

Cancer Care Ontario

Action Cancer Ontario

July 2013

EBP Herceptin Update

Executive Summary

2013 marks the second-year anniversary of the establishment of the Evidence Building Program (EBP). This program was introduced to provide time-limited coverage for cancer drugs in situations where data is collected to answer an evidence gap, to evaluate clinical benefit, and to confirm overall value. The objective of the EBP is to collect real-world data on cancer drugs where there is emerging or evolving evidence and a strong suggestion of clinical benefit, while current evidence is insufficient to support a permanent funding decision. Data collected through the EBP will be evaluated and will inform a final funding decision by the Executive Officer of Ontario Public Drug Programs.

Herceptin (trastuzumab), was approved as the first drug in the EBP, for use with chemotherapy to treat breast tumours of less than or equal to 1 cm in diameter that are node negative and HER2 positive. Since May 2011, 137 patients in Ontario have received or are receiving Herceptin through the EBP.

Presented below is a program summary of patients who have completed or are enrolled in EBP Herceptin during the period from May 2011 to March 2013, all of whom have met the eligibility criteria as established by the program.

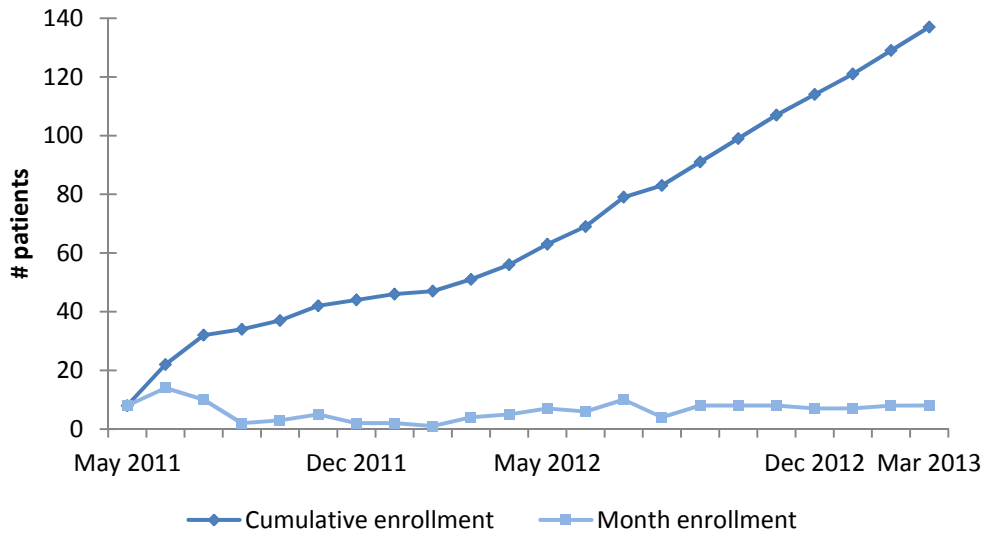
As only two years have elapsed since the program, it is not yet possible to verify if the benefits and harms from giving Herceptin to this group of women are comparable to women with larger tumors. This data collection is ongoing, and sufficient information is expected to be available by 2016 to inform a permanent funding decision.

Eligibility criteria

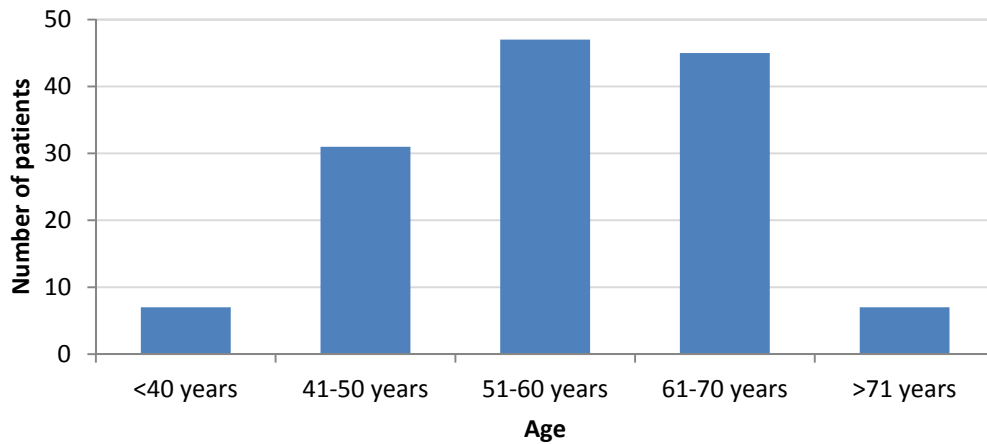
Patients who qualify for this program are breast cancer patients with node-negative, HER2+ tumours smaller or equal to 1 cm in diameter.

Program growth

Between May 2011 and March 2013, 137 patients have been provided Herceptin coverage through the Evidence Building Program, at an average enrollment rate of 6 patients per month.



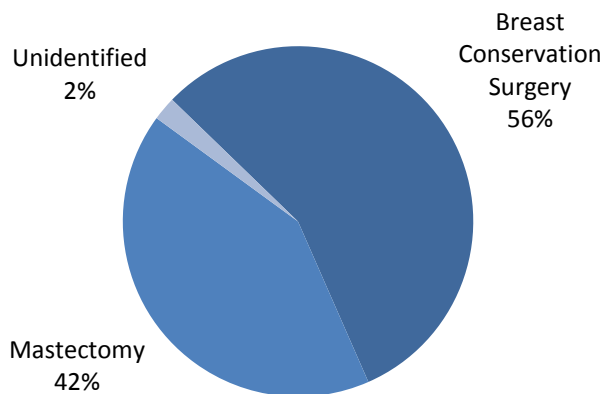
Patient Age of Diagnosis



Age of diagnosis	Count	Percentage
≤ 40	7	5.1%
41-50	31	22.6%
51-60	47	34.3%
61-70	45	32.8%
≥71	7	5.1%
Total	137	100%

Breast Surgery

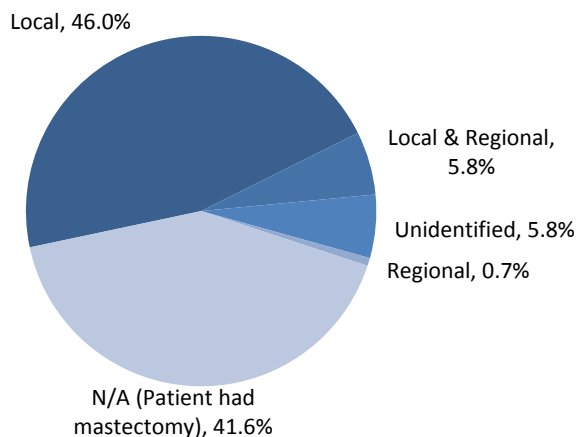
The majority of patients have undergone either breast conservation surgeries or mastectomy procedures prior to receiving Herceptin.



Surgery	Count	Percentage
Breast conservation	77	56.2%
Mastectomy	57	41.6%
Unidentified	3	2.19%
Total	137	100.0%

Planned Adjuvant Radiotherapy

Radiotherapy is given post-chemotherapy treatment, hence after the patient enrolls in the EBP. Local radiotherapy refers to radiation to the breast or chest wall only. Regional radiotherapy refers to radiation to the axillary nodes or supraclavicular area. Radiation is not given to the 57 patients who have had mastectomy as identified above.



Radiotherapy	Count	Percentage
Local	63	46.0%
Regional	1	0.7%
Local & Regional	8	5.8%
Unidentified	8	5.8%
N/A (Patient had mastectomy)	57	41.6%
Total	137	100.0%

Clinical outcome

Clinical outcome measurements on safety, survival and disease-free progression are collected by CCO on an ongoing basis for each patient upon completing the program. This data is undergoing analysis to be released in a follow-up report that will be shared at a later date.

Future direction

As EBP enters in its third year of operation, 60-70 patients are expected to receive coverage for Herceptin on a yearly basis. Their data will continue to contribute as real-world data for the evaluation for clinical benefit and overall value, and subsequently an informed funding decision for this patient group.