Eteplirsen Coverage Guidelines

Prior authorization is required for all Eteplirsen prescriptions.

Coverage guidelines for Eteplirsen are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity, as established by state law. The following factors are guidelines *only*. Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail.

Payment will be considered for patients when the following guidelines are met:

• Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing.

(NOTE: physician must provide results of genetic testing)

• Must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy.

• Patient is currently ambulatory and able to achieve an average distance of at least 180 meters while walking independently over six minutes.

(NOTE: physician must attach a baseline 6 – Minute Walk Test [6MWT])

- Patient is currently stable on oral corticosteroid regimen for at least 6 months.
- Must be dosed on FDA approved dosing: 30mg/kg once weekly.

If guidelines for coverage are met, initial authorization will be given for 6 months only.

<u>Requests for continuation of therapy will be considered at 6 month intervals when the following are</u> <u>met:</u>

•Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent).

• An updated 6MWT must be provided documenting the patient is able to achieve a distance of at least 180 meters.