New Product Evaluation Summary

Sulthiame for the management of refractory paediatric epilepsy

Decision Summary

<table>
<thead>
<tr>
<th>Date of DTG</th>
<th>DTG Decision</th>
<th>Supported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of LAPC</td>
<td>Traffic Light List</td>
<td>RED</td>
</tr>
<tr>
<td>Date of funding</td>
<td>Funding decision</td>
<td></td>
</tr>
<tr>
<td>Commissioning</td>
<td>Other considerations</td>
<td>QA support for pharmaceutical quality</td>
</tr>
</tbody>
</table>

Application summary

- The application is for the use of sulthiame for the management of refractory paediatric epilepsy as monotherapy.
- Sulthiame is a product licensed in Germany. It is an unlicensed product in the UK.
- The evidence submitted for consideration reviews a small number of clinical trials incorporating around 200 paediatric patients. Both monotherapy and combination therapy are considered. For monotherapy (which is the indication requested), 25 out of 31 patients treated with sulthiame remained seizure free for the 6 months of the trial, compared to 10 out of 35 patients on placebo. In a trial which was mixed monotherapy and combination therapy, around 50% of patients achieved complete seizure control on sulthiame. Two other trials where concomitant therapies are unclear show similar levels of effectiveness. For all trials, it is unclear as to the patients’ previous treatment with antiepileptic medicines.
- The cost of sulthiame is broadly similar to other antiepileptic medicines. As it is proposed that this would be a RED traffic light drug, there would be no cost implications for primary care.

Place in therapy / pathway

Refractory paediatric epilepsy when other AED’s have failed at optimal doses and the patient has experienced multiple seizures/month

Points for consideration

- Sulthiame is an unlicensed medicine in the UK (licensed in Germany). The unlicensed status is reflected in the requested place in therapy, after failure of other licensed antiepileptic medicines.
- The application is for the use of sulthiame as monotherapy for patients who have refractory epilepsy despite failure to control seizures on other antiepileptic medicines.
- The trial data submitted considers both monotherapy and combination therapy with other antiepileptics. For the trials that consider monotherapy, it is unclear whether the patient cohort was treatment naïve or whether they had epilepsy unresponsive to other treatments. It is therefore unclear whether the benefits seen in the trials would be likely to be seen in the proposed patient cohort.

Dave Abbott
Medicines Information Pharmacist
24/9/2014