

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.

methoxy polyethylene glycol-epoetin beta for injection (Mircera[®])

SMC has accepted Mircera[®] for the treatment of anaemia associated with kidney disease.

- 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.
- Methoxy polyethylene glycol-epoetin beta (Mircera[®]) is a drug given by injection which acts like the hormone erythropoietin. It increases the amount of red blood cells and haemoglobin produced.
- Studies have shown that Mircera[®] corrected the amount of haemoglobin produced and kept the levels at the target amount for up to a year in patients undergoing dialysis (treatment which does the work of the kidneys when they do not function properly). It also worked as well as other similar drugs.
- In studies, the side effects of Mircera[®] were like those of other similar drugs. The long-term safety of the drug is not yet known but is being monitored.
- SMC accepted Mircera[®] because it was as effective as other similar drugs and costs about the same.

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:

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nelarabine (Atriance®)

SMC has accepted nelarabine for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not been improved or has returned following treatment with at least two chemotherapy regimens. It should only be used by specialists as a treatment to bridge to stem cell transplant.

- Leukaemia and lymphoma are both cancers involving white blood cells in the body. T-cell acute lymphoblastic leukaemia (T-ALL) is a type of leukaemia and T-cell lymphoblastic lymphoma (T-LBL) is a type of lymphoma.
- Treatment involves giving anti-cancer drugs to kill the cancer cells (this is called chemotherapy). If the cancer returns following chemotherapy, a procedure called a stem cell transplant may be used. This procedure gives patients an intensive high dose of chemotherapy (and sometimes radiotherapy) to kill the cancer cells. The patient is then given healthy cells from a donor so that the patient can make normal blood cells again.
- Treatment is necessary to allow patients to become well enough before undergoing the stem cell transplant procedure. Studies have shown that nelarabine (a drug given by a drip) can enable patients to go on to have a stem cell transplant.
- Changes in the sense of feeling in hands or feet and muscle weakness (called peripheral neuropathy) are common side effects of nelarabine.
- SMC accepted nelarabine to treat patients who would be suitable for a stem cell transplant following two unsuccessful cycles of chemotherapy because it is likely to be of similar value for money as another drug used in this way (called clofarabine).

vildagliptin (Galvus®)

SMC has accepted vildagliptin, in combination with a commonly used drug called metformin, to treat type 2 diabetes in patients who are taking metformin at its highest dose but whose blood sugar levels are still inadequately controlled. The combination of vildagliptin and metformin should only be given to patients taking metformin who cannot be given one of a group of drugs called sulphonylureas.

- Diabetes mellitus is a condition in which there is too much sugar present in the blood. Type 2 diabetes develops when the body does not make enough insulin (a hormone which helps sugar to be used by the body) or when the insulin that is produced does not work properly. Keeping blood sugar levels as near to normal as possible reduces the risk of long-term diabetes complications such as heart disease, blindness, stroke and kidney failure.
- For many people, type 2 diabetes can be managed with diet alone. However, there are already several types of oral medicine to reduce blood sugar levels (metformin, sulphonylureas, glitazones). Vildagliptin is one of a new type of medicine (DPP-4 inhibitors) which works by blocking a particular enzyme called dipeptidyl peptidase type 4, causing an increase in blood

levels of insulin and some other related hormones. It is given as an oral tablet.

- A study has shown that vildagliptin works as well as one of the glitazone drugs (both given with metformin) to control blood sugar levels.
- A side effect of drugs to treat diabetes can be weight gain, and patients treated with vildagliptin had less weight gain than those treated with a glitazone.
- SMC felt that treatment with vildagliptin and metformin would be value for money compared with other treatment options in patients with poor blood sugar control who currently take metformin on its own and who cannot be given a combination of metformin with a sulphonylurea. The manufacturer did not ask SMC to consider the use of vildagliptin in combination with other groups of anti-diabetic drug that are licensed.

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

paliperidone 3, 6 and 9mg prolonged-release tablets (Invega®)

SMC did not recommend paliperidone for the treatment of schizophrenia.

- Schizophrenia is a common and serious mental illness, the cause of which is unknown. Symptoms include delusions (false ideas), hallucinations (seeing or hearing things that are not real) and disordered thoughts.
- Medication (known as antipsychotic drugs) is used to reduce the symptoms. It is usually taken long term to prevent further episodes. Paliperidone is an antipsychotic drug (known as an atypical antipsychotic) given as a tablet once daily.
- Studies have shown that paliperidone is better than placebo (a dummy treatment that does not contain an active drug) at reducing the symptoms of schizophrenia. Based on the studies available, it was difficult to assess the benefit of paliperidone compared with current treatments.
- Paliperidone is less likely than some other atypical antipsychotics to interact with other medications.
- SMC decided not to accept paliperidone for use within NHSScotland because there were weaknesses in the economic case put forward by the manufacturer. There was also not enough convincing evidence that paliperidone is as effective as current treatment.

maraviroc (Celsentri®)

SMC did not recommend maraviroc in combination with other medicines as treatment for HIV in adults infected with only CCR5-tropic HIV-1 detectable.

- 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 because the HIV virus can adapt quickly to stop one single medicine working. Maraviroc is a new type of anti-HIV medicine. It works by blocking a receptor called CCR5, one of two types of protein that the virus uses to gain entry into blood cells. Maraviroc should not be used in patients infected with HIV which enters using the other protein (CXCR4).
- Studies have shown that in patients given maraviroc plus the combination of drugs most likely to work for them, the amount of HIV in the blood had reduced more than in patients given placebo (a dummy treatment that does not contain an active drug) plus the same combination of drugs.
- Although maraviroc appears to have relatively few side effects compared with other anti-HIV medicines, information is not yet available about its long-term safety.
- SMC decided not to recommend maraviroc in combination with other medicines to treat adults with only CCR5-tropic HIV because there were weaknesses in the economic case put forward by the manufacturer.

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.