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

Best Practice/Intervention:	Bacon et al. (2011). Boceprevir for Previously Treated Chronic HCV Genotype 1 Infection, *The New England Journal of Medicine, 364* (13), 1207-1217.
Date of Review:	May 13, 2011
Reviewer(s):	Alison Marshall

Part A

Category:	**Basic Science ☐ Clinical Science ☒ Public Health/Epidemiology ☐** **Social Science ☐ Programmatic Review ☐**
Best Practice/Intervention:	**Focus: Hepatitis C ☒ Hepatitis C/HIV ☐ Other: HCV Genotype 1 Infection** **Level: Group ☒ Individual ☐ Other: _____** **Target Population: 403 adults randomized to one of three treatment groups, 2 groups with boceprevir; mean age 52.7 yrs. Majority (64%) had had a relapse after previous HCV therapy; screened patients in North America and Europe. Non-responders excluded in this study.** **Setting: Health care setting/Clinic ☒ Home ☐ Other: _____** **Country of Origin: Multinational Study** **Language: English ☒ French ☐ Other: _____**

Part B

	YES	NO	N/A	COMMENTS
Is the best practice/intervention a meta-analysis or primary research?	☐	☐	☐	**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 *with previously treated HCV genotype 1 infection*** **--See chart on p. 1209 for overview of Study Design**

The best practice/intervention has utilized an evidence-based approach to assess:				
Efficacy	☒	☐	☐	
Effectiveness	☐	☒	☐	
The best practice/intervention has been evaluated in more than one patient setting to assess:				
Efficacy	☒	☐	☐	
Effectiveness	☐	☒	☐	
	YES	**NO**	**N/A**	**COMMENTS**
The best practice/intervention has been operationalized at a multi-country level:				
There is evidence of capacity building to engage individuals to accept treatment/diagnosis	☐	☐	☒	
There is evidence of outreach models and case studies to improve access and availability	☐	☐	☒	
Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?	☒	☐	☐	
Are the best practices/methodology/results described applicable in developed countries?	☒	☐	☐	
Are the best practices/methodology/results described applicable in developing countries?	☐	☒	☐	--Depends: costs and availability of drugs; skilled workers; oral administration of boceprevir to be taken three times daily with food and intervals of 7-9 hours between doses
Evidence of manpower requirements is indicated in the best practice/intervention	☐	☒	☐	
Juried journal reports of this treatment, intervention, or diagnostic test have occurred	☒	☐	☐	
International guideline or protocol has been established	☐	☒	☐	

The best practice/intervention is easily accessed/available electronically	☒	☐	☐	The New England Journal of Medicine, NEJM.org
Is there evidence of a cost effective analysis? If so, what does the evidence say? ***Please go to Comments section***	☐	☒	☐	
How is the best practice/intervention funded? ***Please got to Comments section***	☐	☒	☐	
Other relevant criteria: ***Notable Findings*** **Overall, study showed promising benefits for previously treated persons who had experienced relapses	☐	☐	☐	--sustained virologic response rate was significantly higher in groups that received boceprevir [Group 2: 59%; Group 3: 66%] --Anemia was significantly more common in groups that received boceprevir; however, discontinuation for this reason was low (5 out of 161 patients in Group 3). Erythropoietin was administrated to 41% and 46% of patients in Group 2 and Group 3, respectively --small differences were seen between Group 2 & Group 3. Group 3 had higher # of patients with undetectable HCV RNA level during treatment weeks 8-36. This difference appeared to be related to percentage of patients with cirrhosis at baseline who had an undetectable HCV RNA level at week 8 (18% in Group 2 to 73% in Group 3). --median duration of treatment 2.4-3.2 times longer in Group 2 and Group 3 --high rates of sustained virologic response in black patients and patients with advanced liver disease. These groups usually have poor response rates. --102 patients had a poor response to interferon; 33-34% of these patients achieved a sustained virologic response after boceprevir was added to their treatment regimen