

SMC | briefing note

Scottish Medicines Consortium advice to NHSScotland

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

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

rilpivirine (Edurant[®])

SMC accepted rilpivirine in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load $\leq 100,000$ HIV-1 RNA copies/mL.

- The human immunodeficiency virus, better known as HIV, is a virus which attacks the body's immune system. The immune system is the body's natural defence against disease and infection.
- There is no cure for HIV, so treatment involves slowing the progression of the virus and prolonging life. Treatment involves a combination of medicines called antiretroviral drugs, because the HIV virus can adapt quickly to stop one single medicine working. Rilpivirine is an antiretroviral drug that works by blocking an enzyme that the virus needs to multiply.
- Studies have shown that rilpivirine (in combination with other antiretroviral medicines) reduced levels of HIV virus circulating in the bloodstream as well as another similar medicine in patients who had not previously been treated.
- In the studies, fewer patients given rilpivirine experienced side effects compared with patients given the other medicine.
- SMC accepted rilpivirine in combination with other antiretroviral medicines for treatment of HIV-1 infection because it was considered to offer value for money.

About SMC

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

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

Because the NHS has limited resources, SMC works to make sure that those medicines 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. SMC is part of Healthcare Improvement Scotland.

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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rivaroxaban (Xarelto®)

SMC accepted rivaroxaban for the treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.

- A deep vein thrombosis (DVT) develops when a blood clot forms in a vein in the lower limbs. Blood flow can be restricted around the clot and may cause pain and swelling. There is a risk that all or part of the clot breaks off and is transported through the venous system to become lodged in the lungs where it forms a pulmonary embolism (PE), which can be fatal.
- Rivaroxaban is a blood-thinning medicine used to prevent harmful blood clots forming. It works by blocking Factor Xa, which is an important component of blood clotting. It is given as a tablet.
- Rivaroxaban has previously been accepted by SMC for the prevention of venous thromboembolism (VTE) in adults undergoing hip and knee surgery. It has now also been licensed for use in the treatment and prevention of DVT and PE.
- A study showed that rivaroxaban worked as well as standard therapy for the treatment and prevention of DVT.
- A side effect of all blood-thinning drugs can be unwanted bleeding. The risk of unwanted bleeding in patients taking rivaroxaban appears to be similar to that in patients taking a low molecular weight heparin.
- SMC accepted rivaroxaban for the treatment of DVT, and prevention of recurrent DVT and PE following an acute DVT, because it offers value for money.

rivaroxaban (Xarelto®)

SMC accepted rivaroxaban for restricted use in the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Use is restricted to patients who have poor INR control (a measure of how blood is clotting) despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic to or unable to tolerate coumarin anticoagulants.

- Blood clotting is the normal mechanism the body uses to give protection against blood loss following injury to a vein or artery (blood vessels). A blood clot causing a blockage in any artery (other than those in the lungs) is called a systemic embolism. If the embolism occurs in the arteries of the brain it prevents its supply of oxygen and can cause a stroke. Blood thinning drugs (known as anticoagulants) are used to reduce the risk of these events happening. Warfarin is a type of anticoagulant known as a coumarin anticoagulant and it is currently the most commonly used anticoagulant.
- Rivaroxaban is a blood-thinning medicine used to prevent harmful blood clots forming. It works by blocking Factor Xa, which is an important component in blood clotting. It is given as a tablet.

- Rivaroxaban has previously been accepted by SMC for the prevention of venous thromboembolism (VTE) in adults undergoing hip and knee surgery. It has now also been licensed for use in the prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation.
- A study showed that rivaroxaban worked as well as standard therapy for the prevention of systemic embolism.
- A side effect of all blood-thinning drugs can be unwanted bleeding. The risk of unwanted bleeding in patients taking rivaroxaban appears to be similar to that in patients taking warfarin.
- SMC accepted rivaroxaban for restricted use in the prevention of stroke and systemic embolism because it offers value for money in patients who have poor INR control despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic to or unable to tolerate coumarin anticoagulants.

tocilizumab (RoActemra[®])

SMC accepted tocilizumab for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate.

- Juvenile idiopathic arthritis is a rare condition in which the body's immune system attacks the lining of the joints causing them to become inflamed. The cause is unknown. A minority of patients with JIA have a systemic form of the condition (sJIA) which causes symptoms not only in the joints but elsewhere in the body.
- In people with arthritis a protein called IL-6 is overproduced in the body. Tocilizumab works by blocking the action of IL-6 and so reducing the inflammation and damage.
- Studies have shown that tocilizumab improved the symptoms of sJIA better than placebo (a dummy medicine containing no active treatment).
- In the studies, the most common side effects of tocilizumab were upper respiratory tract infection, headache, nasopharyngitis (inflammation of the nose and pharynx), and diarrhoea. Long-term safety of the medicine is unknown.
- This SMC advice takes account of the benefits of a patient access scheme (PAS)¹. A PAS is a scheme proposed by a manufacturer in order to improve the cost effectiveness of a medicine and thus enable patients to receive access to new medicines that may otherwise not have

¹ In March 2009, it was announced that an agreed national framework would be introduced to allow the operation of PAS in NHSScotland. A patient access scheme assessment group (PASAG) has been established to review and advise NHSScotland on the feasibility of proposed schemes for implementation. PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of SMC.

been judged to be a cost-effective use of NHS resources. The proposed PAS gives a discount on the price of the medicine.

- SMC accepted tocilizumab for use in NHSScotland because it is the first licensed treatment for this rare condition and offers value for money when the PAS is taken into account.

midazolam oromucosal solution (Buccolam[®])

SMC accepted midazolam for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years).

- A seizure occurs when the brain functions abnormally, leading to a change in consciousness and movement. Seizures can occur in children for a variety of reasons in different parts of the brain. A convulsive seizure involves a large portion of the brain and causes uncontrollable muscle jerking lasting for a few minutes, followed by a period of drowsiness. Often the child will not remember the seizure itself but may have an injury such as a bitten tongue or broken bone caused by the jerking.
- Midazolam belongs to a group of medicines known as benzodiazepines. It can be used to stop a prolonged, convulsive seizure and also causes drowsiness and induces sleep. It is given buccally, meaning that it is administered into the space between the cheek and the gum. Buccolam[®] is a new formulation of midazolam in a pre-filled syringe for buccal administration in children.
- Studies have shown that midazolam given buccally was as effective at stopping convulsive seizures as another benzodiazepine given rectally, but it was not possible to determine if midazolam worked better.
- A side effect of benzodiazepines can be difficulty breathing. In studies, the occurrence of breathing problems was similar among patients given buccal midazolam compared with patients given the other medicine.
- SMC accepted midazolam oromucosal solution for use in NHSScotland because it is the first formulation of midazolam that can be administered buccally, and provides an alternative, more tolerable method of administration for this medicine at an acceptable cost.

SMC did not accept the following medicine for NHSScotland.

aztreonam lysine (Cayston[®])

SMC did not accept aztreonam lysine for the suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 18 years and older, who cannot be treated with colistin.

- Cystic fibrosis (CF) is a life-threatening inherited disease that affects the mucus glands of internal organs, especially the lungs, but also of the liver, pancreas, and the digestive system. CF in the lungs leads to them clogging with thick sticky mucus. Many people with CF have a chronic respiratory infection caused by a bacteria called *Pseudomonas aeruginosa* that settles into the thick mucus and makes it hard to breathe.
- Aztreonam lysine is an inhaled antibiotic used to help reduce infection and improve breathing symptoms in people with CF who have *P. aeruginosa* in their lungs. It is taken three times a day.
- Studies have shown that aztreonam lysine improved breathing symptoms over 28 days compared with placebo (a dummy medicine containing no active treatment) and another antibiotic. It is unclear whether or not the benefit is long term.
- A greater proportion of patients given aztreonam lysine experienced side effects thought to be due to the medicine, compared with patients given the other antibiotic.
- SMC did not accept aztreonam lysine for use in NHSScotland because the balance of costs and benefits meant the medicine was not value for money.

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

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

www.scottishmedicines.org.uk