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206-988-2000
206-988-2001
prnotification@kp.org

Kaiser Foundation Health Plan of Washington
Kaiser Foundation Health Plan of Washington Options, Inc.
Provider Communications, RCR-A3W-04
PO Box 34262, Seattle WA 98124-1262

August 17, 2026

UPDATED PRIOR AUTHORIZATION CRITERIA FOR NUSINERSEN (SPINRAZA)

Dear Provider,

Nusinersen (Spinraza) is on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective November 1, 2026,** the criteria for Nusinersen (Spinraza) will be updated to include a quantity limit. **This letter is a notification of the upcoming change in coverage for this medication under the medical benefit.**

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) require prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician's office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

BRAND NAME	GENERIC NAME	HCPCS
Spinraza	**Nusinersen**	**J2326**

Prior Authorization Criteria for Nusinersen (Spinraza) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA

Nusinersen (Spinraza)	Covered for patients with spinal muscular atrophy (SMA) who meet all of the following:
	• Prescribed by or in consultation with Pediatric Neurology, Neurology, or other specialist with expertise in managing SMA.
	• Documented diagnosis of 5q-autosomal recessive SMA (biallelic deletions or mutations in the *SMN1* gene).
	• Two to four copies of the *SMN2* gene.
	• If patient is 22 to 65 years old, patient is ambulatory with baseline Hammersmith Functional Motor Scale-Expanded Exam (HFMSE) score ≥35 and documented disease progression.
	• Required documentation:
	  ○ Baseline labs (CBC, PT/PTT, urinalysis)
	  ○ Baseline functional motor assessment
	  ▪ <u>Infants:</u>
	  • Hammersmith Infant Neurological Examination Section 2 (HINE-2) OR Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ▪ <u>Children (age > 24 months), adolescents, adults:</u>
	  • <u>HFMSE</u> AND Revised Upper Limb Module (RULM)
	  ▪ <u>All ambulatory:</u> 6-minute walk test (6MWT)
	  ○ Spine evaluation to assess ease of lumbar puncture entry
	  ○ Risk assessment for procedure: objective respiratory testing
	  ▪ Age ≥ 6 years: pulmonary function tests (PFTs)

DRUG NAME	COVERAGE CRITERIA
	▪ Age < 6 years: pulse oximetry and End-Tidal CO2 (ETCO2) measurements; Also consider screening sleep studies in non-ambulatory, hypotonic infants and young children Not covered for patients: • Age > 65 years at time of treatment initiation • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Contraindication to lumbar puncture • Concurrent treatment with risdiplam (Evrysdi) • Prior or planned treatment with gene therapy for SMA Reassessment every 12 months to determine need for continued therapy. Therapy should be discontinued if patient meets at least one of the discontinuation criteria: • Non-adherence to follow-up assessment including medical treatment plan (e.g., nutrition, pulmonary, physical therapy). • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Loss of function or progressive weakness (physical and/or pulmonary) • Risdiplam or other therapy for SMA is initiated **Quantity Limits:** • **Loading dose:** ○ **four 12 mg loading doses** ▪ **first three 12 mg doses should be administered at 14-day intervals;** ▪ **fourth 12 mg dose should be administered 30 days after the 3rd dose.** • **Maintenance dose:** ○ **12 mg once every four months thereafter (starting 4 months after the last loading dose).**

Additional Information
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/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form (login required) located on the Kaiser Permanente provider website. You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide for our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday, from 8:00 a.m. to 5:00 p.m.

Sincerely,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee