

# SMC | briefing note

Scottish Medicines Consortium advice to NHSScotland

Number 50 January 2012

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

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

## erlotinib 25, 100 and 150mg film-coated tablets (Tarceva<sup>®</sup>)

SMC accepted erlotinib for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.

- NSCLC is a type of lung cancer. About 80 out of every 100 lung cancers are diagnosed as NSCLC, and it is usually caused by smoking.
- Epidermal growth factor receptors (EGFRs) are located on the surface of many types of cancer cells and they allow epidermal growth factor (a protein present in the body) to attach to them causing chemical processes to occur inside the cell that make it grow and divide more quickly. Erlotinib is an EGFR inhibitor that prevents the receptor from being activated and stops the cancer cells from growing so quickly. It is taken as a tablet once daily, at least 1 hour before or 2 hours after food.
- SMC has previously accepted erlotinib for restricted use for second-line treatment in locally advanced or metastatic NSCLC. This submission relates to a licence extension allowing erlotinib to be used as a first-line treatment in patients whose cancer cells have EGFR receptors (around 11% of patients with metastatic NSCLC).
- A study showed that erlotinib increased progression-free survival by 4.2 months compared with another chemotherapy regime.

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

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- There were no new safety issues associated with erlotinib. Skin rash and diarrhoea were more commonly reported with erlotinib compared with placebo (a dummy medicine containing no active treatment).
- This SMC advice takes account of the benefits of a patient access scheme (PAS)<sup>1</sup>. 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 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 erlotinib for first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR activating mutations because the balance of costs and benefits when the PAS was taken into account meant that it was considered to offer value for money.

## linagliptin 5mg film-coated tablet (Tradjenta<sup>®</sup>)

SMC accepted linagliptin for restricted use in the treatment of type 2 diabetes mellitus to improve glycaemic control. It is restricted to use in combination with metformin, when diet and exercise plus metformin alone do not provide adequate glycaemic control and the addition of a sulphonylurea is inappropriate.

- 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 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.
- Linagliptin works by inhibiting DPP-4, an enzyme that breaks down two hormones involved in the regulation of blood sugar. This helps to lower blood sugar levels by stimulating insulin secretion from the pancreas and decreasing levels of glucagon (a hormone that raises blood sugar) in the circulation. It is given as a tablet.
- Studies have shown that linagliptin, in combination with metformin, controlled blood sugar as well as glimepiride plus metformin, and better than metformin plus placebo (a dummy medicine containing no active treatment).
- In the studies, fewer patients given linagliptin experienced side effects compared with patients given another medicine.
- SMC accepted linagliptin for restricted use in the treatment of type 2 diabetes mellitus because it was considered to offer value for money. SMC cannot recommend the use of linagliptin as monotherapy or in combination with metformin and a sulphonylurea as the company's submission related only to its use in combination with metformin.

<sup>1</sup>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.

## exenatide 2mg powder and solvent for prolonged-release suspension for injection (Bydureon<sup>®</sup>)

SMC accepted exenatide once weekly for restricted use as third-line treatment of type 2 diabetes mellitus in combination with:

- metformin
- sulphonylurea
- thiazolidinedione
- metformin and sulphonylurea
- metformin and thiazolidinedione

in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

- 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 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.
- Exenatide is one of a new class of diabetes drugs that help to lower blood sugar levels by stimulating insulin secretion from the pancreas, curbing inappropriately elevated glucagon secretion (a hormone that raises blood sugar), and slowing the emptying of the stomach. It is injected under the skin once weekly.
- Exenatide, in an injection that is given twice daily, has previously been accepted by SMC for restricted use for the treatment of type 2 diabetes in combination with metformin and/or sulphonylureas and in combination with metformin and a thiazolidinedione as a third-line pre-insulin treatment option. The current submission is for a new prolonged-release formulation of exenatide that allows once weekly administration.
- Four studies showed that exenatide given once weekly worked better than comparators in patients receiving oral anti-diabetic agents and/or diet and exercise regimens. In a fifth study, exenatide did not work better than a comparator.
- The most common side effects of exenatide were vomiting, upper respiratory tract infections, diarrhoea and constipation.
- SMC accepted exenatide for restricted use as third-line treatment in combination with a range of anti-diabetic medicines (metformin, sulphonylureas, thiazolidinediones, metformin plus sulphonylurea or metformin plus thiazolidinedione) because it offers value for money.

SMC did not accept the following medicines for NHSScotland.

## entecavir, 0.5mg and 1 mg film-coated tablets and 0.05 mg/mL oral solution (Baraclude<sup>®</sup>)

SMC did not accept entecavir for the treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease.

- Hepatitis B is a virus that is transmitted by infected blood and body fluids. It can cause an infection with flu-like symptoms, but usually corrects itself without treatment. However, in some cases the virus can cause chronic illness that lasts for months and potentially for life, with symptoms that come and go. Hepatitis B can cause liver disease in which the liver cells are damaged from the hepatitis infection and cannot function normally (known as decompensated liver disease). Chronic hepatitis B infection can also cause cirrhosis and liver cancer.
- If chronic illness develops, antiviral treatment may be used to prevent cirrhosis and/or liver cancer. Entecavir is a new antiviral medicine that stops the hepatitis B virus from spreading. It can lessen or stop the symptoms of chronic liver disease (a phase called remission). It is given as a tablet or solution orally.
- SMC has previously accepted entecavir for the treatment of chronic HBV infection in adults with compensated liver disease. This submission relates to a licence extension to allow use in patients with decompensated disease. These patients have a significant risk of severe liver disease and death, due to the development of progressive liver failure and liver cancer.
- A study in adults with chronic HBV and decompensated liver disease has shown that entecavir more effectively reduced the amount of virus to a target level after 48 weeks of treatment, compared with another similar medicine. However, the case presented by the manufacturer did not compare entecavir with the medicine most commonly used in Scotland.
- In studies, entecavir was tolerated as well as a comparator antiviral medicine.
- SMC did not accept entecavir because there were weaknesses in the economic case presented by the manufacturer.

## ranolazine 375mg, 500mg and 750mg prolonged-release tablets (Ranexa<sup>®</sup>)

SMC did not accept ranolazine as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or do not tolerate first-line antianginal therapy such as beta-blockers and or calcium antagonists.

- Stable angina pectoris is chest pain that is caused by insufficient blood reaching the heart muscle. This is the result of a build up of fatty deposits lining the arteries (blood vessel) and

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making them narrower, reducing the flow of blood to the heart. Symptoms may only appear at times when the heart needs more blood supply and has to work harder, such as during exercise or periods of stress.

- A number of medicines can be taken to treat the symptoms of stable angina and slow down progression of the condition. Ranolazine acts to improve blood flow by altering the sodium currents across cells, to avoid build up of the salts sodium and calcium inside cells and the damaging effects of intracellular calcium. Unlike other medicines used to treat stable angina, it does not alter heart rate or blood pressure. Ranolazine is a tablet taken twice daily.
- A study showed that after 12 weeks of treatment patients treated with ranolazine in addition to standard doses of antianginal medicines increased their exercise duration by at least 23 seconds and had fewer angina attacks per week compared with those treated with placebo (a dummy medicine containing no active treatment).
- The most common side effects of ranolazine were constipation, dizziness, nausea, headache and asthenia (physical weakness). Ranolazine can also cause abnormal electrical activity of the heart and can interact with other medicines.
- SMC did not accept ranolazine for use in NHSScotland because a number of key weaknesses in the clinical and economic case presented by the manufacturer 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](http://www.scottishmedicines.org.uk)