NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 56 draft remits and draft scopes and summary of comments and discussions at scoping workshops

Topic ID	Topic title
1229	Lifitegrast for treating dry eye disease
1153	Letermovir for the prophylaxis of cytomegalovirus infection in people who are sero-positive and have received an allogeneic haematopoietic stem cell transplant
1009	Cytomegalovirus-specific T-cells for preventing and treating cytomegalovirus infection after allogeneic haematopoietic stem cell transplantation

Provisional Title	Lifitegrast for treating dry eye disease		
Topic Selection ID Number	8733	**Wave / Round**	R210
ID Number	1229		
Manufacturer	Shire		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of lifitegrast within its marketing authorisation for treating dry eye disease		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of lifitegrast for treating dry eye disease is appropriate. The proposed remit is appropriate. No changes are required. Consultees discussed the expected position of lifitegrast within the treatment pathway for dry eye disease, and the relevant comparators for the appraisal. The population and comparators in the scope have been amended consistent with the technology's expected use in adults with dry eye disease that has not responded to treatment with ocular lubricants and/or topical anti-inflammatory drugs (including ciclosporin). Minor changes have also been made to the outcomes and subgroups.		
Population size	The number of people in England who would be eligible for treatment with lifitegrast is uncertain but likely to be large. Dry eye disease affects an estimated 966,000 people in England, of whom 58,000 have severe keratitis that has not improved despite treatment with artificial tears (consistent with the NICE recommendation for ciclosporin in TA369). The scope for this appraisal includes a broader population than that for which ciclosporin is recommended. Source: NICE resource impact report for TA369.		
Process (TA/HST)	TA		
Proposed changes to remit (in bold)	None		
Costing comments	If licensed, lifitegrast will offer an additional topical treatment option for people with dry eye disease. The cost of lifitegrast is not yet known, so the resource impact cannot yet be assessed. The additional cost of this drug may be offset by the decreased use of existing treatment options.		
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible		

Provisional Title	Letermovir for the prophylaxis of cytomegalovirus infection in people who are sero-positive and have received an allogeneic haematopoietic stem cell transplant		
Topic Selection ID Number	8274	**Wave / Round**	R180
ID Number	1153		
Company	Merck, Sharp & Dohme		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of letermovir within its marketing authorisation for preventing cytomegalovirus infection in sero-positive patients having allogeneic haematopoietic stem cell transplantation.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of letermovir for treating preventing cytomegalovirus infection in sero-positive patients having allogeneic haematopoietic stem cell transplantation is appropriate. The proposed remit is appropriate. No changes are required. The company stated that his product has progressed through the early stages NHSE's application process for specialised commissioning, and given the small patient population and stable budget impact, they believe this should be the continued process for review of letermovir. NHSE have confirmed that work has stopped on the commissioning policy given the pending NICE STA for this product. NHSE supports a NICE appraisal of this technology.		
Population size	Approximately 1600 people in England would be eligible for treatment with letermovir. This estimate is based on the number of allogeneic HSCTs carried out in 2015 as all patients would be eligible for treatment.		
Process (TA/HST)	TA		
Proposed changes to remit (in bold)	None other than to reword for compliance with NICE style. To appraise the clinical and cost effectiveness of letermovir within its marketing authorisation for preventing cytomegalovirus infection in **people** ~~patients~~ who are sero-positive ~~having~~ **and have received an** allogeneic haematopoietic stem cell transplant~~ation~~.		
Costing comments	Letermovir would be an additional treatment option for people undergoing allogeneic HSCT. The cost of the drug is not yet known. The additional drug treatment costs may be offset by decreased use of current antiviral agents.		
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.		

Provisional Title	Cytomegalovirus-specific T-cells for preventing and treating cytomegalovirus infection after allogeneic haematopoietic stem cell transplantation		
Topic Selection ID Number	8242	**Wave / Round**	R174
ID Number	1009		
Company	Cell Medica		
Anticipated licensing information	Marketing authorisation expected: No marketing authorisation required as it is not considered a medicinal product (cell therapy). Expected wording of marketing authorisation: N/A		
Draft remit	To appraise the clinical and cost effectiveness of cytomegalovirus-specific donor T-cells for preventing and treating cytomegalovirus after allogeneic haematopoietic stem cell transplantation		
Main points from consultation	Patients who require this treatment have few treatment options available to them. The antivirals currently used to prevent or treat CMV reactivation in this population can have significant adverse effects including renal impairment and cytopaenias. Clinicians stated that cytovir CMV would only be used in cases where resistance to anti-viral therapy is evident or where treatment with anti-viral therapy is contraindicated due to their side effects. Company and experts both feel NICE TA route is not the best for this technology especially due to the small population and the price of conducting an appraisal. NHS commissioning may be more suitable which may make it applicable to the MIB. Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal/evaluation of cytovir CMV for treating preventing and treating cytomegalovirus infection after allogeneic haematopoietic stem cell transplantation is **not appropriate**. There may be a role for the Commissioning Support Programme or a Medtech Innovation Briefing.		
Population size	Approximately 90 people in England would be eligible for treatment with Cytovir CMV. This calculation is based on expert opinion approx. 5% of adults and around 10 paediatric patients would benefit from treatment with cytovir CMV. (5% of 1,610 [adults received a transplant in 2015] plus around 10 paediatric patients)		
Process (TA/HST)	No referral is sought as a TA or HST		
Proposed changes to remit (in bold)	None		

Costing implications of remit change	The price of Cytovir CMV is £20,000. Cytovir CMV is an alternative treatment option for these people and so there are likely to be offsetting savings from people transferring from the current treatment options.
Timeliness statement	Considering that this product is already commercially available in the UK, although is not subject to licensing by the EMA/MHRA, publication of timely guidance will not be possible.