February 13, 2015 Comments from Patient Group
HepCBC Hepatitis C Education and Prevention Society
about the Scope of a Proposed Chronic Hepatitis C Treatment Regimen
Therapeutic Review by CADTH

CADTH: Do you think that the project as proposed in the project scope document will be useful to those making policy or clinical practice decisions? Why or why not?

The policy questions he project scope document raises are generally the right ones, as issues regarding reimbursement, treatment criteria, and retreatment are so critical at this juncture. We really like the greatly expanded scope into all genotypes, and with far greater variety of drugs and combinations being considered. However, we suggest enhancements to one question and adding two questions.

First, we'd like to split Policy Question #2 into several questions:

(a) Upon what basis does CADTH make decisions regarding HCV treatment criteria: scientific evidence? Short-term fiscal expediency? Compare short-term cost of curing HCV and preventing CHC (and serious sequelae) versus long-term cost of treating patients with incurable chronic diseases such MS, diabetes, or HIV over a patient's lifetime.

(b) Should reimbursement for DAAs for CHC be given to everyone who is HCV+ upon their doctor's recommendation, or

(c) Should reimbursement of the DAAs for CHC instead be limited to those who can prove a minimum degree of physical damage to their bodies, even though we know the treatment works better and results in greater increase in QALYs the earlier it is treated?

(i) If we select the exclusiveness of (c) over the inclusiveness of (b), what place does fibrosis staging have in determining the degree of physical damage? In other words, are there other factors we should be looking at as well, such as autoimmune responses, mental health, or extrahepatic manifestations?

(ii) Should reimbursement in this case be limited (as it has most often been done recently) to those with fibrosis stages greater than or equal to F2?

(iii) If fibrosis staging has a place, how accurate are the various means of determining fibrosis score and how cost-effective are they?

Second, we'd like to add a Policy Question #4:

(4) What recommendations, if any, do we want to make to limit the reimbursement of the DAAs for CHC in those with various degrees of liver de-compensation?

Finally, we'd like to add a Policy Question #5:

(5) Should we reimburse for drugs or treatments used to enable a patient approaching de-compensation to qualify for DAA treatment, or to enable any patient to remain on treatment? These could include

drugs to control or reverse conditions such as hepatic encephalopathy, low platelets, anemia, or fluid retention which now preclude patients from going on to treatment, or which can result in patients having to stop treatment.

CADTH: Do you have any suggestions for improving the project as proposed in the project scope document?

Yes, we would like you to address these questions:

(1) How can CADTH/CDR streamline future reviews of regimens for which all of its components are already approved in other regimens, rather than doing an entirely new review?

(2) Is CADTH/CDR doing all it can to ensure equitable pricing and access? In some cases it has called for lower prices, but there does not seem to be a clear pattern of when this call is made, and in those cases where it is, specific target pricing or pricing structures are not defined. It would be helpful to all stakeholders if CADTH/CDR would take leadership on this issue, possibly even mandating a particular equitable pricing structure or formula.

CADTH: Please provide any additional comments you may have about this document or the project itself, including any studies you think should be included in our review. (A list of included studies and the final project protocol will be posted at a later date.)

As a patient group whose members collectively possess broad, longtime and extensive experience in treatment with interferon, ribavirin, telaprevir, and boceprevir, we strongly protest any of these harsh and often debilitating drugs being prescribed instead of the next generation DAAs for short-term fiscal expedience. The very common side-effects of these drugs (experienced by most who take them) are within the realm of “cruel and unusual punishment”, and unless their use is of proven scientific value in a particular case, they should be completely struck from provincial formularies.