Table I-8. Applicability rating for pharmacokinetic effects for innovator versus generic antiepileptic drugs Key Question 2

| Outcome | Brand AED | GenericAEDs | Strength of Applicability | Conclusion With Description of Applicability | Overall AED Analysis |
| --- | --- | --- | --- | --- | --- |
| Cmax | CarbamazepinePhenytoinLamotrigine | 16 Generics | Moderate | Studies were conducted in USA, Europe & Asia. Average age ranged from 10.6 to 67 years and percent of male participants ranged from 35 to 75%. Average body weight ranged from 35.8 to 53.9 kg in the two studies that reported it. Patients with various different seizure types were enrolled in these studies. All studies had fairly small sample size (total n=149). | The standardized mean difference in the generic antiepileptic medication group was non-significantly higher than the innovator antiepileptic medication group (SMD 0.10 [-0.13 to 0.32]). |
| Cmin | CarbamazepineLamotrigine | 10 Generics | Low | Studies were conducted in Europe & Asia, but none were conducted in USA. Average age ranged from 7 to 45.1 years and percent of male participants ranged from 40 to 70%. Average body weight ranged from 35.8 to 53.9 kg in the two studies that reported it. Patients with various different seizure types were enrolled in the 4 studies that reported it. All studies had fairly small sample size (total n=103). | The standardized mean difference in the generic group was non-significantly higher than the generic antiepileptic medication group (SMD 0.05 [-0.21 to 0.31]).  |
| Css | CarbamazepinePhenytoin | 12 Generics | Low | Studies were conducted in USA, Europe & Asia. Average age ranged from 10.6 to 70 years and percent of male participants ranged from 40 to 100%. Average body weight ranged from 49 to 83 kg in the two studies that reported it. Patients with both partial and generalized seizure types were enrolled in the two studies that reported it. All studies had fairly small sample size (total n=136). | The standardized mean difference in the generic group was non-significantly higher than the innovator antiepileptic medication group (SMD 0.18 [-0.09 to 0.45]). |
| AUC | CarbamazepineLamotriginePhenytoin | 16 Generics | Moderate | Studies were conducted in USA, Europe & Asia. Average age ranged from 10.6 to 67 years and percent of male participants ranged from 35 to 80%. Average body weight ranged from 50 to 83 kg in the two studies that reported it. Patients with various different seizure types were enrolled in these studies. All studies had fairly small sample size (total n=131). | The standardized mean difference in the generic group was non-significantly higher than the innovator antiepileptic medication group (SMD 0.05 [-0.18 to 0.28]). |
| Tmax | Carbamazepine | 9 Generics | Moderate | Studies were conducted in USA, Europe & Asia. Average age ranged from 10.6 to 45.1 years and percent of male participants ranged from 40 to 75%. Average body weight was 53.9 kg in the one study that reported it. Patients with various different seizure types were enrolled in these studies. All studies had fairly small sample size (total n=103). | The weighted mean difference for Tmax in generic carbamazepine group was same as the innovator carbamazepine group([WMD 0.00 [-0.43 to 0.43] hours). |

AED = antiepileptic drug; RCT = randomized controlled trial