BTS
British Transplantation Society

The Voice of Transplantation in the UK

Campath/ Alemtuzumab Fact Sheet

24 March 2020

Compiled by a Working Party of
The British Transplantation Society

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The MHRA issued a safety notice in February 2020 concerning the use and indications for use of Lemtrada/ Alemtuzumab in patients with multiple sclerosis. The BTS believe that experience with Campath/ Alemtuzumab is a safe drug to use in the setting of solid organ transplantation and we have prepared this advice for our membership which highlights the differences between use of Alemtuzumab in multiple sclerosis and solid organ transplant patients.

	Multiple Sclerosis (MS)	**Transplantation (SOT)**
Route of administration	IV infusion over 4 hours	SC injection or IV infusion
Dose	60mg over 5 days (12mg od), 12 months later 36mg over 3 days and up to 2 more 36mg doses at 12 monthly intervals. Usual dose is 96mg by 13 months with additional 72mg over next 24 months.	30mg x 1 Maximum total dose 50mg
Location of administration	Out-patient in day case unit	In theatre, at time of surgery Peri-transplant with cardiac monitoring
Frequency and intensity of post administration follow	Infrequent	Intensive post-transplant monitoring - Weekly follow up until 4-6 weeks, then 2 weekly until 6 months then 4 weekly until 12 months post-transplant, then 2 monthly in second year, thereafter 3-4 monthly.
Pharmaceutical product	Licensed product (Lemtrada) 12mg/1.2ml (10mg/ml) solution	Unlicensed product (Campath) 30mg/1ml solution in vial
Approximate cost *(incl for information only)*	£8,500/12mg syringe 60mg (year 1) = £42,300	Free of charge – patient access scheme

- Campath /Alemtuzumab has been used in many thousands of solid organ transplants in the United Kingdom.
- Alemtuzumab-based induction therapy has been compared with basiliximab-based induction therapy in 820 kidney transplant recipients in a UK-wide randomized trial. There were no excesses in any of the potential hazards identified by the MHRA safety alert in this randomized trial (and there was a highly-significant benefit in the prevention of rejection) during the first year after transplantation. These findings were consistent across the different types of patient studied. Longer-term follow-up is ongoing.
- In our experience autoimmune complications whilst a recognised adverse effect of alemtuzumab are uncommon (2.5%) and can occur long after administration hence the requirement for close monitoring and long term follow up.
- Solid organ transplantation has close patient and drug monitoring embedded in its service design and this is particularly true in the early stages after transplantation, which is when alemtuzumab is used in our specialty.

When prescribing an unlicensed medicine, the GMC advises that the prescriber:-

a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
b. takes responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
c. makes a clear, accurate and legible record of all medicines prescribed and, where not following common practice, states reasons for prescribing an unlicensed medicine.

From patient perspective, the patient needs to be made aware of the unlicensed use of Alemtuzumab in order to give informed consent for the use of the unlicensed medicine.