National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Maribavir for treating refractory or resistant cytomegalovirus infection after transplant [ID3900]

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Wording	Takeda	The remit does not accurately reflect the proposed marketing authorisation. Please modify to: Adults with cytomegalovirus infection that is refractory or resistant to one or more treatments after haematopoietic stem cell transplantation or solid organ transplant	Thank you for your comment. The remit has been amended to specify haematopoietic stem cell transplantation or solid organ transplant. The remit is intended to broadly reflect the anticipated marketing authorisation as well as the clinical evidence base for maribavir, and the referral to NICE from the Department of Health and Social Care for this

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			appraisal. No further changes have been made to the scope.
	Anthony Nolan	Yes [the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider]	Thank you for your comment. No action required.
	British Infection Association	Should include more information about scale of the problem and cost effectiveness	Thank you for your comment. The remit is intended only to outline the disease, patient population and technology that will be covered under the appraisal. Where appropriate, information about the scale of the problem and cost effectiveness will be included in the submission and assessed by the appraisal committee during the appraisal.
	Leukaemia Care	N/A	Thank you. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Renal Association	Yes [the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider]	Thank you for your comment. No action required
	UK Renal Pharmacy group	Suggest after transplant add (haematopoietic stem cell transplant or solid organ transplant)	Thank you for your comment. The remit has been amended to specify haematopoietic stem cell transplantation or solid organ transplant.
Timing Issues	Takeda	Maribavir demonstrated superiority over conventional anti-CMV therapy in the Phase 3 SOLSTICE trial. Marketing authorisation is expected to be received between [redacted] and Takeda wish to provide access for patients in the UK at the earliest possible opportunity.	Thank you for your comment. NICE aims to provide guidance to the NHS within 3 months from the date when marketing authorisation for a technology is granted. NICE has scheduled this topic into its work programme.
	Anthony Nolan	This appraisal could support the management of resistant or refractory CMV infections in stem cell transplant recipients, where existing protocols have been shown to be ineffective or limited in their control.	Thank you for your comment. NICE aims to provide guidance to the NHS within 3 months from the date when marketing authorisation for a technology is granted. NICE has

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			scheduled this topic into its work programme.
	British Infection Association	Currently no drug therapy options for a small proportion of patients who develop CMV resistance. For them this is urgent.	Thank you for your comment. NICE aims to provide guidance to the NHS within 3 months from the date when marketing authorisation for a technology is granted. NICE has scheduled this topic into its work programme.
	Leukaemia Care	CMV infection is a major cause of mortality for those who receive stem cell transplants. Therefore, this is urgently needed to improve outcomes of a resource intensive treatment.	Thank you for your comment. NICE aims to provide guidance to the NHS within 3 months from the date when marketing authorisation for a technology is granted. NICE has scheduled this topic into its work programme.
	Renal Association	Small number of cases with refractory/ resistance following kidney transplantation, but would be useful as a choice with different (slightly better) side effect profile and cost effectiveness. But may be an issue at larger scales as CMV can occur in larger proportion following other transplants and also in context of other intense immunosuppressive treatment	Thank you for your comment. No action required

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	UK Renal Pharmacy group	Not clinically urgent as low numbers of SOT patients with refractory CMV disease but will be helpful for patients who can't tolerate alternative agents e.g. foscarnet.	Thank you for your comment. No action required
Additional comments on the draft remit	Takeda	None	Thank you for your comment. No action required
	Anthony Nolan	N/A	Thank you. No action required.
	British Infection Association	N/A	Thank you. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	I wonder if the remit may want to include other immunosuppressive states apart from organ transplantation, where CMV infections can happen such as following lupus or vasculitis treatment	Thank you for your comment. The remit only outlines the disease, patient population and technology that will be covered under the appraisal. The remit is intended to reflect the anticipated marketing authorisation and the clinical evidence base for maribavir, and the referral to NICE from

Section	Consultee/ Commentator	Comments [sic]	Action
			the Department of Health and Social Care for this appraisal. Currently, the maribavir clinical evidence only covers treatment of resistant or refractory CMV infection after transplant. No changes have been made to the scope.
	UK Renal Pharmacy group	N/A	Thank you. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Takeda	We agree with the background information and have no comments	Thank you for your comment. No action required.
	Anthony Nolan	The background adequately sets out the context of CMV infection within HSCT patients. However, it is limited in its explanation of how CMV infections are actively managed at a clinical level. Letermovir, a CMV prophylatic, is not explicility referenced within the background, despite the potential for a patient to have first received Letermovir before then later being prescribed Maribavir.	Thank you for your comment. The background section of the scope aims to provide a brief summary of the disease and how it is managed, it is not

Section	Consultee/ Commentator	Comments [sic]	Action
			designed to be exhaustive in its detail. No changes were made to the scope.
	British Infection Association	No concerns [about the accuracy and completeness of the background information].	Thank you. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	Yes	Thank you. No action required.
	UK Renal Pharmacy group	Suggest include kidney transplant in list of SOT transplant in para 1. Add “Foscarnet and cidofovir are both nephrotoxic agents and may not be a treatment option for patients with significantly impaired renal function as both can be contraindicated due to poor renal function”. Furthermore if renal function is impaired it is preferable to maintain this level of function rather than precipitate a decline, in extreme necessitating dialysis support, by using these nephrotoxic medicines. Some patients experience disabling side effects (e.g. extremity paraesthesia) from the alternative available treatments. Also there have been previous problematic supply issues (multiple times) with sourcing one of these medicines, however not an issue at present. Unreliability of supply is extremely problematic when a patient has refractory CMV.	Thank you for your comment. The background section has been updated to include kidney in the list of SOT transplants and the statement about foscarnet and cidofovir. The background section of the scope aims to provide a brief summary of the disease and how it is managed, it is not designed to be exhaustive in its detail. So, no other changes

Section	Consultee/ Commentator	Comments [sic]	Action
			were made to the scope.
The technology/ intervention	Takeda	No comments.	Thank you. No action required.
	Anthony Nolan	N/A	Thank you. No action required.
	British Infection Association	No concerns [about the accuracy of the description of the technology]	Thank you. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	Yes [the description of the technology is accurate].	Thank you. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.
Population	Takeda	The population is appropriate, however please modify to "**Adults** with cytomegalovirus infection that is refractory or resistant to **one or more** treatments after haematopoietic stem cell transplantation or solid organ transplant" to reflect the expected marketing authorisation	The population in the scope is kept broad. If the marketing authorisation is narrower, the appraisal committee will consider that population in the appraisal. No action required.

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	Anthony Nolan	The defined population refers to “people” yet the largest studies that match this indication appear to include only adult HSCT recipients. There should be more specificty in the HSCT populations applicable for this indication, in terms of age etc. Should trial data demonstrate an increased efficacy over and above its comparators, use of Maribavir for non-resistant CMV infections may also be relevant given incidence of antiviral resistance and toxicity profiles.	The population in the scope is kept broad. If the marketing authorisation is narrower, the appraisal committee will consider that population in the appraisal. No action required.
	British Infection Association	In the technology section - the word ‘years’ should appear after 12. Should the age be specified in the population section? The population may include children aged 12 year to 18 years, but the numbers are likely to be low.	The population in the scope is kept broad. If the marketing authorisation is narrower, the appraisal committee will consider that population in the appraisal. No action required.
	Leukaemia Care	The population is appropriate. It is also appropriate to include children, as stem cell transplant in children with blood cancers does occur.	Thank you for your comment. No action required.
	Renal Association	Yes for transplantation side, but wonder if need to consider expansion as in the additional comments on the draft remit	Thank you for your comment. The remit of this appraisal reflects the anticipated marketing authorisation and the clinical evidence base for

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			maribavir, and the referral to NICE from the Department of Health and Social Care for this appraisal. Currently, the maribavir clinical evidence only covers treatment of resistant or refractory CMV infection after transplant. No changes have been made to the scope.
	UK Renal Pharmacy group	N/A	Thank you. No action required.
Comparators	Takeda	We agree with the list of comparators, however following discussions with UK clinicians we understand the evidence base for use of immunoglobulins is limited.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The potential comparators listed in the scope represent treatments used to treat treatment resistant or refractory CMV infection after transplant in NHS clinical practice. Any

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			exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal. No changes were made to the scope.
	Anthony Nolan	Ganciclovir and foscarnet have licensed indications for the prevention or treatment of cytomegalovirus disease in immunocompromised patients. Where as, cidofovir and valganciclovir can be used off-label for HSCT recipients. Brincidofovir is another off-label comparator not referenced within the draft scope, and should be consdered [sic] in context. Patients can develop resistance to ganciclovir due to viral gene mutations. Foscarnet or a combination therapy tends to be 2nd line treatment, with cidofovir being 3rd line in practice. Clinical approach is dependent on each patient and the best approach will be determined by this. The population would need to be more defined, such as levels of CMV DNA in order to define a 'best alternative'.	Thank you for your comment. At the scoping workshop consultees indicated that brincidofovir has been withdrawn from the UK market and is no longer accessible to clinicians. No changes were made to the scope.
	British Infection Association	No concerns	Thank you. No action required.
	Leukaemia Care	All comparators we are aware of have been included.	Thank you for your comment. No action required.

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	Renal Association	Yes agree	Thank you for your comment. No action required.
	UK Renal Pharmacy group	UK use of hyperimmune globulin in CMV treatment in SOT is limited by cost, efficacy and poor evidence base. More widespread use of this agent in USA.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The potential comparators listed in the scope represent treatments used to treat treatment resistant or refractory CMV infection after transplant in NHS clinical practice. Any exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal. No changes were made to the scope.
Outcomes	Takeda	We broadly agree that the listed outcomes provided capture the most important health related benefits of this technology. However, following	Thank you for your comment. At the scoping workshop,

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		discussion with UK clinicians we note that resistance rates are not generally used in the decision-making process in clinical practice.	consultees indicated that viral load, CMV clearance, recurrence rate and resistance rates represent similar outcomes. Therefore, CMV clearance, recurrence rates and resistance rates have been removed from the scope.
	Anthony Nolan	Yes, although more information on how health-related quality of life will be measured would be beneficial.	Thank you for your comment. Outcomes are defined broadly at the scoping stage. Specific outcomes can be defined in the submission and will be assessed by the appraisal committee during the appraisal.
	British Infection Association	The outcome measures to be considered include: • CMV clearance – this statement is not clear. CMV causes lifelong infection. Does this refer to CMV viral load? • recurrence rates – this needs to be clearly defined – CMV viral load may increase but the patient may not develop disease	Thank you for your comment. At the scoping workshop, consultees indicated that viral load, CMV clearance, recurrence rate and resistance rates represent similar

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		• resistance rates – this should be clearly defined – does this mean detection of viral resistance or clinical resistance? • tissue invasive disease – this should be clearly defined – is this based on clinical disease or histology/PCR	outcomes. Therefore, CMV clearance, recurrence rates and resistance rates have been removed from the scope. Please note, outcomes are defined broadly at the scoping stage. Where appropriate, tissue invasive disease can be defined in the submission and will be assessed by the appraisal committee during the appraisal.
	Leukaemia Care	The outcomes are appropriate.	Thank you for your comment. No action required.
	Renal Association	Yes, length of hospital/ inpatient stay during treatment would be additional measure to consider	Thank you for your comment. Length of hospital stay has been added to the scope.
	UK Renal Pharmacy group	Would suggest also include A: preservation of renal function (especially renal transplant graft function). B: Significant health benefit to oral treatment over intravenous treatment. Health/personal benefit to oral treatment:-	Thank you for your comment. Transplant graft function has been included in the scope. Where appropriate, the

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		1. no requirement for temporary central venous access (PICC,CVC) to support intravenous therapy as ganciclovir, foscarnet irritant. 2. No training required for ongoing IV administration at home. 3. Earlier discharge from hospital, if admitted due to clinical symptoms and/or need to have IV treatment, as with oral treatment there is no need for IV administration home training. **4.** No need to return to hospital 2 x day for intravenous administration when IV self-administration not practical. **5.** No infection risk from having IV line insitu	benefits of oral treatment over intravenous treatment would be considered as part of economic modelling. No further changes were made to the scope.
Economic analysis	Takeda	We agree with the scope of the economic analysis.	Thank you for your comment. No action required.
	Anthony Nolan	High quality HRQoL data should be collected to understand the longitudinal benefit of Maribavir during both acute recovery and out to beyond Day 365.	Thank you for your comment.
	British Infection Association	This is not set out clearly enough	Thank you for your comment.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	Unable to comment	Thank you. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.

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Equality and Diversity	Takeda	Takeda note that people from minority ethnic groups are more likely to need a kidney transplant, however are less likely to receive a transplant due to shortage of donors. Although many minority ethnic group patients are able to receive a transplant from a white donor, for many the best match will come from a donor from the same ethnic background. • A third of people (35 per cent) waiting for a kidney across the UK are from minority ethnic groups but in 2017/18, of those providing their ethnicity when registering on the NHS Organ Donor Register, only 3.3 per cent were Asian, 1 per cent were black and 2 per cent were mixed race. • Only 28 per cent of UK kidney transplants in 2017/18 were in minority ethnic groups. • There is a longer waiting time for kidney transplants for black and Asian patients compared to white patients (with and average wait of approx. 2.5 years compared to an average 2 year wait for a white patient). *Reference: NHS Blood and Transplant. Key stats from the BAME supplementary report 2017-18* Takeda also note that age is a consideration when considering who is most eligible for a kidney transplant via the National Kidney Allocation Scheme. Points are awarded based on level of tissue match, time spent waiting for transplant and also the age of the recipient (with a progressive reduction in points given after the age of thirty). The majority of patients developing end-stage renal disease whom are eligible for kidney transplantation are between	Thank you for your comment. At the scoping workshop, consultees agreed that the mentioned equality impacts are related to availability of transplants rather than maribavir. Where relevant and appropriate, the appraisal committee will consider the impact of its recommendations on protected characteristics as stated in equality legislation during the appraisal. No action required.

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		45 and 65 years of age despite evidence to show that age should not be a contra-indication for transplantation. *References: NHS Blood and Transplant. Annual report on kidney transplantation. Report for 2018/19.* ***Heldal, K., Hartmann, A., Lønning, K. et al. Should patients older than 65 years be offered a second kidney transplant?. BMC Nephrol 18, 13 (2017).***	
	Anthony Nolan	N/A	Thank you. No action required.
	British Infection Association	No concerns	Thank you. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	The proposed remit and scope is fair and would not in any way impact people with protected characteristics	Thank you for your comment. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.
Other considerations	Takeda	With regards to the following suggested subgroup analysis, please note the following: **1) People with CMV infection refractory or resistant to other treatments** Takeda highlight that following discussion with UK clinicians we have not identified any difference in the treatment of refractory or resistant patients,	Thank you for your comment. The following subgroups analyses have been removed from the scope: people with CMV infection refractory or resistant to other treatments,

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		therefore it would not be appropriate to provide analysis split by these patient types. **2) People who have had HSCT or SOT** We accept the inclusion of this subgroup. **3) Transplant donor and recipient status** Takeda note that outcomes grouped by donor or recipient status may be challenging to provide any meaningful data, as the majority of solid organ transplant patients were D+/R-, and the majority of the stem-cell transplant patients were R+. **4) Treatment resistance gene mutations** Takeda note that following discussion with UK clinicians we note that resistance rates are not generally used in the decision-making process in clinical practice.	transplant donor and recipient status, and treatment resistance gene mutations.
	Anthony Nolan	N/A	Thank you. No action required.
	British Infection Association	Dosing schedule Orally administered therefore limitations in patients with GI pathology Scale of the problem Role as pre-emptive therapy	Thank you for your comment. The list of issues included in the scope is not designed to be exhaustive. Where appropriate, the dosing schedule and benefits or limitations of oral administrations would be considered as part of economic

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			modelling. Additionally, information about the scale of the problem can be included in the submission and will be assessed by the appraisal committee during the appraisal. Consultees confirmed at the scoping workshop that maribavir is not intended to be used as pre-emptive therapy. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	None	Thank you. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.
Innovation	Takeda	Takeda note the high the cost of getting patients ready for transplantation and the substantial cost of the transplant procedure itself. This combined with the scarcity of organs highlight the need for effective management of CMV infection.	Thank you for your comment. The appraisal committee will consider the extent to which maribavir is innovative

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		The benefits of long-term graft function following maribavir treatment and benefits of no-longer performing re-dialysis will not be captured in the economic model. Additionally, we expect that treatment with maribavir will provide NHS savings by a reduction in the number of patients with uncontrolled CMV which may reduce requirements for re-transplantation following organ failure	in its decision making. No action required.
	Anthony Nolan	For patients who have been resistant to the exsting licenced and off-label protocols, Maribavir could serve as an effective technology in CMV reactivations in CMV IgG seropositive recipients. Maribavir can be administerefd orally which is attractive to clinical teams for several reasons. Firstly, the comparators are adminstered intravenously which limits other recovery approaches. It could serve to replace valganciclovir due to lower myeloud suppression, and could also be prescribed for outpatient treatment in support of post-discharge recovery. These potential benefits may not be captured within the anticipated QALY caculations.	Thank you for your comment. The appraisal committee will consider the extent to which maribavir is innovative in its decision making. No action required.
	British Infection Association	Maribavir may be useful for those patients with CMV resistance for whom current drug therapy is limited.	Thank you for your comment. The appraisal committee will consider the extent to which maribavir is innovative in its decision making. No action required.
	Leukaemia Care	The clinical trial data show a significant improvement over existing antiviral treatments. This treatment would be the only licensed treatment for the condition in the UK. Therefore, this should be considered a step change in the management of relapsed CMV.	Thank you for your comment. The appraisal committee will consider the extent to which

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			maribavir is innovative in its decision making. No action required.
	Renal Association	Yes, this will be a step change as an oral administered drug as other therapies used are intravenous and result in excess hospital stay and associated morbidities. Would be good to have length of stay and number of other additional procedures required for different treatment options	Thank you for your comment. The appraisal committee will consider the extent to which maribavir is innovative in its decision making. No action required.
	UK Renal Pharmacy group	Oral treatment is always optimum treatment rather than intravenous, as venous access is required, there is additional time to administer IV, risk of line infection due to line manipulations to administer CMV treatment. Having an oral treatment available for refractory CMV disease will reduce inpatient stay, nursing burden, improve patient wellbeing as can eb discharged home quicker. The significant harm that foscarnet and cidofovir can cause a patient should not be underestimated. Rehabilitation from drug induced paraesthesia can be significant and may result in extended inpatient stay and intense rehabilitation. Worse case paraesthesia remains and patient then endures a life changing event from a life saving drug treatment, as no alternative available.	Thank you for your comment. The appraisal committee will consider the extent to which maribavir is innovative in its decision making. No action required.
Questions for consultation	Takeda	**Q: Is the population defined appropriately? Is the population expected to include children between 12 and 18?** We have amended the population to reflect the anticipated marketing authorisation.	Thank you for your comment. No further action required.

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		Q: Is maribavir expected to be used as pre-emptive therapy for treating CMV infection? We do not expect maribavir to be used as a pre-emptive therapy for treating CMV infection. **Q: Have all relevant comparators for maribavir been included in the scope? Which treatments are considered to be established clinical practice in the NHS for CMV infection that is refractory or resistant to other treatments after transplant?** Yes. The list in the scope reflects our current understanding of the treatment landscape in the R/R post-transplant population. **Q: Are the same treatments used for refractory and resistant CMV infection? If no, which treatments are used specifically for refractory CMV infection and which treatments are used for resistant CMV infection?** The same treatments are used for refractory and resistant CMV infection and we do not expect there to be a difference between the two populations in terms of treatment options. **Q: Is ganciclovir used after first line to treat CMV infection that is refractory or resistant to other treatments after transplant?** In the absence of toxicities to valganciclovir, we expect ganciclovir to be used after first-line failure (if valganciclovir was the first-line agent used).	

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		Q: Are the outcomes listed appropriate? Yes, however please note our comment above on resistance rates not being part of general practice. **Q: Are the subgroups suggested in 'Other considerations' appropriate? Are there any other subgroups of people in whom maribavir is expected to be more clinically effective and cost effective or other groups that should be examined separately?** Yes, however please note our comment above about genetic testing not being part of routine UK practice in the management of CMV infection. We have not identified any other subgroups at this time that would demonstrate additional clinical or cost-effective benefits.	
	Anthony Nolan	We are not aware of Maribavir being used off-label in the UK, and the full reports of current clinical trials are not yet accessible to the public. A breakdown of the SOLSTICE trial is important as it has only been presented to audiences in abstract to date. With respect to the toxcity profile and relative side effects to comparators, we need to see the trial data in more detail. If the trial shows it is less toxic (i.e. fewer side effects) and effective in treating CMV, then it may serve as an alternative to HSCT patients. The most common reason for	Thank you for your comment. No further action required.

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		Ganciclovir/ valganciclovir failure is cytopenias, and not CMV resistance. Clarification is neded to understand if Maribavir's indication will eventually include this scenario as its not by definition a question of resistance. More data is required on the interaction with Letermovir as some patients may still go onto experience CMV reactivation. **Is Maribavir expected to be used as pre-emptive therapy for treating CMV infection?** Trial seemed to use it as treatment of CMV infection/disease which would suggest the scope is to treat CMV viraemia as well as established CMV disease. We would need to see the full analysis to know more about this however. **How would Maribavir be impacted by the donor graft e.g. haplo, cord or an unrelated donor?** Haplo and unrelated have higher risk of CMV infection/disease compared with siblings, because of increased T cell depletion. Any improvements in CMV management are helpful to this cohort.	
	British Infection Association	None	Thank you. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	None	Thank you. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft scope	Takeda	None	Thank you. No action required.
	Anthony Nolan	We welcome the potential for a new protocol in managing CMV reactivation in HSCT patients, providing Maribavir is demonstrated to be effective, have similar toxicity and other contra-indications to existing technologies.	Thank you for your comment. No action required.
	British Infection Association	There is no discussion about combination therapy with maribavir. Maribavir should not be co-administered with ganciclovir, but no mention of potential of other combinations.	Thank you for your comment. The committee will consider the evidence submitted by the company and stakeholders during the appraisal process in line with the expected marketing authorisation for maribavir. No action required.
	Leukaemia Care	N/A	Thank you. No action required.
	Renal Association	None	Thank you. No action required.
	UK Renal Pharmacy group	N/A	Thank you. No action required.