Evaluation of talimogene laherparepvec use in unresectable and recurrent melanoma

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Background

• Talimogene laherparepvec (T-VEC) is a formulation of herpes simplex virus type 1 which has been genetically modified to replicate within tumors and to produce the immune stimulatory protein GM-CSF.1
• T-VEC was approved by the FDA in October of 2015 for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with recurrent melanoma based on the results of the OPTIM trial.1
  – Randomized, open-label, phase III trial of 436 patients which compared T-VEC with GM-CSF for treatment of unresectable stage IIIB, IIIIC, or IV melanoma.
  – Demonstrated that patients treated with T-VEC had a statistically higher durable response rate (DRR) of 16.3% compared to GM-CSF with a DRR of 2.1% (P<0.0001).
  – There was not a statistically significant difference in overall survival between the two arms.
• T-VEC was added to the Duke University Health System Formulary on January 4, 2016.

Objectives

Primary Objective:
– To determine if T-VEC is being administered in accordance with the DUHS guidelines for use

Secondary Objectives:
– To determine the excess amount of T-VEC that is being discarded due to administration practices within DUHS
– To develop a solution which limits excess waste of T-VEC, if deemed appropriate by the outcomes of the previous secondary objective

Methods

This is a single-center, retrospective medication use evaluation designed to evaluate prescribing patterns following addition of T-VEC to the DUHS formulary. Any patient who received at least one dose of T-VEC between January 4, 2016 and September 30, 2016 was included in this study.

Results

Baseline Characteristics (n=13)

<table>
<thead>
<tr>
<th>Lesion Size (cm)</th>
<th>Maximum Dose (mL)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0.5</td>
<td>0.1</td>
</tr>
<tr>
<td>&gt;0.5–1.5</td>
<td>0.5</td>
</tr>
<tr>
<td>&gt;1.5–2.5</td>
<td>1</td>
</tr>
<tr>
<td>&gt;2.5–5</td>
<td>2</td>
</tr>
<tr>
<td>&gt;5</td>
<td>4</td>
</tr>
</tbody>
</table>

First treatment given with a concentration of 10^6 (1 million) PFU/mL
Subsequent treatments given with a concentration of 10^7 (100 million) PFU/mL
Second treatment should be at least 3 weeks after the initial treatment
Subsequent treatment should be at least 2 weeks after previous treatment

*Maximum dose per treatment for all lesions combined is 4mL
Cost of 10^6 (1 million) PFU/mL per vial is $52.80 (AWP)
Cost of 10^7 (100 million) PFU/mL per vial is $5280 (AWP)

References


Disclosures: Authors have no conflicts of interests regarding personal or financial relationships with commercial entities that may have influenced the content or subject matter of this presentation.

Conclusions

– T-VEC injections were generally administered per guidelines
– Time between treatments and dose administered were the most common deviations from the guidelines
– Waste of both concentrations combined totaled $84,691 (AWP)
– Requiring T-VEC to be administered on specific days of the week would allow syringes to be prepared for multiple patients
– If just those encounters which occurred in the same week were combined on the same day, 5 vials of 100 million PFU/mL could have been saved, totaling $26,400 (AWP)