

Patent Medicines Price Review Board Submission

Thank you for the opportunity to respond to your Guidelines Modernization Discussion Paper. We are a group of blood cancer patients who have organized a national, volunteer-run, advocacy group to provide education and promote access to health care that extends the lives of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) 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.

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 been very active in collecting patient evidence for the pCODR drug review process. 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.

About Chronic Lymphocytic Leukemia (CLL)

Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma are types of blood cancer. The cancer cells of both diseases look the same under the microscope. The difference is in where the cancer appears in the body. In CLL, the cancer is more prominent in the blood where in SLL the cancer is more prominent in the lymphatic system. When we refer to CLL, we are referring to both CLL and SLL. There is no cure and after treatment most patients relapse. The time to relapse varies considerably; it may be a matter of months or it may be many years.

Chronic lymphocytic leukemia (CLL) results from an acquired (not present at birth) change to the DNA of a type of white blood cell called B cell lymphocytes. Scientists do not yet understand what causes this change. CLL cells grow and survive better than normal cells; over time, the uncontrolled growth means they crowd out normal cells. B cell lymphocytes play an important role in the body's immune system, identifying viruses and foreign bodies so they can be destroyed. In CLL, malignant lymphocytes do not function properly, leading to a patient having an ineffective, compromised immune system.

CLL has generally not been associated with any environmental or external factors. 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

Treatment for CLL has changed significantly in the last five years. Previously, upon relapse from their initial treatment, patients would receive additional rounds of chemo-immunotherapy. CLL patients typically died from complications of the adverse impact of repeated chemotherapy. In the last few years, several new therapies that target B cell malignancies have been developed. They are not curative,

¹ Leukemia and Lymphoma Society, Chronic Lymphocytic Leukemia, 2011

but inhibit the growth of cancerous B cells. These drugs must be taken for the rest of the patient's life, only being stopped if the patient develops a reaction to the drug or if the cancer recurs.

Patients who participated in the initial trials six years ago are still healthy and have excellent prospects. Second line inhibitors are in the works and CLL patients are hopeful for even more effective drugs.

Cost

Unfortunately, the annual cost 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 from a compassionate program or through a drug plan.

In the last year, some patients tell us that their private drug plans are capping the cost that is available through that plan. The same pressures that affect private plans will soon impact on public plans. If a 65 year old patient lives to 80, the cost of the B cell inhibitor will be \$1,800,000 (without inflation). This is not sustainable for private or public purses.

Your Mandate

The above illustrates our interest in a review of your guidelines. We don't feel comfortable responding to the technical questions in your discussion paper. However, we support these principles.

- Price comparisons should be linked to countries that also have publically funded health care systems, as opposed to the United States.
- Canadian prices should be more closely in line with prices in the countries that fit the criteria above.
- Whereas all drug prices need oversight, there needs to be additional regulatory focus on high priced drugs.
- Publically and privately funded drug plans must remain viable.

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 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.

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.