Published in final edited form as:
N Engl J Med. 2013 August 15; 369(7): . doi:10.1056/NEJMc1307589.

Current and Future Therapies for Hepatitis C Virus Infection

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To the Editor

In their review of drug therapy for chronic hepatitis C infection, Liang and Ghany (May 16 issue)[1] summarize boceprevir- and telaprevir-based regimens. Figure 2 of the article describes the regimens according to the response to the previous therapy, the response-guided therapy, and the stopping rules. The boceprevir regimen they describe represents the labeling information in the United States.[2] However, the information about boceprevir in European regimens has some differences[3] — the duration of therapy for patients who have not had a response to previous therapy (whether the patient had a relapse, a partial response, or no response) is 48 weeks (peginterferon alfa and ribavirin for 4 weeks, then all three drugs through week 36, and then peginterferon alfa and ribavirin through week 48). For the readers of the *Journal* in Europe, our comments might be useful.

Appendix

The Authors Reply: In our review, we used the Food and Drug Administration (FDA) labeling information1 as the basis for the approved regimens for boceprevir and telaprevir. Ozaras et al. point out that the European Medicines Agency (EMA) labeling information2 for boceprevir for patients who have had a relapse differs from the FDA labeling. The recommended regimen for patients who have received previous treatment was based on a subgroup analysis comparing rates of sustained virologic response between patients with an early response (undetectable level of HCV RNA at weeks 8 through 24) and those with a late response (detectable level of HCV RNA at week 8 but undetectable at week 24) who were receiving response-guided therapy (peginterferon alfa and ribavirin for 4 weeks, then all three drugs through week 32) or standard-duration therapy (peginterferon alfa and ribavirin for 4 weeks, then all three drugs through week 44).3,4

There was a difference of 6 percentage points in the rate of sustained virologic response in favor of response-guided therapy for patients with a late response and a difference of 7 percentage points in favor of standard-duration therapy for those with an early response (neither difference was significant). The FDA reasoned that these differences were probably due to chance, and it recommended response-guided therapy for patients with an early response who had previously had a relapse or a partial response. The EMA highlighted the fact that the higher rate of sustained virologic response among patients with an early response in the standard-duration group than among patients in that group with a late response was entirely due to a higher relapse rate in the group that received response-guided therapy than in the standard-duration group, and it therefore recommended that all patients who had received previous treatment undergo standard-duration therapy.

No potential conflict of interest relevant to this letter was reported.

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Since publication of their article, the authors report no further potential conflict of interest.

1. Highlights of prescribing information: Victrelis (boceprevir) capsules for oral use. Silver Spring, MD: Food and Drug Administration (http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/202258lbl.pdf).

2. Summary of product characteristics: Victrelis. London: European Medicines Agency (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002332/WC500109786.pdf).

3. Victrelis: Application number 202258Orig1s00: summary review. Silver Spring, MD: Food and Drug Administration (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202258Orig1s000SumR.pdf).

4. Assessment report: PegIntron (peginterferon alfa-2b). London: European Medicines Agency (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000280/WC500131791.pdf).

References

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2. Highlights of prescribing information: Victrelis (boceprevir) capsules for oral use. Whitehouse Station, NJ: Merck; (http://www.merck.com/product/usa/pi_circulars/v/victrelis/victrelis_pi.pdf).
3. Summary of product characteristics: Victrelis. London: European Medicines Agency; (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002332/WC500109786.pdf).