In Italy, skin melanoma represented 1.6% of all cancers diagnosed among males and 2.1% among those diagnosed among females; as regards cancer mortality it represented 0.9% of all cancer deaths among males and 1.0% among females. In the area of the Italian Network of Cancer Registries, there were on yearly average 12.5 new skin melanoma diagnoses per 100,000 males and 13.1 per 100,000 females. More than 50% of all cases are diagnosed within the age 59 years. The cumulative risk (0-74 years) of developing a skin melanoma was 8.4% among males (1 case every 119 men) and about 8.1% among females (1 case every 123 women), while the cumulative risk of dying from this cancer was 1.9% among males and 1.1% among females, respectively [1].

Ipilimumab is a fully human anti-CTLA-4 monoclonal antibody (IgG1κ) produced in Chinese hamster ovary cells by recombinant DNA technology that specifically blocks the inhibitory signal of CTLA-4, resulting in T-cell activation, proliferation, and lymphocyte infiltration into tumours, leading to tumour cell death. The mechanism of action of ipilimumab is indirect, through enhancing T-cell mediated immune response [2]. Ipilimumab is the first drug to be licensed in Italy for the treatment of advanced melanoma (unresectable or metastatic) in adults who have received prior therapy [3]. This study aims to estimate the budget impact of ipilimumab in patients who live in the Veneto Region.

### OBJECTIVES

In Italy, skin melanoma represented 1.6% of all cancers diagnosed among males and 2.1% among those diagnosed among females; as regards cancer mortality it represented 0.9% of all cancer deaths among males and 1.0% among females. In the area of the Italian Network of Cancer Registries, there were on yearly average 12.5 new skin melanoma diagnoses per 100,000 males and 13.1 per 100,000 females. More than 50% of all cases are diagnosed within the age 59 years. The cumulative risk (0-74 years) of developing a skin melanoma was 8.4% among males (1 case every 119 men) and about 8.1% among females (1 case every 123 women), while the cumulative risk of dying from this cancer was 1.9% among males and 1.1% among females, respectively [1]. Ipilimumab is a fully human anti-CTLA-4 monoclonal antibody (IgG1κ) produced in Chinese hamster ovary cells by recombinant DNA technology that specifically blocks the inhibitory signal of CTLA-4, resulting in T-cell activation, proliferation, and lymphocyte infiltration into tumours, leading to tumour cell death. The mechanism of action of ipilimumab is indirect, through enhancing T-cell mediated immune response [2]. Ipilimumab is the first drug to be licensed in Italy for the treatment of advanced melanoma (unresectable or metastatic) in adults who have received prior therapy [3]. This study aims to estimate the budget impact of ipilimumab in patients who live in the Veneto Region.

### METHODS

Our analysis was performed from the perspective of the Italian health care system. Two scenarios were analyzed: one with the optimization of vials and the other without. Only drug acquisition costs (excluding VAT 10%) were considered into the analysis. All costs were referred to year 2013.

### RESULTS

Based on the incidence and mortality rates of the last three years, and according to clinicians and regional data, a total of 80 adult patients were assumed to be eligible for the treatment in the Veneto Region. The cost per mg of ipilimumab was €53.70 (excluding VAT 10%); one vial contains 50 mg of ipilimumab and the other one contains 200 mg of ipilimumab (Table n.1). The recommended induction regimen is 3 mg/kg administered intravenously every 3 weeks for a total of 4 doses. The treatment cost per patient with ipilimumab ranged from €45,108 with vial optimization (considering 4-5 patients infused at the same time - average weight 70 kg) to €53,700 without. Optimization can be achieved by a “Drug Day”, with vial sharing. Therefore, Veneto Region identified a single center for the preparation/administration of treatment to minimize drug waste and to reduce the treatment cost per patient, with a saving of €8,592 per patient (Table n.2). Applied to whole eligible patients (average weight 70-75 kg), it allows to obtain savings up to €430,000-690,000 per year (Figure n.1).

### CONCLUSIONS

High prices for new cancer drugs are a growing concern to payers, given the large number of cancer drugs in development and the limited health care resources. Vial optimization may be an useful strategy to decrease waste, maximizing the use of health care resources and ensuring that eligible patients are treated.

### Table n.1 Drug Price

<table>
<thead>
<tr>
<th>Drug</th>
<th>Package Size</th>
<th>Price Veneto Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipilimumab</td>
<td>50 mg 1 vial</td>
<td>€2,685</td>
</tr>
<tr>
<td></td>
<td>200 mg 1 vial</td>
<td>€10,740</td>
</tr>
</tbody>
</table>

* Hospital Price excluding VAT 10%.

### Table n.2 Cost Therapy and Savings for patient

<table>
<thead>
<tr>
<th>Drug</th>
<th>Regimen</th>
<th>Scenario</th>
<th>Cost for cycle (consumption)</th>
<th>Cost Therapy#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipilimumab</td>
<td>3 mg/kg every 3 weeks for 4 doses</td>
<td>Drug Day – Vial Sharing</td>
<td>€11.277 (210 mg)</td>
<td>€45.108</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO Drug Day – NO Vial Sharing</td>
<td>€13.425 (250 mg)</td>
<td>€53.700</td>
</tr>
<tr>
<td>Saving with Drug Day*</td>
<td></td>
<td></td>
<td>€2.148 (40 mg)</td>
<td>€8.592</td>
</tr>
</tbody>
</table>

* Hospital Price excluding VAT 10%.

* Average patient weight 70 Kg

* Administering the therapy for groups of 4-5 patients (and its multiples), it is possible, if not completely eliminate the waste, at least limit the financial impact.

### Figure n.1 Saving in the Veneto Region

**DRUG DAY – VIAL SHARING**

80 patients/year with an average weight of 70 – 75 Kg savings up to €430,000 – €690,000 per year

### BIBLIOGRAPHY

2) RCP Ipilimumab www.ema.europa.eu