Table I-6. Applicability rating for final health outcomes for innovator versus generic antiepileptic drugs Key Question 1

| Outcome | Brand AED | Generic AEDs | Strength of Applicability | Conclusion with Description of Applicability | Overall AED Analysis | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| Seizure Occurrence/ breakthrough seizure | CarbamazepinePhenytoinValproic Acid | 12 Generics | Low | Studies were conducted in USA, Europe & Asia. Average age ranged from 10.7 to 72 years and percent of male participants ranged from 50 to 100%. Body weight ranged from 35 to 94 kg in the four 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 short duration of follow-up with maximum of 3 months per treatment group and small sample size (total n=195). All studies were conducted before 2000. | The risk of experiencing a seizure is non-significantly decreased by 11% when generic antiepileptic medications are used versus their associated innovator products [RR 0.89 (0.65 to 1.21)] |  |
| Seizure Frequency | CarbamazepineValproic Acid | 3 Generics | Low | All 3 studies were conducted in USA. Average age ranged from 17 to 72 years and percent of male participants was 100% in the one study that reported it. Body weight ranged from 35 to 94 kg in the one study that reported it. Seizure type of patients was not reported in these 3 studies. All 3 studies had fairly short duration of follow-up with maximum of 3 months per treatment group and small sample size (total n=94). All studies were conducted before 2000 | The seizure frequency is non-significantly higher in the generic antiepileptic medication group versus the innovator group [SMD 0.03 (-0.08 to 0.14) seizures over the evaluative period] |  |
| Time to first seizure |  |  |  |  |  | No studies to assess strength of evidence |
| Incidence of status epilepticus |  |  |  |  |  | No studies to assess strength of evidence |
| Seizure remission |  |  |  |  |  | No studies to assess strength of evidence |
| Secondary seizure injury |  |  |  |  |  | No studies to assess strength of evidence |

AED = antiepileptic drug; RCT = randomized controlled trial