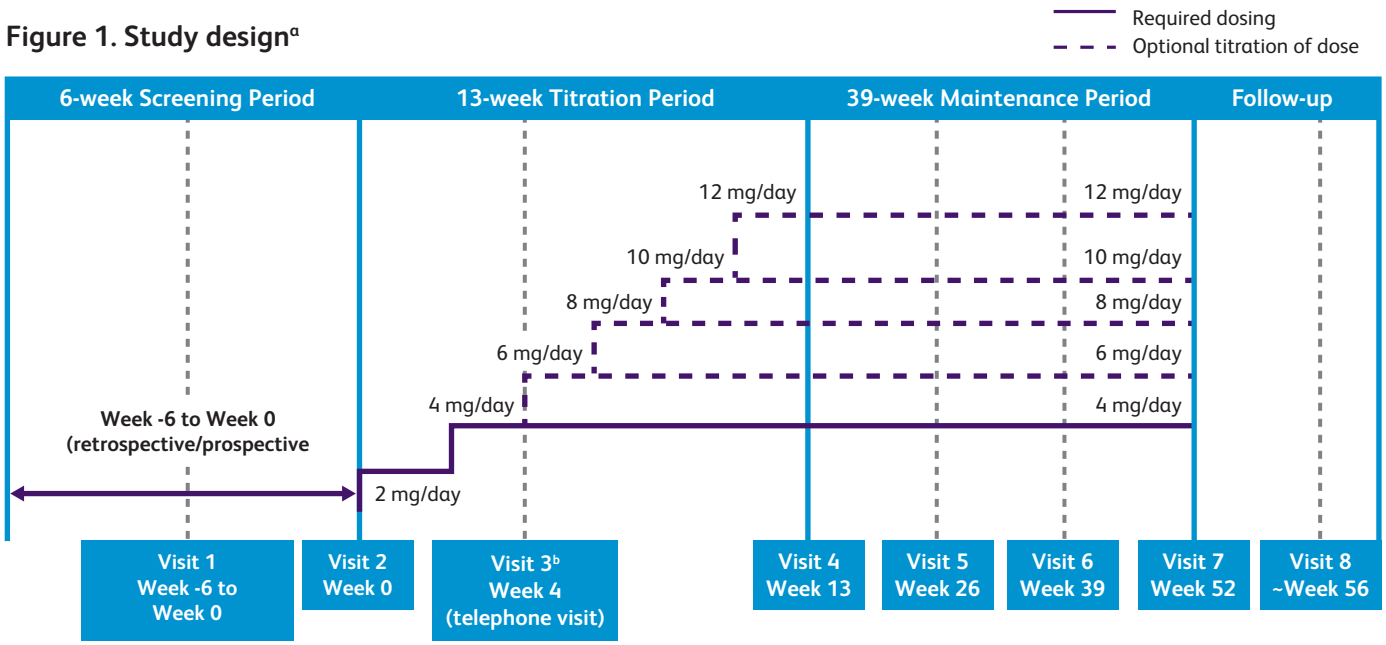
Figure 1. Study design[a]



[a]Treatment Phase: 52 weeks
[b]Patients or guardians/legally authorized representatives will be contacted via telephone by the investigator at Week 4, and then bi-weekly as necessary. Dose adjustments and rationale, as well as adverse events, will be recorded in the case report form