NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 37a draft remit, draft scope and summary of comments and discussions at the scoping workshop

Provisional Title	Daclatasvir for treating chronic hepatitis C		
Topic Selection ID Number	7346	**Wave / Round**	B37a
TA ID Number	766		
Manufacturer	Bristol-Myers Squibb		
Anticipated licensing information	Daclatasvir received a CHMP positive opinion June 2014. "Daklinza is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults (see sections 4.2, 4.4 and 5.1). For HCV genotype specific activity, see sections 4.4 and 5.1" As we are yet to see the summary of product characteristics it is unclear which genotypes this will be licensed for. The manufacturer indicated that the trials that were part of the EMA dossier were: daclatasvir in combination with sofosbuvir with or without ribavirin in treatment naïve and treatment experienced patients with genotypes 1 and 3; and trials of daclatasvir in combination with pegIFN alfa-2a and ribavirin in treatment naïve patients with genotypes 1 and 4. ** CONFIDENTIAL INFORMTAION REMVOED*		
Draft remit	To appraise the clinical and cost effectiveness of daclatasvir in combination with other anti-hepatitis medications within its licensed indication for treating chronic hepatitis C.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of daclatasvir for treating chronic hepatitis C is appropriate. The scoping workshop attendees discussed how the draft remit should describe how daclatasvir is used together with other treatments. They noted that the CHMP positive opinion is 'Daklinza is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults […]'. They agreed that the draft remit should be amended to reflect the wording of the anticipated marketing authorisation in the UK. The population in the draft scope should be amended to adults with chronic hepatitis C infection: those who are treatment naive and those who are treatment experienced. The scoping workshop attendees stated that the current wording of the population in the scope did not reflect terminology used in clinical practice. They also explained that the current wording in the draft scope excluded some patients, such as those who achieved a sustained virological response but who had then		

	been re-infected. The scoping workshop attendees discussed whether the comparators included in the draft scope were appropriate. It noted the importance of genotype in deciding treatment, and stressed that the comparators should be clearly labelled according to genotype. The following comparators should be added to the draft scope: (1) simeprevir in combination with sofosbuvir, with or without ribavirin (for people who have genotype 1 or 4 disease and are ineligible for or intolerant to interferon treatment) (subject to ongoing NICE appraisal) and (2) best supportive care. A consultee highlighted that simeprevir used in combination with sofosbuvir is also licensed for treating genotype 1 and 4 chronic hepatitis C in people who are intolerant to or ineligible for interferon and the scoping workshop attendees agreed that this combination should also be considered as a comparator, subject to the ongoing NICE appraisal. They further agreed that it was appropriate to add best supportive care / no treatment as a comparator for all genotypes as this would currently be used to treat people who were ineligible for or intolerant to interferon and also for those patients who are not willing or able to take other hepatitis C medications. The scoping workshop attendees agreed that resistance should not be included as a treatment outcome. It was noted that, as well as preventing long-term consequences of chronic hepatitis C in an individual, reducing onward transmission was another important aspect of disease management. Attendees agreed that modelling this outcome would be difficult but was important to consider and that this outcome should be added to the draft scope. The scoping workshop attendees decided it was not appropriate to consider people co-infected with HIV separately because they would be treated in the same way as people who were infected with hepatitis C only. They also agreed that other subgroups according to fibrosis stage should be added (possibly using the METAVIR scale, rather than mild, moderate or severe fibrosis). The scoping workshop attendees noted that it could potentially be useful to subdivide cirrhosis into compensated and decompensated, if there was any evidence in people with decompensated cirrhosis. The scoping workshop attendees agreed that subgroups according genotype should be considered. The scoping workshop attendees discussed people for whom current standard treatment regimens were unsuitable because they contained interferon. They agreed that this subgroup should be considered separately and should be added to the scope. It was agreed at DP4 that the wording in the final scope for daclatasvir should maintain consistency, where possible, with other recent hepatitis C scopes.

Population size	The most recent national estimates (2012) suggest that approximately 160,000 people are chronically infected with HCV in England. Most of this infection is due to genotype 1 (46%) and 3 HCV (43%). Genotypes 2, 4, 5 and 6 HCV constitute the remaining 11% of cases.
Process (MTA/STA/HST)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of daclatasvir in combination with other ~~**anti-hepatitis medications**~~ **medicinal products** within its licensed indication for treating chronic hepatitis C.
Costing implications of remit change	Costing comments updated to take into account clarification in remit and to simplify: The estimated number of people who may be eligible to receive declatasvir in combination with other medicinal products within its licensed indication for treating chronic hepatitis C is around 8,300. The cost of declatasvir is unknown. The cost of other treatment options vary significantly but may be as high as around £70,000 (24 week course of sofosbuvir) or around £41,200 (telaprevir/boceprevir) per person. The large eligible population suggests potential for the topic to be high cost. However, the unknown drug cost, the unknown number of people who may switch from current treatments and the variation in the cost of comparators means that the cost impact cannot be estimated from the information available.
Timeliness statement	** CONFIDENTIAL INFORMTAION REMVOED*issuing timely guidance for this technology will not be possible.