Service Notification in response to DHSSPS endorsed NICE Technology Appraisals

Health and Social Care Board

NICE TA 252 and TA 253: Telaprevir and Boceprevir for treatment of Hepatitis C

1	**Name of Commissioning Team** Specialist Services Commissioning Team
2	**Summary of NICE TA 252 and TA 253:** **TELAPREVIR** Telaprevir in combination with peginterferon alfa and ribavirin is recommended as an option for the treatment of genotype 1 chronic hepatitis C in adults with compensated liver disease: • who are previously untreated **or** • in whom previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin has failed, including people whose condition has relapsed, has partially responded or did not respond. **BOCEPREVIR** Boceprevir in combination with peginterferon alfa and ribavirin is recommended as an option for the treatment of genotype 1 chronic hepatitis C in adults with compensated liver disease: • who are previously untreated **or** • in whom previous treatment has failed. These two drugs are administered as oral tablets and each drug, in combination with peginterferon alfa and ribavirin, is prescribed as part of a finite course of treatment, the duration of which will vary depending on patient characteristics and the response to the drug which is assessed at pre-determined intervals. The treatment time duration will be between 3 and 9 months for each patient. The HSCB/PHA have reviewed these 2 Technical Appraisals within a single plan as both relate to the same group of eligible patients who are treated with either Telapriver exclusively, or Boceprevir exclusively, for the same condition, under the same criteria. The choice of which therapy to be utilised is clinically determined by the consultant at the outset of treatment. Patients who fail on the drug they commence treatment on will not move to the remaining alternative drug.

3	**Number of people in Northern Ireland expected to take up service/therapy (new cases per year)** An estimate of the number of new cases of Genotype 1 Hepatitis C based on local data indicates that the maximum number of new cases is likely to be around 25 per year. This differs from the estimate based on the NICE template. Northern Ireland has a significantly lower incidence and prevalence of hepatitis C as demonstrated in the National Health Protection Agency 2011 Report. These levels have been further directly validated with the local specialist clinicians providing the service. This treatment will also be offered to Hepatitis C patients currently within the hepatology service who have never been treated or have failed previous treatment. This 'backlog' of patients is estimated by clinicians to be 60 patients:- • 40 who have previously failed treatment • 20 who have not had any previous treatment It is estimated by the clinical team that one third of these patients will not take up the offer of treatment with these new drugs. The likely 'backlog' demand is therefore estimated at around 40 patients. These patients will be programmed for treatment over the course of the next 3 years. There is no clinical disadvantage to treating the backlog patients over this timescale.
4	**Outcomes**
4.1	**Additional life expectancy gain / progress improvement** Telaprevir: • The addition of this drug is clinically more effective than standard treatment alone in inducing a sustained virological response (cure) • Previously untreated – incremental health gain of 0.84 QALY compared to standard treatment • Previously treated – Incremental health gain of 1.17 QALYs compared to standard treatment Boceprevir: • The addition of this drug is clinically more effective than standard treatment alone in inducing a sustained virological response (cure) • Previously untreated – incremental health gain of 0.91 QALY compared to standard treatment • Previously treated – incremental health gain of 2 QALYs compared to standard treatment

4.2	**Reduction in morbidity** • Patients without liver cirrhosis who achieve a sustained virological response can be considered to be cured • Reduction in the stigma associated with hepatitis C status • Public health benefit at the population level of reduced transmission of Hepatitis C as a result of successful treatment
4.3	**Cost per patient per annum** Each treatment episode is expected to cost £20,000 per patient. The number of new patients may vary slightly year to year but for planning purposes estimates will be based on 25 new patients per year. It is expected that the Trust will build up to this number over the next 2 years. Backlog (non –recurrent costs) are estimated at £1.2m over 2 years.
4.4	**In year cost per patient per annum (for new and prevalent cases)** The costs in 2012/13 are estimated at £525k. New patients £150k Backlog patients £375k
4.5	**Any cost savings and how these will be secured –** Not applicable
4.6	**Recurrent overall cost** Recurrent costs by 2014/15 will be £500k.
4.7	**Cost per QALY** Telaprevir: • £18,000 per QALY gained for previously untreated patients • £10,000 per QALY gained for the previously treated patients Boceprevir: • £11,601 per QALY gained for previously untreated patients • £2,909 per QALY gained for the previously treated patients

4.8	**Other treatments available for this condition** Combined treatment with Peginterferon alfa and ribavirin NICE appraisals TA252 and TA253 have concluded that peginterferon and ribavirin are less clinically effective than the new antiviral drugs in inducing a sustained virological response (cure).
4.9	**Readiness to implement** There is no impediment to immediate implementation for new patients. Treatment for the backlog of patients can be also be commenced immediately.
5	**DHSSPS Legislative / Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.
6	**What will Commissioning Team do to secure funding for the implementation of this TA including any proposals for disinvestment** Funds to recurrently support the regimes of around £440,000 are available from within the SSCT identified resources for specialist drugs in 2012/13. Further recurrent funding of £60k will be sourced by 2013/14.
7	**Commissioning arrangements** These regimes will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team arrangements. An Investment Proposal Template will be completed by the Belfast Health and Social Care Trust and the final profile of resources and monitoring arrangements agreed. A recurrent source of funds is available to fully support the treatment of eligible new patients presenting. Funding for the backlog of patients will be via a non recurrent allocation in line with the timelines agreed to treat this group of patients.
8	**Monitoring arrangements** Following DHSSPS approval, the HSC Board will introduce a formal process with

	the Belfast Trust to monitor the uptake of these therapies. The monitoring process will include a quarterly update report from the Trust, commencing for the quarter July to September 2012. The report should be submitted to the HSC Board by close of play on the second Friday of the month after quarter end. The report will include • Information on the number of patients commenced on a month by month basis. These figures will be split to clearly identify those from the 'backlog' list and newly identified patients. • Information on the number of patients waiting to commence treatment by length of time waiting. • Spend on drugs for the period covered by the report. The follow up arrangements for any issues identified from the quarterly reports will be via the HSC Board Specialist Services Commissioning Team to the Trust Co-Director with responsibility for the service in the first instance.