Connecticut Department of Social Services
Medical Assistance Program **Provider Bulletin 2017-45**
www.ctdssmap.com **June 2017**

TO: Pharmacy Providers, Physicians, Nurse Practitioners, Physician Assistants, Clinics, Long Term Care Providers, and Hospitals
RE: Eteplirsen Coverage Guidelines

Effective July 1, 2017, the Department of Social Services (DSS) is implementing a Prior Authorization (PA) requirement for prescription benefit coverage of Eteplirsen, marketed as Exondys 51, for HUSKY A, HUSKY B, HUSKY C, HUSKY D, and Family Planning program clients.

The U.S. Food and Drug Administration (FDA) has approved Eteplirsen for the treatment of Duchenne muscular dystrophy (DMD) for patients who have a confirmed mutation of the dystrophin gene amenable to exon 51 skipping, which affects about 13 percent of the population with DMD.

PA requests for coverage of Eteplirsen must be submitted by the prescriber in the form of a letter of medical necessity to the Department's Medical Director. Letters of medical necessity should be faxed to (860) 424-4822 with the required documentation outlined in the Eteplirsen Coverage Guidelines.

The Eteplirsen Coverage Guidelines document is attached below and will be available on the www.ctdssmap.com Web page under Pharmacy Information → Pharmacy Program Publications → Eteplirsen Coverage Guidelines.

Please note that Eteplirsen will be authorized for a period of 6 months and will require a re-authorization after the initial PA ends.

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*.

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

•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.