

Summary of recommendations for totally controlled and well controlled weeks

Totally controlled week (TCW)

Rescue treatment not required *

Plus

Zero days with symptoms** above a pre-specified level ***

Well controlled week (WCW)

Rescue treatment used for ≤ 2 days *

Plus

≤ 2 days with symptoms** above a pre-specified level***

*Rescue treatment is defined as any additional treatment that has been specified in the study protocol to deal with disease deterioration. Standard co-treatment such as emollients can be allowed if specified in the treatment protocol. In some study designs, study treatment is used as an “as required” treatment in response to disease worsening and therefore study treatment could be considered as rescue treatment.

** Valid symptom assessment tools include either:

i) Patient global assessment, or ii) Self reported itch/scratch

***Pre-specified symptom level:

5-point Likert scale (0-4)	>1
VAS (0-10cm)	>4