

February 23, 2024

First high concentration, interchangeable Humira biosimilar approved by FDA, but pricing TBD

Late Friday, February 23, the U.S. FDA approved Simlandi as the first citrate-free, high-concentration biosimilar to Humira having the coveted interchangeability tag. As an interchangeable biosimilar, Simlandi can be subbed in for Humira directly at the pharmacy without consulting the prescriber, much like the process for dispensing generic small-molecule drugs. Between 85%–90% of Humira utilization is accounted for by the high concentration formulation, so Simlandi checks off most, but not all, of the important boxes necessary to facilitate biosimilar adalimumab adoption.

However, its success in the market will entirely depend upon it being added to PBM and carrier formularies, allowing it to become a viable freely-substitutable option.

Most importantly (and the final important box remaining un-checked), pricing for Simlandi has not yet been posted to Medispan. If the pricing of Simlandi is similar to the low WAC pricing of Hyrimoz/Cordavis or Hadlima, a parity position for Humira on formularies would not seem to be adequate to forestall aggressive pharmacy-driven interchangeable conversions away from Humira at the point of sale in light of the combination of superior pricing and comparable clinical attributes.

If you have any questions or concerns, feel free to directly contact your Excelsior Solutions team.

