Recently Introduced Products

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Potential Impact</th>
<th>Expected Avg. Annual Cost</th>
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<tbody>
<tr>
<td>Divigel</td>
<td>For treatment of moderate to severe vasomotor symptoms associated with menopause</td>
<td>$</td>
<td>$285.00</td>
</tr>
</tbody>
</table>

$: Est. drug plan expenditure increase of <1%*  $$: Est. drug plan expenditure increase of 1-5%*  $$$: Est. drug plan expenditure increase of >5%*

## Zelboraf® - A New Treatment Option for Metastatic Melanoma (MM)

Melanoma is a type of skin cancer and typically presents in a younger working population. Melanoma, in the advanced or metastatic stage, becomes one of the most deadly cancers with an average survival time of only 6 - 9 months. MM is the spreading of melanoma into the lymph nodes and/or other parts of the body. In Canada, an estimated 900 patients per year are expected to develop MM. There is currently no standard treatment for MM, thus there is an urgent need for new and effective therapies.

Zelboraf® is now an eligible drug benefit in the provinces of BC, AB, SK, MB, and ON. Patients must meet specific criteria to obtain access to Zelboraf® either through the provincial prescription drug plan or as part of a provincial cancer agency.

Currently, treatments for MM are administered intravenously in the hospital. Zelboraf® is the first oral agent available for the treatment of MM. By targeting an abnormal mutation, Zelboraf® stops the growth of cancer cells and promotes cell death. The clinical trial (BRIM 3) demonstrated an overall clinical benefit of Zelboraf® in the treatment of MM.

Health Canada has approved Zelboraf® for the treatment of patients with unresectable or metastatic melanoma that have a BRAF V600 mutation. Approximately 50% of MM tumours harbour the BRAF V600 mutation, which is responsible for abnormal cell growth. The manufacturer has developed a diagnostic test, the cobas® 4800 BRAF mutation test, to identify patients with this mutation. This fast and accurate testing helps avoid unnecessary treatment for patients whose tumours do not exhibit the mutation.

The recommended dosing regimen with Zelboraf® is 960mg (4 x 240mg tablets) taken twice daily until the patient experiences disease progression. The cost per 240mg tablet is $46.54, corresponding to a daily cost of $372 and an annual cost of approximately $136,000.

Due to the significant costs associated with this medication and to ensure that this medication is used for the appropriate patient, it is recommended that Zelboraf® be placed under Special Authorization for ClaimSecure groups that subscribe to the Managed Formulary, Specialty Drug, and Stop Loss Programs. The Special Authorization process seeks to ensure that: 1) the member has a confirmed BRAF V600 mutation and 2) to coordinate benefits with available provincial public programs. Members who experience a beneficial clinical effect, AND who do not have evidence of disease progression, will be eligible for continued coverage beyond four months. For Open Drug Formularies, Zelboraf® will be excluded.

**If you require additional information about Zelboraf®, please contact Lavina Viegas, Clinical Pharmacist, Clinical Services Department, at (905) 949-3031 or 1-888-479-7587 ext. 3031.**

**Recommendation: Special Authorization**

ClaimSecure reserves the right to amend in part or in its entirety stated special authorization clinical guidelines

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References:
1. Zelboraf® Product Monograph. Roche. February 2012

* Based on the Financial Impact Analysis per 100,000 lives covered © 2012 ClaimSecure Inc.