Clinical Expert Summary

Valganciclovir (Valcyte®) powder for oral solution for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor

1. Existing guidelines

One expert cited Cardiff Transplant Unit guidance on the prescribing of valganciclovir for CMV prophylaxis post renal/pancreas transplant, which has been in place for a number of years. The expert highlighted that these guidelines recommend that patients receive CMV prophylaxis with valganciclovir for three months post transplant dependent on the CMV status of organ donor and organ recipient and type of immunosuppression regimen. The British Transplant Society (BTS) Guidelines for the Prevention and Management of CMV Disease after Solid Organ Transplantation[1] were also cited by experts.

2. Disease prevalence

One expert estimated that 100–140 transplants are undertaken per year at the Cardiff Transplant Unit and this activity is increasing. It was suggested that approximately 80% of these (80–112 patients) would be prescribed three months CMV prophylaxis with valganciclovir in line with local guidance. The expert noted that this guidance is not restricted to CMV sero-negative recipients of CMV sero-positive donor organs as described in the manufacturers SPC. It was noted that many CMV-positive recipients of CMV-positive or CMV-negative donors are also prescribed valganciclovir prophylaxis according to their anti-rejection drug regimen. The expert concluded that implementing the license extension would not change the number of patients in Wales receiving CMV prophylaxis with valganciclovir.

Another expert stated that a review of CMV incidence in Cardiff Transplant Unit (01/2004–12/2007) found that 60% of the 339 recipients during this period required CMV prophylaxis.

3. Current treatment options

Experts highlighted oral valganciclovir for 100 days post-transplantation as a current treatment strategy for CMV prophylaxis. One expert stated that the Transplant Unit at University Hospital of Wales (UHW) is the only centre that will initiate treatment for this indication and prescribing elsewhere in Wales will only be continuing supply for patients commenced on prophylaxis by UHW or by solid organ transplant centres in England. Other potential options cited by experts include oral valaciclovir, aciclovir or no oral prophylaxis but monitoring of CMV and pre-emptive treatment with valganciclovir or intravenous ganciclovir when necessary. However, one expert stated that only valganciclovir, not other options, was currently used at Cardiff Transplant Unit. The expert also stated that solid organ transplant patients in Wales may also be prescribed valganciclovir in the following circumstances:

- To treat active CMV disease
- As a repeat CMV prophylaxis post treatment of active CMV disease
- As a repeat CMV prophylaxis following escalation of immunosuppression in selected patients.

4. Unmet needs

One expert suggested that oral solutions are occasionally better tolerated than tablets by some patients. Another expert asserted that there were no areas of unmet need locally in relation to CMV prophylaxis.

5. Knowledge of product in given indication

One expert stated that the license extension to 200 days valganciclovir CMV prophylaxis had been discussed by the Cardiff Transplant Unit team and as yet there were no plans to implement any changes to current CMV prophylaxis guidance. The expert also cited local audit data, which indicates that rates of active CMV disease requiring treatment with, for example, intravenous ganciclovir, are relatively low. Additionally, the data cited by the expert demonstrates that where CMV treatment is required it is relatively straightforward (though may involve short stay in hospital to initiate intravenous ganciclovir) and does not appear to adversely impact on patient outcomes such as incidence of acute organ rejection. It was suggested that these issues need to be considered because CMV prophylaxis with valganciclovir is extremely expensive and the drug is not without side effects. The expert stated that the transplant team will continue to review local CMV guidance if new evidence emerges related to complications of CMV infection/disease in solid organ transplant patients. It was also suggested that the liquid formulation was rarely used, as CMV prophylaxis starts within approximately 10 days of transplantation and patients are usually able to swallow tablets on day one post-transplant. The expert concluded that they were unlikely to need liquid acutely and would only need it for patients with long-term tablet swallowing difficulties.

References

1 British Transplantation Society. Guidelines for the prevention and management of CMV disease after solid organ transplantation. 2011. Available at: http://www.bts.org.uk/EasySiteWeb/GatewayLink.aspx?alId=908. Accessed Mar 2011.