



Medicine: pembrolizumab (brand name: Keytruda®) for advanced urothelial carcinoma

Merck Sharp & Dohme Limited

What is advanced urothelial carcinoma?

Urothelial carcinoma is a cancer of the bladder and urinary system (which includes the tubes that carry urine from the kidneys to the bladder). Advanced urothelial carcinoma may be locally advanced (spread near where it started in the bladder and urinary tract) or metastatic (spread to other parts of the body).

How does pembrolizumab work?

Pembrolizumab is a cancer treatment called an immunotherapy. Some cancer cells produce a protein called PD-L1, this protein binds to a receptor called PD-1 on the surface of certain immune cells and turns them off, preventing them from fighting the cancer. Pembrolizumab blocks the PD-1 receptor, which stops the cancer switching off these immune cells.

What has SMC said?

SMC has not recommended pembrolizumab for the initial treatment of urothelial carcinoma that is locally advanced or metastatic, in patients who cannot be treated with cisplatin chemotherapy, and whose cancer tests positive for a sufficient level of PD-L1.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland. When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.

- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, SMC decided the evidence from the company was not strong enough to be certain that pembrolizumab works well enough and offers value for money to NHSScotland. In addition, SMC decided the evidence from the company was not strong enough to justify the additional cost of the medicine compared to any extra benefits expected in comparison to current treatments. This was despite applying extra flexibility as pembrolizumab is a medicine for a rare, end of life condition.

What does SMC's decision mean for me?

Pembrolizumab should not normally be prescribed on the NHS in Scotland for use as described above. Your healthcare professional should talk to you about other treatment options available to you. If your healthcare professional believes that pembrolizumab would be of benefit, they can make a request to prescribe it for you. All health boards have procedures in place to consider these requests. For further information see:

Medicines in Scotland: What's the right treatment for me?

www.healthcareimprovementscotland.org/medicinesbooklet.aspx



More information

The organisation below can provide more information and support for people with bladder cancer and their families. SMC is not responsible for the content of any information provided by external organisations.

Action Bladder Cancer UK



<http://actionbladdercanceruk.org/>



0300 302 0085

You can find out more about pembrolizumab in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>

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