Physician Appeal Letter

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 EXONDYS 51 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 EXONDYS 51. [Give a brief, yet specific description of why you believe it should be approved].

I have also included documents supporting the use of EXONDYS 51for [patient’s name].

I ask that you reconsider your previous decision based on the information above. Should you have any questions, please do not hesitate to call me at [phone number].

Sincerely,

Your Name

Your Street Address, E-mail Address, Phone Number, Fax Number, Cell Phone Number]

Enclosures: Statement of medical necessity if requested

Journal or peer literature supporting the service in question

Eteplirsen FDA Briefing Book. Sarepta Therapeutics

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM481912.pdf>

Addendum to Briefing book with additional information

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM481913.pdf>

Sarepta Approval Decision Memo by Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration pages 69-83

<https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_summary%20review_Redacted.pdf>

# Longitudinal effect of eteplirsen versus historical control on ambulation in Duchenne muscular dystrophy

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5064753/>