Recently Introduced Products

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Potential Impact</th>
<th>Expected Avg. Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edurant</td>
<td>For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in combination with other antiretroviral agents, in antiretroviral treatment- naïve adult patients</td>
<td>$</td>
<td>$5,037.00</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%*

Afinitor® - First oral treatment for brain tumours caused by tuberous sclerosis complex

Tuberous Sclerosis Complex (TSC) is a genetic disorder that causes benign tumours to grow in the brain and on other vital organs such as the kidneys, lungs, skin, heart and retina. Symptoms may include epilepsy, mental retardation, behavioural disorders, skin abnormalities, lung and kidney disease. The incidence of TSC is 1 in 6000 live births.

Subependymal Giant-cell Astrocytomas (SEGAs) are non-cancerous slow-growing tumours that arise in the fluid-filled spaces within the brain, and occur in approximately 5 to 20% of patients with TSC. SEGAs increase the risk of death when they block the flow of fluid around the brain and spinal cord, leading to brain swelling. Afinitor® is the first drug therapy approved in Canada for the treatment of patients with SEGAs associated with TSC that have demonstrated serial growth.

The current standard of care for SEGAs is surgical resection, which may lead to complications such as hemorrhage, vision loss, seizures and infection. In addition, there are a small proportion of SEGAs that are unresectable, while 44% of resections are incomplete and require an additional surgery. As a new therapeutic option, Afinitor® is intended for use in patients who are not candidates for surgical resections OR for whom immediate surgical intervention is not required.

Afinitor® has been available on the Canadian market since January 2010 for the second line treatment of patients with advanced renal cell carcinoma. For this new indication, Afinitor® has been granted conditional approval by Health Canada i.e. it will be available on the market on the condition that the company undertakes additional studies to verify its clinical benefit. Conditional approval is given to fast track drugs for life threatening conditions such as AIDS or cancer that have demonstrated promising benefits.

Afinitor® works by blocking a specific enzyme that is involved in tumour cell growth and division, thus reducing the size of brain tumours that are caused by TSC. A clinical trial consisting of 28 patients concluded that tumor volume was significantly reduced by ≥ 30% from baseline in 21 patients, while 9 patients experienced reduction of ≥ 50% or more.

Afinitor® is currently available as 5 mg and 10 mg tablets and has now introduced a new 2.5 mg strength. The dose is taken once daily and is determined based on the patient’s body size. All tablets are priced equivalently at $186.00 with an annual cost of $67,890.

Due to the significant cost associated with this medication and to ensure coordination with available provincial programs, Afinitor® will be placed under Special Authorization for ClaimSecure groups that subscribe to the Managed Formulary, Specialty Drug, and Stop Loss Programs. The Special Authorization seeks to ensure that: 1) the member is using the therapy as approved by Health Canada, and 2) coordination of benefits with available provincial public drug programs. For Open Drug Formularies, Afinitor® will be fully covered.

If you require additional information about Afinitor®, 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 entirely stated special authorization clinical guidelines

References:

* Based on the Financial Impact Analysis per 100,000 lives covered © 2011 ClaimSecure Inc.