InterfacePrescribing & NewTherapies Subgroup

GMMMG Greater Manchester Medicines Management Group

NHS

November 2011

Boceprevir or Telaprevir for treatment of Chronic Hepatitis C infection

The Interface Prescribing and New Therapies Subgroup (IPNTS) discussed the above drug at a meeting on the 22nd November 2011. The recommendation of this subgroup is as follows:*

The Interface Prescribing & New Therapies Subgroup of the GMMMG considered the use of Boceprevir or Telaprevir for the treatment of chronic hepatitis genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy. Telaprevir is also licensed for use in patients with cirrhosis (as a sub-group of those with compensated liver disease) and in patients classed as null responders to previous therapy.

The group recommends the use of either Boceprevir or Telaprevir for the above indication and in line with the treatment pathway produced by the GM Hepatitis C Treatment Strategy Group.

The group noted the impressive clinical trial data showing overwhelming benefit (increased rates of cure and likelihood of reducing treatment duration) in this patient population when compared to current standard of care. Numbers needed to treat for both drugs ranged from 2-4 depending on the patient subgroup. Both these treatments show good clinical efficacy from well conducted clinical trials, however this benefit does come at a substantially increased cost.

The cost[1] of treatment with boceprevir is within the range of £16,800 for 24 weeks treatment up to £30,800 for 44 weeks per patient. The cost of 12 weeks of telaprevir is £19,545 per patient (*which includes a 12.5% discount offered to all UK hospitals*). As it is difficult to directly compare the two drugs the Subgroup recommends that where possible the cheapest agent should be used apart from the specific subgroup specified in the pathway (i.e. cirrhotics and null responders where telaprevir should be used) The price will be locally negotiated through a standard procurement process by the GM Hepatitis Treatment Strategy Group on behalf of the Greater Manchester health economy. Access to Home Care should be considered as part of this procurement process.

According to set criteria treatment with one of these agents was deemed to be a high priority for funding.

[1]prices correct at time of publication

Review date: April 2012

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.
▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drugreactions regardless of the severity of the reaction.

Recommendations and Flow Chart from the Hepatitis C Strategy Treatment Subgroup

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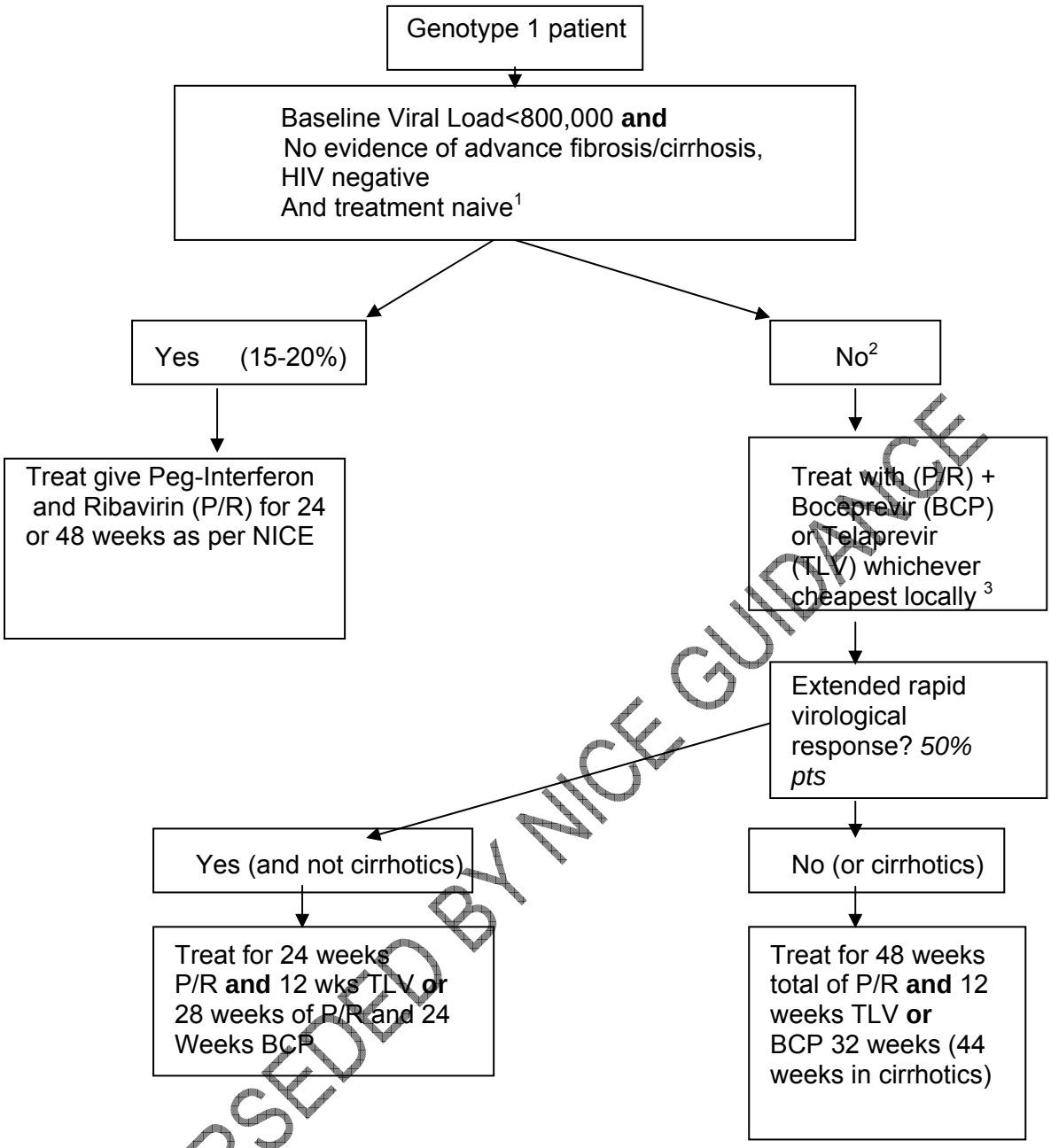
1. These drugs are beneficial for all genotype 1 patients except for naive patients with viral loads <800,000 at baseline (about 15-20% of total cohort of genotype 1) without significant liver disease or HIV who should be treated with standard of care only. The benefit is even higher for some subgroups such as those with severe liver disease and previous treatment failure.
2. We feel that 44 weeks of boceprevir for cirrhotics and null responders represents too high cost and we recommend that cirrhotics are treated with 12 weeks of telaprevir unless there is a contraindication for the use of these drugs. However boceprevir stopping rules can reduce that cost. There is more evidence for benefit for these patients with telaprevir.
3. Null responders should not generally be treated with either drug due to high chance of resistance. These patients should be treated only at the larger units. A 4 week lead in could be considered and the directly acting antiviral should not be added if viral load has not dropped 1 log at week 4.
4. Drug resistance testing for those patients who failed therapy should be available to identify future treatment options for these patients.
5. Telaprevir patients are more likely to experience rash but their duration of treatment is shorter. Anaemia rates might be lower for telaprevir however the shorter duration of treatment could influence this too. Boceprevir lead-in with SOC in naive patients might allow the identification of a subgroup of patients with good response to SOC alone (undetectable at week 4 or >2 log reduction) and thereby prevent the use of a DAA. There is no evidence to use lead-in with telaprevir in treatment naive patients.
6. The following subgroups have an NNT of < 2.5 – re-treatment of relapsers and partial responders. However It must be borne in mind that telaprevir has an NNT of 2.63 once patients with viral load<800,000 are excluded (23% of patients in the study)
7. Except in very few, pre-specified subgroups the cheapest agent (on best local cost obtained through a procurement exercise) should be used.

Flow chart Hepatitis C Genotype 1 care



(1) Treatment experience who were Null responders to previous treatment, should be only within clinical trials or after MDT discussion at one of the 2 larger units
(2) Prior to new drugs these patients received all 48 weeks of P/R
(3) BCP preferred if significant skin issues that could lead to erythroderma with interferon and be confused with TLV drug reaction. BCP or TLV preferred in HIV patients based on the HIV treatment of each patient and drug interactions. It might be other minor exceptions (not more than 2% of total)