Gilenya® (fingolimod) – First-time generic

- On September 22, 2022, Viatris launched an AB-rated generic version of Novartis’ Gilenya (fingolimod) 0.5 mg capsules.
  - Several other manufacturers received FDA approval of AB-rated generic versions of Gilenya 0.5 mg capsule: Accord, Dr. Reddy’s, Glenmark, HEC, Hetero, Prinston, and Sun. Launch plans are pending for these generics.

- Gilenya is approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

- Gilenya is also available as a 0.25 mg capsule with the same indication as Gilenya 0.5 mg.