

Patent Medicines Price Review Board Submission

by Chronic Lymphocytic Leukemia Patient Advocacy Group - CLLPAG



CLL PATIENT
ADVOCACY GROUP

GROUP DE DÉFENSE DES
PATIENTS DE LA LLC

Thank you for the opportunity to respond to *Protecting Canadians from Excessive Drug Prices* and to share our experience as patients.

Your process is very timely for us because there are a number of new and effective treatments for CLL and SLL. Unfortunately, the price of the drugs is only within reach of the wealthiest patients or patients with access to the most generous health care plans.

About CLLPAG

CLL Patient Advocacy Group (CLLPAG) is a national advocacy group founded at an education meeting organized by Ontario CLL patients in 2002.

We are patients, caregivers and their supporters. All work is done on a volunteer basis. We maintain a website at cllpag.ca. CLLPAG has collected patient evidence for nine pCODR or INESSS drug reviews. We have organized patient conferences in 2007, 2009, 2012 and 2015. Our most recent conference attracted 270 persons, mainly from Canada and the United States. Planning for the 2018 conference is underway.

CLL is the most common adult leukemia. CLL is more common in people who are 60 years and older. The incidence of the disease increases from one per 100,000 in individuals aged 30 to 34 years to more than 30 per 100,000 in individuals aged 80 and older.¹

CLL Treatments

CLL is one of the blood cancers that always returns. Time to relapse depends on the patient's genetic profile and other factors. Treatment for CLL has changed significantly in the last five years. Previously, upon relapse from their initial treatment, patients would receive additional rounds of chemotherapy. Complications from the toxicity of repeated chemotherapy led to further deterioration of health.

In the last few years, several new therapies that target B cell malignancies have been developed. They are not curative, but inhibit the growth of cancerous B cells. Most patients who participated in the initial trials of the new therapies six years ago are still healthy and have excellent prospects. Second generation and combination therapies are in development and CLL patients are hopeful of even more effective drugs.

Cost

Unfortunately, the annual list price of these drugs is about \$120,000, an impossible price for individuals who don't qualify for private or public drug plans. As a result, patients either get them through a compassionate program or through a trial. We don't know the number of patients who can't afford these drugs and get chemo instead.

In the last year, some patients tell us that their private drug plans are capping the cost that is available through their plans. The same pressures that affect private plans are impacting public plans². If a 65

¹ Leukemia and Lymphoma Society, Chronic Lymphocytic Leukemia, 2011

year old patient lives to 80, the list price of the B cell inhibitor will be \$1,800,000 (without inflation). This is not sustainable for private or public purses.

Introducing new factors to help determine whether a price is excessive

1. Do you agree that a pharmacoeconomic evaluation is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the evaluation be considered?

Yes a pharma-economic evaluation should be considered and the metric should be aligned with the metric used by pCODR/CADTH in determining a drug's cost/benefit. Over time, this would link pricing to effectiveness and impact on other health care costs.

2. Do you agree that the size of the market for the drug in Canada and other countries is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the size of the market be considered?

The market for CLL drugs is small although the drugs are now being used for other small market blood cancers. Consideration of market size should be balanced by the value of the medication to patients, the potential for savings to the health care system and by changes in the market nationally and internationally as research and other costs are offset.

3. Do you agree that Canada's GDP and GDP growth are important for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should GDP be considered?

This seems like a very technical question and beyond our experience. It is important that prices be controlled and that PMPRB adopt a series of measures that are transparent and effective.

4. Are there any other factors that should be considered by the PMPRB when determining whether a drug is priced excessively? How should the factor(s) be considered and what information should be required from patentees?

Drugs have to be accessible and affordable to public, private and individual purses, especially since the most recently approved oral CLL treatments require life-long drug consumption.

An active CLL research environment has led to the new therapies and access to clinical trials. Many of our members first accessed their medication through a trial. Continuing to make Canada an inviting place for clinical trials is important for us and helps ensure that Canada is among the first to get new medication. It also leverages Canada's considerable investment in medical/health technology.

Amending the list of countries used for international price comparisons

- 1. Are there other countries that should be considered in revising the Schedule?*
- 2. Are there other criteria that should be considered in revising the Schedule?*

² CAPCA, the Canadian Association of Provincial Cancer Agencies presentation to industry and patient group representatives, March 3, 2017

3. *Please provide any other comments you may have on the Schedule of comparator countries.*

Economic standing, similarity of health care system, consumer protection orientation and market characteristics are good benchmarks for choosing comparator countries. At a recent international meeting of CLL patient groups, participants learned from each other that prices of the new CLL drugs are high in all countries. We hope that the list will be reviewed regularly to ensure that Canada has moved to the lower half of the list. It may be that prices in some countries are comparatively lower but all are very high. Comparator countries need to have similar healthcare systems. International solutions might be most effective.

Reducing regulatory burden for generic drugs with a patent

Do you agree that patentees of generic drugs, i.e. drugs that have been authorized for sale by Health Canada through an ANDS should only report information about the identity of the drug and its price in the event of a complaint or at the request of PMPRB?

At the time of treatment, CLL patients may take generic drugs to control side effects. However, the high cost drugs are not available as generics.

Modernizing reporting requirements for patentees

Is the information sought in to relation the new factors relevant and sufficient? 2. Is this information generally available to patentees?

Given the high starting price point of CLL drugs, even reduced pricing will be a burden for public and private purses. Transparency around prices helps us understand how a product is priced and provides the basis for ongoing patient advocacy.

Providing information related to third party rebates

No comment.

Conclusion

Treatments for CLL have changed for the better. Patients can now hope to live much longer than ever before. However, the cost of the new drugs is too high to be sustainable. Private drug plans are already starting to limit access and the viability of public drugs plans will soon be in peril.

We've talked to other cancer patient groups and they are facing similar scenarios.

Many countries are facing similar cost pressures and Canada should be among the leaders at finding ways to balance access and cost.

We appreciate the thinking that is going into the review and hope that you can find a way to make these drugs accessible. It would be a tragedy for them to sit on the shelf.