Physician Appeal Letter – VYONDYS 53

Insurance Company Name

Insurance Company Address

Insurance Company City, State ZIP

Re: Patient’s Name

Type of Insurance

Group/Policy Numbers

Subscriber ID Number

Dear [name of contact person at insurance company],

It is my understanding that [patient’s name] has received a denial for VYONDYS 53 because the procedure is [state specific reason for the denial i.e. not medically necessary, experimental, etc.].

As you know, [patient’s name] has been under my care since [date] for the treatment of Duchenne muscular dystrophy. [Give a brief medical history emphasizing the most recent events that directly influence your decision to recommend the denied therapy.]

For this reason I am writing to provide you with information regarding VYONDYS 53. [Give a brief, yet specific description of why you believe it should be approved].

I have also included documents supporting the use of VYONDYS 53 for [patient’s name]. [Provide LMN and other supporting documentation].

Publications/references:

Center for Drug Evaluation and Research Application Number: 211970orig1s000 Retrieved from:
<https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211970Orig1s000SumR.pdf>

Diane E. Frank, Eugenio Mercuri, Laurent Servais, Francesco Muntoni,et al. on behalf of the SKIP-NMD Study Group; Increased dystrophin production with golodirsen in patients with Duchenne muscular dystrophy Neurology May 2020

Diane E. Frank, Francesco Muntoni, Eugenio Mercuri et al;. Golodirsen Leads to Sarcolemmal Dystrophin Expression in Patients With Genetic Mutations Amenable to Exon 53 Skipping Pediatrics August 2019, 144 DOI: <https://doi.org/10.1542/peds.144.2_MeetingAbstract.241>