Programme de
GESTION THÉRAPEUTIQUE
des médicaments

Intervention Plan
PGTM Clinical Intervention Model (CIM):
Descriptive analysis of ipilimumab in the treatment of metastatic or unresectable advanced melanoma in Quebec's university teaching hospitals - 2016

Background:

Metastatic or unresectable melanoma is the most aggressive form of skin cancer. The life expectancy of affected individuals is short, median survival being 6 months.

Dacarbazine (DTIC), an alkylating agent approved in Canada in the 1970s, used to be the treatment most often used on a first-line basis, but it had never been associated with a survival benefit. In 2012, ipilimumab (Yervoy®), a fully human, immunoglobulin G subclass 1 monoclonal antibody, was approved in Canada for the treatment of metastatic melanoma after failure of chemotherapy, based on the study by Hodi and colleagues published in 2010. This 3-arm study compared ipilimumab with or without a peptide vaccine (gp100) with the vaccine alone. It showed a 34% increase in overall survival with the use of ipilimumab compared to gp100. Median survival among the patients in this study was 10 months.

Subsequent to the Institut national d'excellence en santé et en services sociaux (INESSS)'s approval, in November 2012, of ipilimumab for the treatment of metastatic and locally advanced melanoma after failure of chemotherapy, it has been used to treat patients in Quebec's university teaching hospitals (UTHs). Our study therefore reviewed the charts of patients who were treated with ipilimumab and compared the analyzed data with those in the available literature on ipilimumab as second-line or higher monotherapy for metastatic melanoma.

The PGTM's scientific recommendations

In light of the results obtained for the population treated with ipilimumab for metastatic or unresectable advanced melanoma, the PGTM recommends that:

- The Eastern Cooperative Ongolocy Group (ECOG) performance status of patients selected for such treatment be rigorously assessed and that only those with an ECOG score of 0 to 1 be eligible for this treatment;
- This treatment not be undertaken by patients with a life expectancy of < 4 months;
- The description, in the patient's chart, of the response to the treatment, the toxicities and the management be improved.

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Objective:

To ensure, based on the utilization criteria for the drugs available in Quebec for the treatment of metastatic or unresectable advanced melanoma, optimal use of antibody-based immunotherapy (ipilimumab, nivolumab or pembrolizumab, as the case may be) in Quebec's UTHs. Indeed, it seems appropriate to apply to all of these drugs certain recommendations made with regard to ipilimumab.

Intervention measures:

Each institution is to determine which interventions apply to its situation and make one or more of them priorities.

Timetable:

Institute applicable measures in each UTH within 18 months, commencing with June 2016, the expected date of the Minister's decision regarding the listing of nivolumab in the RAMQ's *List of Medications – Institutions*.

Intervention plan for the PGTM's ipilimumab CIM:

1. Present the results of the descriptive analysis to the Pharmacy and Therapeutics Committee or the Chemotherapy Subcommittee, if applicable;
2. Present the local results to the health professionals concerned, in particular, the pharmacists who work in hematology/oncology, the hematologists/oncologists, and the dermatologists involved in the treatment of melanoma;
3. Create a decision tree for the systemic treatment of metastatic melanoma based on drugs available in Quebec, taking into account the decisions forthcoming in the next 6 months;
4. Pursue authorization on a case-by-case basis and review the charts of patients who have been treated with immunotherapy, in order to compare their data with those in the available literature;
5. Given that certain antibodies have now been accepted as first-line therapy, it is imperative to promote better documentation of the performance status and life expectancy of patients who meet the criteria set out in the RAMQ's *List of Medications – Institutions*;
6. Institute cost-reduction measures (grouping patients and examining, on a case-by-case basis, dose rounding to the nearest vial).