PHARMACY POLICY STATEMENT

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S	Prior Authorization Required

Vyondys 53 is an antisense oligonucleotide initially approved by the FDA in 2019. It is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys 53. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials
