### Best Practice/Intervention:

### 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

<table>
<thead>
<tr>
<th>Is the best practice/intervention a meta-analysis or primary research?</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| | | | | 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:

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td>✗</td>
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</table>

The best practice/intervention has been evaluated in more than one patient setting to assess:

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
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</table>

The best practice/intervention has been operationalized at a multi-country level:

<table>
<thead>
<tr>
<th>There is evidence of capacity building to engage individuals to accept treatment/diagnosis</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is evidence of outreach models and case studies to improve access and availability</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Are the best practices/methodology/results described applicable in developed countries?</td>
<td>✗</td>
<td>NO</td>
</tr>
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<td>NO</td>
<td>✗</td>
</tr>
</tbody>
</table>

Evidence of manpower requirements is indicated in the best practice/intervention:

| Evidence of manpower requirements is indicated in the best practice/intervention | NO | ✗ | N/A |

Juried journal reports of this treatment, intervention, or diagnostic test have occurred:

| Juried journal reports of this treatment, intervention, or diagnostic test have occurred | ✗ | NO | N/A |

International guideline or protocol has been established:

| International guideline or protocol has been established | NO | ✗ | N/A |

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--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.
The best practice/intervention is easily accessed/available electronically

<table>
<thead>
<tr>
<th>The New England Journal of Medicine, NEJM.org</th>
</tr>
</thead>
</table>

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 go 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 administered 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