Temsirolimus

Product:
TEMSIROLIMUS (Torisel®)

Class of drugs:
anti-cancer agent; mTOR inhibitor

Indication:
metastatic renal cell carcinoma (mRCC)

Manufacturer:
Pfizer Canada Inc.

CED Recommendation

The CED recommended that temsirolimus (Torisel®) not be funded. The CED noted that while temsirolimus may provide survival benefits in a subgroup of patients with metastatic renal cell carcinoma (mRCC), cost-effectiveness of this treatment has not been demonstrated.

Executive Officer Decision

Based on the CED's recommendation and an agreement with the manufacturer that addresses utilization and cost, the Executive Officer decided to fund temsirolimus (Torisel®) through the New Drug Funding Program according to specific criteria.

Status

Funded through the New Drug Funding Program.

Highlights of Recommendation:

- Temsirolimus is an intravenous anti-cancer drug indicated for the treatment of metastatic renal cell carcinoma (kidney cancer that has spread to other parts of the body).
- The focus of the CED's review was a single clinical study evaluating the efficacy and safety of temsirolimus in patients with metastatic renal cell carcinoma and "poor-risk" disease (i.e. patients with risk factors that suggest a poor prognosis).
- The study found that when compared with interferon-alpha (an older conventional treatment for this disease), temsirolimus prolonged survival by an average of 3.6 months.
- The study also reported that temsirolimus was better tolerated than interferon-alpha.
- Temsirolimus costs approximately $5,000 per month. This treatment has not been shown to provide value for money.
- **Overall, the Committee acknowledged that temsirolimus provides survival benefits in patients with metastatic renal cell carcinoma and poor-risk disease. However, the high cost of treatment has not been shown to be cost-effective.**

Background:

Metastatic renal cell carcinoma (mRCC) refers to kidney cancer that has spread to other parts of the body (e.g. to the lungs, lymph nodes, brain and liver).

The expected survival time for patients with mRCC can be quite variable and depends on the individual's tumour type as well as other prognostic factors. Patients who present with features that predict a poor prognosis (e.g. poor performance status, metastases in multiple organs) are categorized as having "poor-risk" disease.

For patients with inoperable or metastatic disease, cure is usually not possible and treatment is directed at controlling symptoms and prolonging survival. Drug treatments for mRCC include cytokines (interferon-alpha, interleukin-2) and tyrosine kinase inhibitors (sunitinib, sorafenib). Temsirolimus belongs to a class of drugs called mTOR inhibitors, which block the actions of an enzyme called mTOR thought to be involved in the division and growth of cancer cells.

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Detailed Discussion:

- In a randomized controlled study *(Hudes et al. New England Journal of Medicine 2007)*, 626 previously untreated patients with mRCC received one of three treatments: temsirolimus alone, interferon-alpha alone, or temsirolimus in combination with interferon-alpha. Patients enrolled in the study had advanced disease and three or more factors indicating a poor prognosis.
- The study reported that median overall survival was longer in patients treated with standalone temsirolimus than those treated with standalone interferon-alfa (10.9 months versus 7.3 months, a difference of 3.6 months).
- The study also found that combining interferon-alpha with temsirolimus did not significantly improve the overall survival time and was associated with more serious adverse events than using standalone temsirolimus.
- With respect to toxicity, the incidence of severe adverse events was lower in patients who received temsirolimus compared with those who received interferon-alpha.
- No studies comparing temsirolimus to newer treatments such as sunitinib or sorafenib were submitted for review.
- Patients with poor-risk mRCC currently have limited treatment options. These patients are often unable to tolerate the side effects of older conventional therapies like interferon-alpha. The Committee recognized that there is a need for alternative drug therapies in this setting.
- Temsirolimus costs approximately $5,000 per month. Based on available information, it is very difficult to determine whether the high cost of treatment is justified.
- **Overall, the Committee acknowledged that temsirolimus provides survival benefits in patients with poor-risk mRCC and that there is a clinical need for effective treatment options in this setting. The Committee was, however, concerned with the high drug cost and the lack of evidence to support value for money.**

The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as it does all other cancer drugs.

NDFP Funding:

Based on the CED's recommendation and an agreement with the manufacturer that addresses utilization and cost, the Executive Officer decided to fund temsirolimus (Torisel®) through the New Drug Funding Program (NDFP) according to specific criteria.

The NDFP eligibility criteria can be found at the Cancer Care Ontario website: http://www.cancercare.on.ca/toolbox/drugs/ndfp/

Ontario
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