

## PGTM Clinical Intervention Model (CIM)

### *Descriptive analysis of pertuzumab/trastuzumab in metastatic breast cancer at Quebec's university teaching hospitals - 2019*

#### **Background:**

Since its approval by INESSS in July 2015, pertuzumab has been routinely used as first-line therapy in patients with HER2-overexpressing metastatic breast cancer at Quebec's four university teaching hospitals. The budget of all four UTHs devoted to purchasing this antineoplastic for the 86 patients who were treated in this descriptive analysis (DA) is estimated at more than \$3 million. This figure justifies the need to optimize the use of pertuzumab, both in terms of safety and the desired efficacy.

#### **The TDMPs scientific recommendations**

In light of the results obtained for the population receiving pertuzumab, the following recommendations can be made:

- Ensure that the patient's performance status (ECOG) is rigorously assessed and recorded throughout the treatment and that only patients with an ECOG status of 0 or 1 are eligible. The UTHs should consider adding a place to indicate the patient's ECOG status on the preprinted prescriptions;
- Allow the prescriber to choose between docetaxel and paclitaxel, since the data do not show a difference in the response rate or disease stabilization rate (49% vs. 46.9%);
- Ensure that each patient undergoes baseline cardiac imaging to document the LVEF before the start of treatment and that this assessment is done at an appropriate frequency during and up to 24 months after treatment with pertuzumab;
- Given the toxicities experienced by the patients over 70 years of age in our study (81.8% vs. 62.8% in the overall population during the initial phase and 27.3% vs. 9.3% during the maintenance phase), raise clinicians' awareness of the importance of targeting patients who can tolerate this drug combination, taking into account their performance status, their comorbidities and the risk of drug interactions in cases of polypharmacy;
- Improve the documentation, in the patient's chart, of information on the diagnosis and the response to treatment, as well as on toxicities and their management;
- Conduct a follow-up study to document progression-free survival and overall survival with more mature data.

#### **Objective:**

To promote the optimal use of pertuzumab/trastuzumab.

#### **Intervention measures:**

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

#### **Timetable:**

Institute applicable measures at each UTH within 12 months of January 2019.

**The PGTM's intervention plan for the pertuzumab/trastuzumab in metastatic breast cancer CIM:**

1. Present the results to the Pharmacology and Therapeutics Committee and/or the Cancer/Oncology Subcommittee, if applicable, and to other committees concerned, if relevant;
2. Present the local results to the clinical practitioners concerned, specifically, pharmacists, hematologists/oncologists and oncological surgeons who prescribe chemotherapy for the treatment of breast cancer, if applicable;
3. For the purpose of meeting the selection criteria for patients eligible for pertuzumab/trastuzumab therapy, discuss with the oncologists the best methods/tools to be developed for recording in the patient's chart the various elements/criteria to be considered in order to guide the decision to initiate, continue or stop treatment at the appropriate time, in particular:
  - Documenting the patient's performance status as soon as treatment is initiated and throughout the treatment;
  - Confirming that the patient has not previously received any treatment (anti-HER2/chemotherapy) for metastatic breast cancer;
  - Determining the patient's HER2 receptor status prior to initiating treatment;
  - Monitoring the patient's cardiac function every 3 months during treatment and for up to 24 months after the end of treatment;
  - Performing a radiological or medical evaluation every 4 months during treatment.
4. Each UTH could opt to document in the patient's chart certain elements/criteria on a form deemed appropriate, e.g., a prewritten prescription, a preprinted oncology medical visit form or an eligibility form specific to this treatment, like those created by Cancer Care Ontario. These tools, which could be used to ensure the tackability of the criteria for using medications with exception drug status, would also promote their judicious use;
5. Conduct a follow-up study to evaluate progression-free survival and overall survival with more mature data in the 71 patients alive at the end of the data gathered for the present analysis;
6. Monitor the availability of trastuzumab biosimilars with regard to ministerial directives that could influence the terms of use of the reference biologic drug in combination with pertuzumab.