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# DRUG REVIEW

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## Recently Introduced Products

| Drug Name | Indication | Potential Impact | Approx. Cost Per Bottle |
|---|---|---|---|
| Jublia | For the treatment of select* mild to moderate fungal infection of toenails in immunocompetent adult patients<br><br>*Fungus: Trichophyton rubrum and Trichophyton mentagrophytes | $ | $68.80 |

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

## Bosulif® – Beyond 2nd Line Therapy for Chronic Myelogenous Leukemia

Chronic Myelogenous Leukemia (CML) is a type of cancer originating from the bone marrow and arising from blood stem cells. As per its name, CML relates to abnormal development of myeloid stem cells, which normally mature into red blood cells, platelets, etc. CML has a tri-phasic clinical course: a chronic-phase (CP), an accelerated-phase and a blast-phase; categorization is dependent on the number of immature cells in the blood and bone marrow as well as the severity of symptoms. The majority of patients (90%) are diagnosed with CML in the chronic phase, CP. If left untreated, CP CML is likely to progress to other, more aggressive phases of the disease within 3-5 years' time.

CML is, by and large, an adult disease even though all age groups can be affected. In the adult population, CML accounts for ~15% of all leukemia cases. In Canada, it is estimated that 5,500 Canadians have CML and its prevalence is expected to rise in the future.

Current treatment guidelines suggest the use of targeted therapy for CML – Tyrosine Kinase Inhibitors (TKIs). These include 1st generation TKI, Gleevec® – typically 1st treatment of choice as well as 2nd generation TKIs, Sprycel® and Tasigna®.

Bosulif® is a new drug entity within the class of TKIs. There is substantial data to support its use in CML patients who are refractory, resistant or intolerant to prior TKI therapy, and therefore, has been approved as more advanced lines of treatment for the disease. As a 2nd line agent, Bosulif® demonstrated efficacy similar to 2nd generation TKIs in patients previously treated with Gleevec®. More importantly, it is the first TKI to show efficacy beyond 2nd line therapy – ~40% of patients achieved major clinical response with Bosulif® after failing >1 prior TKI. Bosulif®'s mild and manageable side effect profile also sets it apart from existing TKIs because of intolerance in select patient populations. Since the development of resistance and intolerance is a major concern (i.e. affecting up to 25% of patients) with therapies currently available, Bosulif® presents as a favourable option for patients with CML who failed prior TKI therapy, and for whom subsequent treatment with Gleevec®, Sprycel®, and Tasigna® is not clinically appropriate.

Bosulif® is approved as 2nd or more advanced lines of treatment for CML. Due to its place in therapy and high cost, it is recommended that Bosulif® 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 Bosulif® is used only in patients with CML after failure of one or more existing TKIs and that there is opportunity to coordinate benefits with provincial public programs where possible. For Open Drug Formularies, Bosulif® will be fully covered.

***If you require additional information about Bosulif®, please contact the Clinical Services Department, at (905) 949-3025 or 1-888-479-7587 ext. 3025.***

**Recommendation: Special Authorization**

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

References:
1. Bosulif® Product Monograph. Pfizer Canada Inc. July 2014.
2. Summary Basis of Decision for Bosulif®.
3. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_bosulif_152211-eng.php#sbd



* Based on the Financial Impact Analysis per 100 000 lives covered