The results of a clinical trial show that, compared with trifluridine-tipiracil alone, trifluridine-tipiracil plus bevacizumab increases how long people have before their cancer gets worse and how long they live. The results of an indirect comparison also suggest that trifluridine-tipiracil plus bevacizumab increases how long people have before their cancer gets worse and how long they live compared with regorafenib.

When considering the condition's severity and its effect on quality and length of life, the most likely cost-effectiveness estimates are within the range that NICE normally considers an acceptable use of NHS resources. Therefore, trifluridine-tipiracil plus bevacizumab is recommended.

NICE estimate that at year 5 in Devon, 80 people will be eligible for treatment and that 44 people will receive trifluridine-tipiracil with bevacizumab.

## [Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer TA1007](#)

**This guidance updates and replaces TA611 (published November 2019) when rucaparib for the maintenance treatment of relapsed platinum -sensitive ovarian, fallopian tube or peritoneal cancer was available through the Cancer Drugs Fund.**

## Recommendations

Rucaparib is **recommended**, within its marketing authorisation, as an option for the maintenance treatment of relapsed platinum-sensitive high-grade epithelial, ovarian, fallopian tube or primary peritoneal cancer that has completely or partially responded to platinum-based chemotherapy in adults. Rucaparib is only recommended if the company provides it according to the commercial arrangement.

If people with the condition and their healthcare professional consider rucaparib to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should be taken into account.

## The Technology

Ovarian cancer is a cancerous growth that occurs in the ovary or fallopian tubes. The most common type of ovarian cancer, high-grade serous type, is thought to arise from the peritoneum or fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage 1 to stage 4.

Ovarian cancer may be categorised according to the response to initial platinum chemotherapy as follows:

- Platinum-sensitive (disease responds to platinum-based therapy but relapses after 6 months or more, which can be subdivided into fully and partially platinum-sensitive disease).
- Platinum-resistant (disease which recurs within 6 months of completion of platinum-based chemotherapy)
- Platinum-refractory (does not respond to initial platinum-based chemotherapy)

NICE has published the following related guidance:

- [TA389](#) Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer
- [TA784](#) Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer
- [TA908](#) Olaparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube or peritoneal cancer after 2 or more courses of platinum-based chemotherapy.

## Financial Factors

This technology is commissioned by NHS England.

Standard maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer includes niraparib and olaparib.

The company considers niraparib to be the main comparator for rucaparib. Using NICE's cost comparison methods, rucaparib only needs to provide similar or greater health benefits at similar or lower costs to 1 relevant comparator to be recommended as a treatment option. A cost comparison suggests that rucaparib has similar or lowers cost and similar overall health benefits to niraparib. Therefore, rucaparib is recommended.

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

NICE estimate that at year 5 in Devon, 14 people will be eligible for treatment.

## [Empagliflozin for treating type 2 diabetes in people 10 to 17 years \(terminated appraisal\) TA1006](#)

NICE is **unable to make a recommendation** about the use in the NHS of empagliflozin for treating type 2 diabetes in people aged 10 to 17 years. This is because the company did not provide an evidence submission.

## [Futibatinib for previously treated advanced cholangiocarcinoma with FGFR2 fusion or rearrangement TA1005](#)

### Recommendations

Futibatinib is **recommended**, within its marketing authorisation, as an option for treating locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that has progressed after at least 1 line of systemic treatment in adults. Futibatinib is only recommended if the company provides it according to the commercial arrangement.

### The Technology

Cholangiocarcinoma is cancer of the bile duct. Most people already have advanced cholangiocarcinoma when they are diagnosed because early disease is often asymptomatic. When symptoms occur, they include jaundice, itchy skin, weight loss, abdominal pain, fatigue and fever.

Cholangiocarcinoma can be classified into 3 subtypes, depending on which part of the bile duct the cancer starts in:

1. Intrahepatic cholangiocarcinoma (iCCA) starts in the bile ducts inside the liver
2. Peri-hilar cholangiocarcinoma starts just outside the liver
3. Distal cholangiocarcinoma starts in the bile ducts near the bowel

The overall incidence of cholangiocarcinoma is increasing. Around 10-15% of iCCA will have fusion or rearrangements of fibroblast growth factor receptors (FGFRs). This is less common in other types of cholangiocarcinoma. FGFRs play a role in the growth and spread of the cancer cells.

Surgery is currently the only curative treatment for cholangiocarcinoma. When surgery is not an option, people can be offered systemic chemotherapy. After systemic chemotherapy, British and European guidelines recommend that FGFR inhibitors, such as pemigatinib, are considered for people with FGFR2 alterations. [TA722](#) recommends pemigatinib as an option for treating advanced cholangiocarcinoma with FGFR2 fusion or rearrangement after systemic therapy in adults. Alternatively, people may be offered modified folinic acid, fluorouracil and oxaliplatin (mFOLFOX) in the second line setting.

## Financial Factors

This technology is commissioned by NHS England.

There are no clinical trials directly comparing futibatinib with pemigatinib. An indirect comparison of futibatinib and pemigatinib suggests that they may have similar effectiveness, but this is uncertain. A cost comparison suggests that futibatinib has similar costs to pemigatinib. Therefore, futibatinib is recommended.

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

NICE estimate that in Devon, 1 person will be eligible for treatment.

## Faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion TA1004

### Recommendations

Faricimab is **recommended**, within its marketing authorisation, as an option for treating visual impairment caused by macular oedema after central or branch retinal vein occlusion in adults. It is only recommended if the company provides it according to the commercial arrangement.

If people with the condition and their healthcare professional consider faricimab to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

### The Technology

The macular is the central part of the retina responsible for colour vision and perception of fine detail. Macular oedema refers to the accumulation of fluid within the retina at the macular area, causing persistent swelling, which can lead to severe visual impairment in the affected eye.

Retinal vein occlusion (RVO) is a common cause of reduced vision due to retinal vascular disease. It is classified into central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). In general, visual loss is more severe if the central retinal vein is occluded. Such blockages in the retinal veins increases retinal capillary pressure leading to discharge of blood and plasma into the macula. These changes trigger an increased amount of vascular endothelial growth factor (VEGF), which can increase the growth of new abnormal blood vessels in the retina.

RVO is most common in people aged 60-80. It is associated with risk factors such as arterial hypertension, diabetes, hyperlipidaemia, glaucoma, smoking and a history of certain conditions such as stroke or coagulation disorders.

The impact of vision loss associated with RVO can have a profound effect on vision-related quality of life. Patients may struggle with daily tasks, lose confidence and become increasingly dependant

on family and carers. RVO is also associated with an increase in the risk of vascular causes of death.

The aims of current treatment are to preserve vision and prevent complication. Treatment is usually through anti-VEGF injections or steroid implants injected into the eye. The injections have to be repeated over a period of time to work effectively.

NICE has published the following related guidance:

- [TA229](#) Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion
- [TA283](#) Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion
- [TA305](#) Aflibercept for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion
- [TA409](#) Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion

## Financial Factors

This technology is commissioned by ICBs.

Using NICE's cost comparison methods, if a treatment has similar benefits and costs to a comparator recommended in technology appraisal guidance, it can be recommended as a treatment option.

Evidence from clinical trials shows that faricimab is likely to work as well as aflibercept for people who have not had an anti-VEGF treatment. There is limited evidence for how well faricimab works for people who have had an anti-VEGF treatment. But clinical experts agreed that faricimab is likely to work as well as aflibercept for people who have had an anti-VEGF treatment.

A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept. Therefore, faricimab is recommended as an additional treatment option.

NICE estimate that at year 5 in Devon, 563 people will be eligible for treatment. After discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

## Exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia in people 12 years and over TA1003

### Recommendations

Exagamglogene autotemcel (exa-cel) is **recommended** with **managed access** as an option for treating transfusion-dependent beta-thalassaemia in people 12 years and over:

- when a haematopoietic stem cell transplant (HSCT) is suitable, but a human leukocyte antigen-matched related haematopoietic stem cell donor is not available
- only if the conditions in the managed access agreement for exa-cel are followed.

### The Technology

Thalassaemia is a group of hereditary blood disorders caused by a genetic mutation of the haemoglobin subunit beta (HBB) gene. The condition is characterised by reduced production or absence of healthy red blood cells and haemoglobin in the body, which is used by red blood cells to carry oxygen around the body.

There are two main forms of thalassaemia:

- Alpha-thalassaemia
- Beta-thalassaemia- comprises of several phenotypes with different severity. Beta-thalassaemia major is the most severe type which is transfusion-dependant requiring regular red blood cell (RBC) transfusions. However, people with severe forms of thalassaemia intermedia may also require regular RBC transfusions and therefore, could also be considered 'transfusion-dependant.'

Thalassaemia causes varying degrees of anaemia, leading to symptoms such as tiredness, weakness, shortness of breath and pale skin caused by the lack of haemoglobin. In transfusion-dependant beta-thalassaemia, haemoglobin production is reduced to such a low level that normal growth, skeletal and endocrine development and quality of life can only be achieved by regular red cell transfusions from infancy.

The most severe cases can lead to heart failure from anaemia, liver complications from excess iron due to regular transfusions and pulmonary hypertension or other complications related to thrombotic events.

Transfusion dependant beta-thalassaemia requires lifelong treatment with blood transfusions and medication. The frequency of blood transfusions can vary but is typically every 2-4 weeks. Repeated transfusions are associated with increased risks of allo-immunisation, infections, graft versus host disease, or other serious hazard of transfusion events. In addition, treatment with transfusions causes too much iron to build up in the body. With more severe and prolonged iron overload, heart failure and cardiac arrhythmias can lead to ill health and death and late effects such as liver cirrhosis, portal hypertension and liver failure. Therefore, chelation therapy (medication to

remove excess iron from the body) is also a key component in managing transfusion-dependant beta thalassaemia.

The only potentially curative intervention is a hematopoietic stem cell transplant, but these transplants carry significant risks and are only considered for people under the age of 18 years who have a matching donor.

## Financial Factors

This technology is commissioned by NHS England.

Exa-cel has the potential to be cost effective compared with standard care. But the cost-effectiveness estimates are highly uncertain. This is because of the uncertainty in exa-cel's long-term effects and impact on quality of life and in the outcomes for people on standard care. Some of the most likely cost-effectiveness estimates are higher than what NICE normally considers an acceptable use of NHS resources, even when accounting for exa-cel's potential impact on health inequalities. Therefore, exa-cel is not recommended for routine use in the NHS.

Collecting more data through a managed access agreement may resolve some uncertainty in the evidence. Therefore, exa-cel is recommended for use with managed access.

## [Evinacumab for treating homozygous familial hypercholesterolaemia in people 12 years and over TA1002](#)

## Recommendations

Evinacumab alongside diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies is **recommended**, within its marketing authorisation, as an option for treating homozygous familial hypercholesterolaemia (HoFH) in people 12 years and over. It is only recommended if the company provides it according to the commercial arrangement.

## The Technology

Familial hypercholesterolaemia (FH) is an inherited disorder where the liver is incapable of metabolising or removing excess low-density lipoprotein cholesterol (LDL-C) caused by a genetic defect. This can lead to very high LDL-C levels which increase the risk of premature cardiovascular disease (CVD).

There are two forms of FH:

- Heterozygous FH
- Homozygous FH (HoFH) is much less common than heterozygous FH and is more severe. In HoFH, the inherited gene mutations affecting LDL-C is from both parents (so the individual has 2 genetic mutations).

The signs of HoFH are lumps and bumps around the knuckles or Achilles tendon (caused by cholesterol deposits), yellow cholesterol build-up around the eyes and eyelids, or a pale ring around the iris of the eye. People with HoFH have severe hypercholesterolaemia. Long-term exposure to hypercholesterolaemia greatly accelerates the build-up of fatty deposits (atherosclerosis) in the coronary arteries and all major arteries in the body.

Cholesterol and calcium deposits can also cause supravulvar aortic stenosis, where the aortic valve becomes narrowed and stiff. This leads to signs of heart failure, including breathlessness, chest pain and blackouts. The first major cardiovascular event in people with HoFH frequently occurs in adolescence, with angina and myocardial infarction in early childhood.

If left untreated, people with HoFH typically live to around 18 years old. Treatment for HoFH follows a stepped approach. NICE has published the following related guidance, [CG71](#) (Familial hypercholesterolaemia: identification and management).

## Financial Factors

This technology is commissioned by NHS England.

There are some uncertainties in the cost-effectiveness evidence comparing evinacumab with lomitapide in adults with HoFH. But, overall, there are cost savings with evinacumab compared with lomitapide. This means that, despite the uncertainties in the evidence, evinacumab is a cost-effective use of NHS resources when compared with lomitapide in adults.

The cost-effectiveness evidence in people aged 12-17 years is uncertain. Evinacumab costs more than LDL-C lowering therapies alone. But because LDL-C lowering therapies have limited effectiveness in people with HoFH, there is a high unmet need in young people for effective treatments. Therefore, evinacumab is recommended for the whole population for which it is licensed.

## [Zanubrutinib for treating marginal zone lymphoma after anti-CD20-based treatment TA1001](#)

### Recommendations

Zanubrutinib is **recommended**, within its marketing authorisation, as an option for treating marginal zone lymphoma in adults who have had at least 1 anti-CD20-based treatment. It is only recommended if the company provides it according to the commercial arrangement.

### The Technology

Lymphomas are cancers of the lymphatic system, which is part of the body's immune system. They are divided into Hodgkin and non-Hodgkin lymphomas.

Non-Hodgkin lymphomas are a heterogeneous group of conditions ranging from 'indolent' (low-grade) to 'aggressive' (high-grade) depending on the rate at which the abnormal lymphocytes

divide. Indolent lymphomas are slow growing, with long median survival times but are less likely to be cured by treatment.

Marginal zone lymphoma is a type of indolent non-Hodgkin lymphoma that develops from B lymphocytes that are normally found at the edge of areas of lymph node tissue. Mucosa associated lymphoid tissue (MALT) lymphoma is the most common type of marginal zone lymphoma and it most commonly affects the stomach. Nodal marginal zone lymphoma starts in the lymph nodes and splenic marginal zone lymphoma starts in the spleen but can also be found in the bloodstream.

Released disease refers to cancer that returns, while refractory disease refers to cancer that stops responding to treatment.

There are no NICE recommended treatment options for marginal zone lymphoma.

### Financial Factors

This technology is commissioned by NHS England.

Zanubrutinib is an oral treatment and can be easily administered and fitted into the existing care pathway. Comparator treatments are administered by intravenous infusion or orally.

The cost-effectiveness estimates for zanubrutinib compared with standard care are within the range NICE normally considers an acceptable use of NHS resources. Therefore, zanubrutinib is recommended.

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

NICE estimate that at year 5 in Devon, the eligible population will be 6 people.

### Iptacopan for treating paroxysmal nocturnal haemoglobinuria TA1000

#### Recommendations

Iptacopan is **recommended**, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria (PNH) in adults with haemolytic anaemia. Iptacopan is only recommended if the company provides it according to the commercial arrangement.

#### The Technology

Paroxysmal nocturnal haemoglobinuria (PNH) is a rare, chronic blood condition caused by an acquired mutation (a mutation that is not present from birth) of the PIGA gene within stem cells in the bone marrow. The body's immune system attacks and ruptures red blood cells. The breakdown of red cells can happen within the blood vessels (intravascular haemolysis) or outside the blood vessels (extravascular haemolysis). This often results in anaemia, and can lead to

transfusion dependence, severe disabling symptoms of haemolysis and thrombosis (blood clotting).

The risk of thrombosis is further increased in people with PNH who are pregnant. PNH is a chronic condition that is associated with complications that can be severely debilitating and life threatening. These can include abdominal pain, kidney problems, fatigue, shortness of breath, bleeding and blood clots, dysphagia, organ damage and premature mortality.

PNH can occur at any age but is most frequently diagnosed between the ages of 30 and 40 years old. The severity of PNH is varied and not everyone with the condition will need treatment. The National PNH service is commissioned by NHS England as a specialised service. Clinical management includes treatment with complement inhibitors, although some people will experience haemolysis despite treatment with complement inhibitors (breakthrough haemolysis):

- Eculizumab, a C5 inhibitor, is commissioned for PNH with high disease activity.
- Ravulizumab, a C5 inhibitor, is recommended for adults with haemolysis with clinical symptoms suggesting high disease activity, or whose disease is clinically stable after having eculizumab for at least 6 months ([TA698](#))
- Pegcetacoplan, a C3 inhibitor, is recommended for adults who have anaemia after at least 3 months of treatment with a C5 inhibitor ([TA778](#)).

Allogeneic stem cell transplantation may be curative but is associated with significant risks and is only considered for patients with severe bone marrow failure. Other interventions, notably red blood cell transfusions, folic acid, iron tablets and anticoagulant treatments are offered to prevent or treat complications.

## 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 PNH is a rare condition and the technology is a further treatment option with the overall cost of treatment for this patient group being unlikely to change significantly with the introduction of iptacopan.

Iptacopan is an oral treatment and comparator treatments are intravenous or subcutaneous and require the initial loading dose to be administered in hospital, following which treatment is provided via a funded homecare service. Treatment with iptacopan will therefore save a limited number of outpatient appointments as this is delivered entirely via a funded homecare service

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

NICE estimate that at year 5 in Devon, the eligible population will be 5 people.

## Vibegron for treating symptoms of overactive bladder syndrome TA999

### Recommendations

Vibegron is **recommended** as an option for treating the symptoms of overactive bladder syndrome in adults. It is only recommended if antimuscarinic medicines are not suitable, do not work well enough or have unacceptable side effects.

If people with the condition and their healthcare professional consider vibegron to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

This recommendation is not intended to affect treatment with vibegron 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 healthcare professional consider it appropriate to stop.

### The Technology

Overactive bladder typically results from involuntary contractions of the bladder that produce an urge to urinate, even though the bladder may only contain a small amount of urine. Overactive bladder may be associated with Parkinson's disease, spinal cord injury, diabetic neuropathy, multiple sclerosis, dementia or stroke; however, most cases have no specific cause. Approximately 12% of the total adult population have symptoms of overactive bladder.

[NG123](#) and [CG97](#) recommend that bladder training and lifestyle advice should be offered as first-line treatments. An antimuscarinic (also known as anticholinergics) should be offered at second line. [NG123](#) recommends that the anticholinergic treatment with the lowest acquisition cost is offered. [TA290](#) recommends mirabegron as an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective or have unacceptable side effects. [NG123](#) advises that for people with overactive bladder that has not responded to non-surgical management or pharmacological treatment, more invasive procedures may be considered.

### Financial Factors

This technology is commissioned by ICBs.

Cost-comparison results suggest vibegron is likely to be cost saving compared with mirabegron. Therefore, vibegron is recommended.

The key driver of financial resource impact is population growth over time. If no population growth is included, there would be a saving. Population growth causes more people to have the treatment options and creates a cost. The lower price of vibegron than mirabegron means that as people choose vibegron rather than mirabegron, the increasing cost is reduced.

As both treatment options are oral, there is no capacity impact. There will be an increase in capacity impact as a result of population growth.

NICE estimate that in Devon 6,270 people will be eligible for treatment at year 5, and that 941 people (15%) will have treatment with vibegron.

## Highly Specialised Technology Guidance (HSTs)

### [Burosumab for treating X-linked hypophosphataemia in children and young people HST8 \(UPDATE\)](#)

**September 2024: NICE amended the recommendation to match the updated marketing authorisation for burosumab:**

Burosumab is **recommended**, within its marketing authorisation, for treating X-linked hypophosphataemia (XHL) with radiographic evidence of bone disease in babies, children and young people 1 to 17 years. It is recommended only if the company provides burosumab according to the commercial arrangement.

## NICE Guidelines (NGs)

None published this month.

## 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)

## [Single-step scaffold insertion for repairing symptomatic chondral knee defects IPG793](#)

This guidance updates and replaces IPG560 (published June 2016)

### Recommendations

Use single-step scaffold insertion as an option for repairing symptomatic chondral knee defects with **standard arrangements** in place for clinical governance, consent and audit.

Healthcare professionals should enter details about everyone having single-step scaffold insertion for repairing symptomatic chondral knee defects onto a suitable registry, such as the International Cartilage Regeneration & Joint Preservation society Registry.

*There is good clinical evidence for the efficacy and safety of this procedure. The evidence shows that it reduces symptoms, stimulates cartilage regeneration and is safe in the short and medium term. It is an established procedure and more long-term data is being collected. So, it can be used with standard arrangements.*

### The Condition

Chondral cartilage is the material that covers the end of the bones in the knee joint, to protect them from friction when moving. Damage to this cartilage (chondral knee defect) can cause symptoms such as knee pain and stiffness and reduced mobility. Untreated full-thickness cartilage lesions may be associated with significant pain and eventually arthritis. This is a major cause of disability.

There are several approaches to managing chondral knee defects. Surgical options depend on the characteristics of the of the person and the defect. There are 2 main categories of procedure:

- Procedures that mainly aim for symptom relief include:
  - debridement
  - osteotomy
  - knee replacement
- Procedures that aim for symptom relief and also re-establish the cartilage surface include:
  - marrow stimulation techniques (such as Pridie drilling and microfracture)
  - mosaicplasty
  - osteochondral allograft transplantation
  - focal articular resurfacing implants

- autoglas chondrocyte implantation (in which chondrocytes harvested from the knee are cultured and implanted into the damaged cartilage).

Sometimes matrix-induced autologous chondrocyte implantation is done. This is a 2-step procedure because cells have been cultured outside the body. The cells are harvested for culturing in the first operation, then cultured cells and scaffold are introduced in the second.

### **The Procedure**

In this procedure, a scaffold is inserted into the area of damaged cartilage to encourage cells to grow into new cartilage. This is a single-step procedure because the cells are not cultured outside the body. A range of techniques can be used to introduce the cells that grow into the new cartilage, supported by the scaffold. For example, tiny holes can be drilled into the bone to release the cells, or substances like bone marrow aspirate can be put into the area of damage. Whichever method is used, it is always done in the same operation as the scaffold insertion.

There are different types of scaffold and ways of doing the procedure. For example, some scaffolds are solid and some are injectable gels. Some of the solid scaffolds must be cut to size and applied over the defect. Other scaffolds are a standard size and shape and are implanted into the subchondral bone in the damaged area.

The procedure aims to repair the damaged cartilage, reduce symptoms and keep the joint working.

## **Medical Technologies Guidance (MTGs)**

None published this month

## **Diagnostics Guidance (DGs)**

None published this month.

## **Health Technology Evaluations (HTE)**

None published this month.

## **NICE Quality Standards**

None published this month.

## Current NICE Consultations

| Title/link                                                                                                          | End date of consultation |
|---------------------------------------------------------------------------------------------------------------------|--------------------------|
| <a href="#">Digital technologies to support self-management of COPD: early value assessment</a>                     | 04/10/2024               |
| <a href="#">Rozanolixizumab for treating antibody-positive generalised myasthenia gravis [ID5092]</a>               | 04/10/2024               |
| <a href="#">Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention</a> | 07/10/2024               |
| <a href="#">Fosdenopterin for treating molybdenum cofactor deficiency type A [ID6264]</a>                           | 10/10/2024               |
| <a href="#">Cabotegravir for preventing HIV-1 in adults and young people [ID6255]</a>                               | 17/10/2024               |