

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](http://www.scottishmedicines.org)

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

## sitagliptin (Januvia®)

SMC accepted sitagliptin for restricted use as monotherapy to improve glycaemic control in patients with type 2 diabetes mellitus for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.

- 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 and exercise alone. However, there are already several types of oral medicine to reduce blood sugar levels (such as metformin, sulphonylureas, glitazones). Sitagliptin is one of a new type of medicine (known as 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 once a day.
- A study has shown that sitagliptin worked as well as metformin in patients who had received no previous treatment for diabetes. However there are no data available to compare the effectiveness of sitagliptin with other medicines taken as monotherapy.

## 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](http://www.scottishmedicines.org.uk)

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- Although the licensed indication for sitagliptin has also recently been extended to include use as part of a triple therapy regimen and as add-on therapy to insulin, SMC cannot recommend the use of sitagliptin in combination with metformin plus thiazolidinediones or as add-on therapy to insulin as the manufacturer did not submit evidence for its use in these settings.
- A side effect of drugs to treat diabetes can be weight gain, however the effect of sitagliptin on body weight in studies was minimal.
- SMC accepted sitagliptin as monotherapy for restricted use in NHSScotland because it was considered value for money in a subgroup of patients.

## epoetin theta (Eporatio®)

SMC accepted epoetin theta for the treatment of symptomatic anaemia associated with chronic kidney failure in adults.

- Kidneys produce a 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. It occurs in patients with kidney disease, because the damaged kidneys cannot produce enough erythropoietin.
- The active substance in Eporatio® is a recombinant human erythropoietin that stimulates the production of red blood cells from the bone marrow. It can be given as an injection under the skin (preferably to patients who are not undergoing haemodialysis) or as an infusion. Haemodialysis is a treatment for removing waste products from the blood when the kidneys are not working properly.
- The results of four controlled studies showed that epoetin theta was as effective as another erythropoietin analogue in maintaining stable haemoglobin levels in kidney failure-associated anaemia in patients who have not received haemodialysis (treatment via injection) and in patients receiving haemodialysis (treatment via infusion).
- Epoetin theta has a similar safety profile to other epoetins, with side effects of high blood pressure, flu-like illness and headache most commonly reported.
- SMC accepted epoetin theta for use in NHSScotland because it is value for money compared with another epoetin analogue. Other erythropoiesis stimulating agents are available at lower cost.

## ketoprofen/omeprazole (Axorid<sup>®</sup>)

SMC accepted ketoprofen/omeprazole for the symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential.

- Rheumatoid arthritis, ankylosing spondylitis and osteoarthritis are conditions affecting joints and the surrounding soft tissues. Rheumatoid arthritis is a chronic condition in which the immune system attacks the lining of the joints, causing them to become inflamed and stop working properly. Ankylosing spondylitis is the persistent inflammation of the spine and sacroiliac joints (joints that lie at the junction of the spine and the pelvis) in the pelvis eventually causing fusion of the spine. Osteoarthritis is a condition characterised by the breakdown of the cartilage (the smooth surface that lines the bones which allows joints to move easily) of the joint. Symptoms of these rheumatic disorders vary, ranging from mild discomfort to progressively debilitating which interferes with movement and daily activities.
- Treatment for these rheumatic conditions include NSAIDs (such as aspirin and ibuprofen) to reduce symptoms of inflammation, relieve pain and swelling. A serious unwanted effect of NSAIDs is the increased risk of ulcers developing in the gastrointestinal tract. Axorid<sup>®</sup> contains a prolonged-release form of the NSAID ketoprofen in combination with a proton pump inhibitor omeprazole, which reduces the amount of acid produced in the stomach. This new formulation reduces the risk of NSAID-related side effects on the stomach and duodenum in patients already suffering from ulcers that need continuous anti-inflammatory treatment. Ketoprofen/omeprazole is taken as a tablet once daily depending on symptoms.
- No clinical efficacy and safety studies were considered necessary as ketoprofen and omeprazole are already approved for their respective indications. Several studies in healthy volunteers showed the bioequivalence of this combination product to the reference products.
- SMC accepted ketoprofen/omeprazole for use because the combined product was less expensive than the treatment with the same medicines prescribed separately. However, other nonsteroidal anti-inflammatory drugs can be co-prescribed with proton pump inhibitors at lower cost.

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

## lapatinib (Tyverb<sup>®</sup>)

SMC did not accept lapatinib, in combination with capecitabine, for the treatment of patients with advanced or metastatic (spreading) breast cancer whose tumours overexpress ErbB2 (HER2) and who have progressive disease following prior therapy with other cancer drugs.

- Breast cancer is a cancer that starts in the cells of the breast in women and men. It is the second most common cancer worldwide.
- The proteins ErbB1 and ErbB2 are types of human epidermal growth factor receptor and play a role in the development of breast cancer. Lapatinib is a tyrosine kinase inhibitor that blocks these receptors and stops cancer cells from growing. It is taken as a tablet once daily.
- A study showed that lapatinib plus capecitabine significantly increased the time taken for the cancer to spread compared with capecitabine alone by 8 weeks. The combination treatment did not lead to a significant increase in overall survival.
- Diarrhoea, rash and increases in liver enzymes were commonly reported in those patients who received lapatinib in combination with capecitabine. Other serious side effects were similar between treatment groups, however a small number of patients experienced a temporary reduction in heart function.
- SMC did not accept lapatinib for use within NHSScotland because compared with capecitabine monotherapy, the health benefits of the treatment did not outweigh its cost which meant it was not considered to be value for money. In addition, the manufacturer's model included the unlicensed use of trastuzumab and capecitabine as one of the comparators. There were some weaknesses in the way the manufacturer estimated the benefits of lapatinib relative to this treatment option, and additionally trastuzumab and capecitabine may itself offer poor value for money. As such, SMC was uncertain of whether lapatinib treatment offers value for money to the NHS.

## mifamurtide (Mepact<sup>®</sup>)

SMC did not accept mifamurtide, in combination with post-operative multi-agent chemotherapy, for the treatment of high-grade resectable non-metastatic osteosarcoma after complete resection (removal) in children, adolescents and young adults.

- Osteosarcoma is a rare bone cancer that is mainly diagnosed in children and young adults. About 30 children in the UK develop osteosarcomas each year.<sup>1</sup> Any bone in the body can be affected but it most commonly affects arms or legs. Pain is the most common symptom with swelling and there is limited movement as the tumour grows.

<sup>1</sup> [www.macmillan.org.uk](http://www.macmillan.org.uk)

- Current treatment for osteosarcoma is to remove the local tumour by surgery (resection) and chemotherapy. Mifamurtide is an anti-cancer drug that is used after a surgical resection, and in combination with other anti-cancer drugs. It works by activating the immune system to kill off the remaining cancer cells. It is given as an infusion twice weekly at least 3 days apart for 12 weeks, followed by once-weekly treatments for an additional 24 weeks for a total of 48 infusions in 36 weeks.
- Mifamurtide has been shown to increase overall survival compared to multi-agent chemotherapy alone in patients under 30 years with newly diagnosed resectable osteosarcoma.
- The most common reported side effects of mifamurtide include anaemia (low red blood cell count), weight loss, tachycardia (rapid heart beat), blood pressure changes and digestive symptoms. Serious side effects which may have been related to mifamurtide included allergic reactions, pleural and pericardial effusions (fluid next to the lungs and fluid around the heart) and toxicity to the nervous system.
- SMC did not accept mifamurtide for use in NHSScotland because the treatment's health benefits did not outweigh its cost so it was not considered to be 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](http://www.scottishmedicines.org.uk)