

Kaiser Foundation Health Plan of Washington  
 Kaiser Foundation Health Plan of Washington Options, Inc.  
 CONTRACT MANAGER NAME  
 Provider Communications, RCB-C2W-02  
 PO Box 34262, Seattle WA 98124-1262

December 31, 2019

**SITE OF CARE PRIOR AUTHORIZATION REQUIREMENT FOR EXONDYS 51® (ETEPLIRSEN)**

Dear Provider,

**Effective March 1, 2020**, Site of Care prior authorization criteria will apply to the medication noted in Table 1 below. Site of Care is a prior authorization for the location at which an infused medication is administered under the medical benefit. When Site of Care is applied to a medication, the following site of care types are acceptable: an **outpatient standalone clinic, infusion center, provider’s office, or home infusion**. Outpatient hospital-based infusion sites are not approved sites. This letter is notification that prior authorization approval is required before administering this medication under the medical benefit.

This only applies to Kaiser Foundation Health Plan of Washington Core and SoundChoice Health Maintenance Organization (HMO) members and Kaiser Foundation Health Plan of Washington Options, Inc. Options Point Of Service (POS), Access PPO and Elect PPO Preferred Provider Organization (PPO) members. This change will **NOT** affect Medicare Advantage members.

The following injectable drug will be added to the list of drugs requiring prior authorization for Site of Care:

Table 1. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
DUCHENE MUSCLULAR DYSTROPHY	EXONDYS 51®	ETEPLIRSEN	J1428

Prior authorization clinical criteria was previously established for Exondys 51® (eteplirsen) J1428. Members who are initiating treatment with Exondys 51® (eteplirsen) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior authorization clinical criteria for Exondys 51® (eteplirsen):

Covered for patients with Duchenne muscular dystrophy who meet ALL of the following:

- Prescribed by or in consultation with pediatric neurology, adult neurology or Physical Medicine & Rehabilitation
- Documented deletion/mutation amenable to exon 51 skipping
- At least 4 years old
- Ambulatory: cane or walker use acceptable
- Documented minimum distance for unassisted 6-minute walk test of 180m at baseline
- Must be on a stable dose of glucocorticoid for at least 6 months
- Forced Vital Capacity % (FVC%) greater than or equal to 50% predicted

Not covered for patients that are:

- Non-ambulatory
- Ambulatory with some level of wheelchair dependency

Reassessment every 12 months to determine need for continued therapy. Patient must meet ALL of the following functional criteria for continued coverage:

- Ambulation test: Limited home level or greater
- Sit to stand test: Moderate assist or Independent
- No ventilator support (excluding use of nocturnal CPAP)

**Note:** Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel.

You can request prior authorization using one of the following methods:

- Use the Kaiser Permanente provider website. You can send your request for authorization using our Referral Request tool. Using this method is easy and is the quickest way to obtain your authorization, sometimes immediately if your request is auto approved.
- Fax your request to the Review Services department at 1-888-282-2685.
- Contact Review Services at 1-800-289-1363, Monday – Friday from 8 am to 5 pm. After business hours, please leave a voice message with your contact information. Messages received after normal business hours are returned on the next business day.

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at <https://wa-provider.kaiserpermanente.org/provider-manual> under the “Authorizations & Clinical Review” section. Site of Care reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Medical Policy Committee’s criteria for coverage.

#### **Site of Care Prior Authorization Criteria Exceptions:**

A hospital outpatient setting may be used for infusion of drugs on the site of care optimization list only if **one** of the following is met:

1. Member is medically unstable based upon submitted clinical history. Examples, including, but not limited to, cardiopulmonary conditions that may increase risk of adverse reactions, inability to safely tolerate intravenous volume loads, unstable vascular access requiring ultrasound guidance; or
2. Previous experience of a severe adverse event following infusion. Examples, including, but not limited to, anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or
3. Continuing experience of adverse events that cannot be mitigated (e.g. not mitigated by pre-medications or by reducing the rate of infusion); or
4. Physically and/or cognitively impaired AND no home caregiver available; or
5. The member’s home is not eligible for home infusion services (such as home is not within the service area determined by the home infusion provider or is deemed unsuitable for care by the home infusion provider). Clinical notes supporting an exception must be included (e.g., dates of prior anaphylactic experience, specific details of adverse reactions and attempts to mitigate).

Note: For new start members, alternative Site of Care criteria will be waived for payment of the administration of the first dose for all drugs, to allow for adequate transition time to arrange for a non-hospital outpatient setting for the infusion. Further dose exceptions may be applicable depending on the drug (see Table 1) and/or to ensure continuity of care.

#### **Additional Information**

Coverage determinations, once completed, will be available online using the Referral Status Inquiry application and will be mailed to the member.

Failure to obtain a prior authorization for the above medications will result in a denial of payment.

Please refer to the provisions of your agreement with Kaiser Permanente, including obtaining the member's prior written agreement to be financially responsible for the specific non-covered service, to determine when providers may bill a member for non-covered services.

If you have any questions about these changes, please contact the Provider Assistance Unit toll-free at 509-241-7206 or toll-free at 1-888-767-4670, Monday – Friday from 8 am to 5 pm.

Sincerely,

A handwritten signature in cursive script that reads "Bruce Wilson MD". The signature is written in black ink and is positioned above the printed name.

Bruce Wilson, MD, Chair  
Pharmacy & Therapeutics Committee