OPTIMA HEALTH PLAN

PHARMACY/MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-723-2094**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is NOT complete, correct, or legible, authorization will be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Exondys 51™ (eteplirsen) **IV (J1428/C9484) (Medical)**

❑ **URGENT REVIEW. In checking this box, prescriber attests to the fact that by applying the standard review timeframe may seriously jeopardize the member's life, health, or ability to regain maximum function.**

❑ **STANDARD REVIEW**. In checking this box, the timeframe does **NOT** jeopardize the life or health of the member or the member's ability to regain maximum function and would **NOT** subject the member to severe pain.

DRUG INFORMATION: Complete **all** information below or authorization will be delayed.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

RECOMMENDED DOSING: 30 mg per kilogram administered once weekly as a 35 to 60 minute intravenous infusion

CLINICAL CRITERIA: Check below **ALL** that apply. **ALL** criteria **must** be met for approval. To support each line checked, **ALL** documentation, including lab results, diagnostics, and/or chart notes, **must** be provided or request will be denied.

Initial Approval Length – is 6 months

- ❑ Prescriber is or in consultation with a **Pediatric Neurologist; AND**
- ❑ Member diagnosed with Duchenne Muscular Dystrophy (DMD); **AND**
- ❑ Provider **MUST** submit medical records **(e.g., chart notes, lab values)** confirming the mutation of the DMD gene is amenable to Exon 51 skipping; **AND**
- ❑ Member is ≥ 7 years of age; **AND**
- ❑ Member not taking Exondys 51™ with any other RNA antisense agent (e.g., drisapersen) or any other gene therapy; **AND**
- ❑ Exondys 51™ dosing for DMD **MUST** be in accordance with the United States Food and Drug Administration approved labeling; max dosing of 30 mg/kg once weekly; **AND**

(Continued on next page; signature page MUST be attached to this request form)

- ❑ Must have a trial of **one** of the following for **at least 52 weeks** with failure to maintain ambulation:

❑ deflazacort	❑ prednisone	❑ prednisolone

AND

- ❑ 6-minute walking test baseline value of: _____ (**must** be provided)

AND

- ❑ Dystrophin level baseline: _____ (**must** be provided)

Reauthorization Approval Length - 6 months. Check below **ALL** that apply to qualify. To support each line checked, **ALL** documentation (lab results, diagnostics, and/or chart notes) **must** be provided or request will be denied.

- ❑ Documentation supports positive response to therapy **(must meet all of the following)**:
  - ❑ Increase in dystrophin level,

    AND
  - ❑ Improved 6-minute walking test,

    AND
  - ❑ Improvement in respiratory or muscle strength

Medication being provided by (check box below that applies):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy - PropriumRx**

Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by the Pharmacy and Therapeutic Committee**: 10/19/2017
UPDATED: ~~12/18/2017~~; **(Reformatted)** ~~3/15/2019~~; ~~5/21/2019~~; **7/11/2019**;