Britain’s NICE Recommends That Bavencio Be Covered for Merkel Cell Carcinoma

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Britain’s National Institute for Health and Care Excellence (NICE) has recommended that the National Health Service cover Bavencio (avelumab) as a treatment for adults with metastatic Merkel cell carcinoma (mMCC), a rare form of skin cancer.

The institute’s Final Appraisal Determination (FAD) recommends Bavencio for health service coverage in England, Wales and Northern Ireland for the treatment of adult mMCC patients, if they have had one or more lines of chemotherapy for a metastatic disease.

Patients with untreated mMCC in England can obtain access to Bavencio through the Cancer Drugs Fund. Now patients in Wales will be able to access it through the New Treatment Fund (NTF), which covers all treatments that NICE recommends. In Scotland, confirmation of coverage is awaited, with a decision expected in the first half of 2018.

The NICE recommendation applies only to patients who began treatment after the recommendation was published.

“Merck and Pfizer are really pleased with today’s decision by NICE, which will result in patients in England, Wales and Northern Ireland being able to access the first targeted systemic treatment option licensed in the UK for metastatic Merkel Cell Carcinoma,” Belinda Byrne, Merck’s medical director, said in a press release. “We have worked closely with NICE and the CDF to ensure all mMCC patients can get access to avelumab as early as possible in their treatment.”

mMCC is a rare and aggressive form of skin cancer in which cancer cells form in the top layer of the skin, close to nerve endings. The condition is also known as neuroendocrine carcinoma of the skin. It often starts in areas of the skin that are most often exposed to the sun, including the head, neck, and arms.

Bavencio is a monoclonal antibody against programmed death ligand-1 (PD-L1), a cell-surface protein produced in excessive amounts in mMCC and other cancers. In healthy individuals, the PD-L1 protein binds to its receptor PD-1, found on the surface of immune T-cells, to restrain their activity.

This suppression serves as check on T-cells, preventing the immune system from becoming overactive and mistaking healthy cells as invaders and attacking them. But cancer cells also make use of this protein, producing it to prevent the immune system from recognizing and attacking a tumor.

Bavencio is designed to prevent or lessen immune suppression (or to block the binding of the protein to its receptor) so that T-cells are more active and more likely to attack cancer cells.

When Bavencio binds to PD-L1, it inhibits the interaction between PD-L1 and PD-1, promoting an immune response against cancer cells.

The incidence of MCC is rising in both the United Kingdom and the United States, studies have shown, possibly due to an aging population or increased UV exposure. MCC is aggressive, with frequent lymph node involvement and early metastases. While earlier-stage MCC can be managed with surgery and radiation, treatment options for mMCC are much more limited.

In the U.K., Bavencio was the first treatment approved for this condition. Before Bavencio, patients could only rely on cytotoxic chemotherapy, which has limited efficacy and is not generally well-tolerated.

In the United States, Bavencio is jointly manufactured and developed by EMD Serono and Pfizer. The therapy was granted accelerated approval by the U.S. Food and Drug Administration (FDA) for mMCC in March 2017.

In the United Kingdom, Bavencio is co-developed and co-commercialized by Merck and Pfizer, as part of a strategic alliance formed in November 2014. Bavencio received marketing authorization from the European Medicines Agency in September 2017 and was launched in the U.K. in November 2017.