

Criteria Grid
Best Practices and Interventions for the Diagnosis and Treatment of Hepatitis C

Best Practice/Intervention:	Poordad et al. (2011). Boceprevir for Untreated Chronic HCV Genotype 1 Infection. <i>The New England Journal of Medicine</i> , 364 (13), 1195-1206.			
Date of Review:	May 16, 2011			
Reviewer(s):	Alison Marshall			
Part A				
Category:	Basic Science <input type="checkbox"/> Clinical Science <input checked="" type="checkbox"/> Public Health/Epidemiology <input type="checkbox"/> Social Science <input type="checkbox"/> Programmatic Review <input type="checkbox"/>			
Best Practice/Intervention:	Focus: Hepatitis C <input checked="" type="checkbox"/> Hepatitis C/HIV <input type="checkbox"/> Other: _____ Level: Group <input checked="" type="checkbox"/> Individual <input type="checkbox"/> Other: _____ Target Population: <u>938 nonblack participants and 159 black participants; history of no previous treatment for HCV infection</u> Setting: Health care setting/Clinic <input checked="" type="checkbox"/> Home <input type="checkbox"/> Other: _____ Country of Origin: <u>Multinational</u> Language: English <input checked="" type="checkbox"/> French <input type="checkbox"/> Other: _____			
Part B				
	YES	NO	N/A	COMMENTS
<i>Is the best practice/intervention a meta-analysis or primary research?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Primary Research ----Objective: compare the safety and efficacy of two therapeutic regimens of boceprevir in combination with peginterferon and ribavirin to therapy with peginterferon and ribavirin alone in patients <u>with previously untreated HCV genotype 1 infection</u>
<i>The best practice/intervention has utilized an evidence-based approach to assess:</i>				

<i>Efficacy</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Effectiveness</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>The best practice/intervention has been evaluated in more than one patient setting to assess:</i>				
<i>Efficacy</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Effectiveness</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

	YES	NO	N/A	COMMENTS
<i>The best practice/intervention has been operationalized at a multi-country level:</i>				
<i>There is evidence of capacity building to engage individuals to accept treatment/diagnosis</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<i>There is evidence of outreach models and case studies to improve access and availability</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<i>Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Are the best practices/methodology/results described applicable in developed countries?</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Are the best practices/methodology/results described applicable in developing countries?</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	--Depends: affordability and access to drugs; skilled workers; oral administration of boceprevir to be taken three times daily with food and intervals of 7-9 hours between doses
<i>Evidence of manpower requirements is indicated in the best practice/intervention</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>Juried journal reports of this treatment, intervention, or diagnostic test have occurred</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>International guideline or protocol has been established</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>The best practice/intervention is easily accessed/available electronically</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The New England Journal of Medicine, NEJM.org

<p><i>Is there evidence of a cost effective analysis? If so, what does the evidence say?</i> Please go to Comments section</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<p><i>How is the best practice/intervention funded?</i> Please go to Comments section</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>--Not yet funded.</p>
<p><i>Other relevant criteria:</i> Notable Findings</p> <hr/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>--Adding of boceprevir to standard therapy significantly increased rates of sustained virologic response in previously untreated black and nonblack patients infected with HCV genotype 1 infection [for nonblacks, 67% in Group 2 and 68% in Group 3; Among blacks, 42% in Group 2 and 53% in Group 3] compared to a treatment of peginterferon-ribavirin alone --Rates are similar at 24 weeks and 44 weeks of boceprevir --Due to differences in sustained virologic response rates between blacks and non-blacks, self-identified blacks and non-blacks were placed separately into two cohorts --Anemia lead to dose reductions in 13% of controls and 21% of recipients receiving boceprevir --Serious adverse events and discontinuation from an adverse event were not significantly different between patients that received boceprevir and those that did not. Similar adverse events have been seen with ribavirin but generally speaking, with this treatment therapy there were not a lot of additional symptoms and the side effects were not hard to mange. However, would likely experience greater difficulties implementing treatment with these possible side effects in a developing country.</p>