



Dear SMA community,

In response to your request for information, we are pleased to share that Medicines and Healthcare Products Regulatory Agency (MHRA) has granted marketing authorisation to the high dose regimen (50/28 mg) of SPINRAZA™ (nusinersen) for the treatment of 5q spinal muscular atrophy (SMA).¹

The authorisation is based on data from the three-part, Phase 2/3 DEVOTE study and its ongoing long-term extension, which assessed the high dose regimen of nusinersen in both treatment-naïve individuals and those previously treated with the 12 mg regimen.

The new high dose regimen comprises of a more rapid loading phase than the existing 12 mg regimen, with two 50 mg loading doses administered 14 days apart, and 28 mg maintenance dose injections every four months thereafter. Individuals transitioning from the 12 mg dose will receive one 50 mg dose in place of their next 12 mg dose, followed by 28 mg maintenance doses every four months thereafter.

Biogen will seek to engage with local health authorities to support timely access for appropriate patients across the United Kingdom.

We also sincerely thank the SMA community for your continued engagement and advocacy in supporting those living with the condition.

With kind regards,

Nisha Tailor
External Affairs Lead, Biogen UK & Ireland

1. Spinraza (nusinersen) Summary of Product Characteristics. April 2026.