

Monthly briefings are produced in order to help members of the media and other interested groups understand the work and advice of the Scottish Medicines Consortium. The full advice for each drug that we have assessed can be found at www.scottishmedicines.org.

SMC has this month accepted the following drugs for use within NHSScotland.

dabigatran etexilate 75mg and 110mg hard capsules (Pradaxa®)

SMC has accepted dabigatran etexilate for the primary prevention of venous thromboembolic events (blood clots in the veins that can travel to the lungs) in adults who have undergone surgery to replace a hip or knee.

- Blood clotting is the normal mechanism the body uses to give protection against blood loss following injury to a vein or artery (blood vessels). However, blood is only supposed to clot outside blood vessels and clotting elsewhere can be dangerous. After certain types of surgery, including hip or knee replacement, patients can be at more risk of developing blood clots in large veins. These clots can break free from the vein and travel to the lungs, blocking blood flow through the lungs (pulmonary embolus) and causing severe breathlessness which can even prove fatal. Blood-thinning drugs are used to reduce the risk of this happening.
- Dabigatran etexilate is a new blood-thinning drug used to prevent harmful blood clots. It is given as a tablet.
- Studies have shown that dabigatran etexilate worked as well as another blood-thinning drug, a low molecular weight heparin, given by injection under the skin.
- A side effect of blood-thinning drugs can be unwanted bleeding. The risk of this side effect in patients taking dabigatran etexilate appears to be similar to that in patients taking low molecular weight heparin.
- SMC accepted dabigatran etexilate because it works as well as low molecular weight heparin, costs about the same and is given by mouth.

About SMC

The purpose of the Scottish Medicines Consortium (SMC) is to accept for use those newly licensed drugs that clearly represent good value for money to NHSScotland.

SMC analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price.

Because the NHS has limited resources, SMC works to make sure that those drugs which represent good value for money are accepted for routine use as quickly as possible so that they can benefit patients.

The Consortium is made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry, the public and the Scottish Government.

■ Contact Details

If you are interested in the work of SMC you can visit our website at:

www.scottishmedicines.org.uk

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epoetin zeta (Retacrit®)

SMC has accepted epoetin zeta for the treatment of anaemia associated with chronic kidney failure in patients on haemodialysis and adult patients on peritoneal dialysis (dialysis is a process which does the work of the kidneys when they do not function properly). It is also accepted for the treatment of severe anaemia associated with kidney disease in patients not yet undergoing dialysis.

- In patients with kidney disease, the damaged kidneys cannot produce enough of the hormone called erythropoietin. This hormone stimulates the bone marrow to produce red blood cells that contain a protein called haemoglobin. Haemoglobin carries oxygen around the body. When haemoglobin cannot be produced in normal amounts then the body does not receive enough oxygen to meet its needs. This is called anaemia.
- Epoetin zeta is a drug given by injection which acts like the hormone erythropoietin and is one of a class of drugs called erythropoiesis stimulating agents (ESA). It increases the amount of red blood cells and haemoglobin produced.
- Studies have shown that epoetin zeta corrected the amount of haemoglobin produced by the body and kept the levels at the target amount as well as another ESA.
- The side effects of epoetin zeta are similar to those of the other ESA.
- SMC accepted epoetin zeta because it works as well as the other ESA and offers good value for money.

adalimumab 40mg solution for injection (Humira®)

SMC has accepted adalimumab for restricted use in the treatment of severe chronic plaque psoriasis in adults who have failed to respond to, or cannot be treated with, other therapies such as cyclosporine, methotrexate or PUVA (a treatment involving a drug and the use of ultra-violet light).

- Psoriasis is a skin disease which causes red, raised skin patches that produce dead, flaky skin cells. Plaque psoriasis is the most common type of this skin condition and can affect any part of the body. Symptoms include red, itchy and sometimes painful skin.
- The exact cause of psoriasis is unknown but a protein called tumour necrosis factor (TNF) is involved. People with psoriasis have too much TNF. Adalimumab improves skin symptoms by blocking TNF. It is given as an injection to treat persistent psoriasis that has not responded to other treatments.
- Studies have shown that adalimumab improves symptoms of psoriasis and the patient's quality of life compared with placebo (a dummy treatment which contains no active drug).
- Adalimumab appears to have similar side effects as other related medicines ie anti-TNF medicines.

- SMC accepted adalimumab because it offers value for money in patients with severe chronic plaque psoriasis for whom other treatments have been ineffective or not tolerated.

clostridium botulinum neurotoxin type A 100 unit powder for solution for injection (Xeomin[®])

SMC has accepted clostridium botulinum neurotoxin type A (Xeomin[®]) for the relief of symptoms of a disorder that affects muscles and movements in the eye (blepharospasm) and neck (cervical dystonia or spasmodic torticollis) in adults.

- Dystonia is a disorder that affects muscles and movement. There are several types of dystonia which affect different areas of the body. The most common type is cervical dystonia, also known as spasmodic torticollis, which affects the neck muscles and can make the head turn and twist involuntarily. The second most common type is blepharospasm which affects the eye muscles and can cause excessive uncontrollable blinking.
- There is no cure for the condition but medicines can be given to relieve muscle spasms and reduce pain. Xeomin[®] is a preparation containing a small amount of botulinum toxin type A (a poisonous substance that is regarded as safe when given in small doses) and can be injected into the affected muscles to reduce contractions and weaken the overactive muscles.
- Studies have shown that this preparation of botulinum toxin type A (Xeomin[®]) improves symptoms of blepharospasm and cervical dystonia as much as a similar medicine containing botulinum toxin.
- Patients receiving botulinum toxin type A (Xeomin[®]) in studies did not experience more side effects than patients receiving a similar medicine containing botulinum toxin.
- SMC accepted Xeomin[®] because it is as effective and under certain circumstances is no more expensive than a similar medicine containing botulinum toxin type A.

nilotinib (Tasigna[®])

SMC has accepted nilotinib for restricted use in the treatment of Philadelphia chromosome positive chronic myelogenous leukaemia (known as CML) in adult patients who are resistant to or unable to take at least one prior course of treatment that included a drug called imatinib. Its use is restricted to the chronic phase of the disease.

- Chronic myelogenous leukaemia (CML) is a rare slow-growing cancer of the white blood cells, affecting about 700 people each year. CML is caused by a change in the genetic code in some of the cells in the bone marrow (that makes the body's blood cells) which creates an abnormal chromosome called the Philadelphia chromosome. The Philadelphia chromosome makes an enzyme called tyrosine kinase that signals the body to make more white blood cells than the body needs.
- There are three phases of CML: chronic, acute and blast, and treatment depends on the phase

of the illness. In the chronic and acute phases, treatment for CML can include chemotherapy, interferon alpha, drugs that block the abnormal production of white blood cells by inhibiting tyrosine kinase (such as imatinib) and bone marrow transplant surgery. Some of these treatments do not work because patients may not be able to tolerate some of their side effects, or cancerous cells may not respond to treatments (such as imatinib) because they develop resistance to the drugs. Nilotinib is a new tyrosine kinase inhibitor and it is given as a tablet twice daily.

- A study was carried out in patients with Philadelphia chromosome positive CML who were intolerant of imatinib, or for whom imatinib had failed to stop the disease progressing (this is known as resistance). The study showed that nilotinib reduced the total number of white blood cells and the number of cells carrying the cancerous mutation (Philadelphia chromosome positive cells), in both the chronic and acute phases of the illness. Patient survival was 95% at 12 months in the chronic phase and 91% at six months in the accelerated phase with nilotinib.
- A reduction in the production of blood cells by the bone marrow (known as myelosuppression) was the most severe side effect of nilotinib, and more common in acute rather than chronic phase patients. In patients treated with nilotinib, myelosuppression indicates that treatment is working.
- SMC accepted nilotinib for restricted use because it is effective and offers value for money in the chronic phase of CML.

SMC decided that the following drugs are not value for money for NHSScotland.

anidulafungin 100mg powder and solvent for concentrate for solution for infusion (Ecalta[®])

SMC did not recommend anidulafungin for the treatment of invasive candidiasis in adults with normal levels of white blood cells.

- Invasive candidiasis is a fungal infection in the bloodstream and other body sites caused by a yeast called Candida. Symptoms include fever and chills.
- Drugs known as antifungal drugs are used to treat the condition. Anidulafungin is an antifungal drug that destroys the yeast by targeting an important part of its cell wall. It is given through a drip.
- A study has shown that anidulafungin works as well as another antifungal drug (fluconazole) when treating the least serious type of Candida infection in the blood stream only.
- In the study, the frequency of side effects experienced by patients treated with anidulafungin was similar to that in patients treated with fluconazole.
- SMC did not to accept anidulafungin for use within NHSScotland because the economic case submitted by the manufacturer failed to show that the drug is good value for money.

bevacizumab 100mg and 400mg vials (Avastin®)

SMC did not recommend bevacizumab in combination with fluoropyrimidine-based chemotherapy (a standard existing treatment) for the treatment of patients with cancer of the colon or rectum (large bowel) that has spread to other areas of the body.

- Cancer is the term given to a group of abnormal cells which have clumped together and grow to form a tumour.
- Cancer chemotherapy is given to try and kill cancer cells or stop them spreading. Bevacizumab is given in combination with (that is, at the same time as) other cancer chemotherapy drugs. It helps block the growth of new blood vessels that supply the cancer cells with nutrients.
- A study has shown that patients treated with bevacizumab plus chemotherapy survived for about six weeks longer, without the cancer progressing, than patients treated with placebo (a dummy treatment that does not contain an active drug) plus chemotherapy.
- Diarrhoea was a more common side effect in study patients treated with bevacizumab plus chemotherapy than in those treated with placebo plus chemotherapy.
- SMC did not accept bevacizumab in combination with chemotherapy because the economic case submitted by the manufacturer failed to show that the drug is good value for money compared with current treatment.

glucosamine (as hydrochloride) 625mg tablets (Alateris®)

SMC did not recommend glucosamine for the relief of symptoms in mild to moderate osteoarthritis of the knee.

- osteoarthritis is a condition that causes stiffness, pain and loss of movement in joints such as knees and hips. It occurs when the surface of bones become damaged or worn away.
- Patients with mild or moderate cases of osteoarthritis often used simple pain killers (eg paracetamol) or anti-inflammatory drugs to relieve the pain. Glucosamine is a dietary supplement that may help relieve symptoms.
- The effectiveness of this particular product of glucosamine (glucosamine hydrochloride) has not been studied in clinical trials. Studies have shown that other products containing glucosamine are not consistently better than placebo (a dummy treatment containing no active drug) at improving symptoms of osteoarthritis of the knee.
- There are no safety issues of particular concern.
- SMC did not accept glucosamine because the evidence submitted by the manufacturer failed to show that this product offers good value for money.

For drugs that have not been accepted by SMC, all NHS boards have procedures in place to consider individual requests when a doctor feels the drug would be right for a particular patient. SMC has told the manufacturers why the drug was not accepted and would be pleased to receive any resubmission.

For further information and to view the complete advice for the drugs listed above, visit our website at:

www.scottishmedicines.org.uk