Dear SMA Community,

Thank you for the countless conversations, shared experiences, and honest reflections that continue to shape our work. As part of our continued efforts to respond to the needs and priorities you have shared with us, we are pleased to announce that on March 27, 2026, the U.S. Food and Drug Administration approved a **High Dose Regimen of SPINRAZA® (nusinersen)** for the treatment of SMA in pediatric and adult patients.

Why this matters:
Every family's experience with SMA is unique, and we consistently hear how important it is to have effective treatment options. High Dose SPINRAZA offers another dosing option that you can explore with your healthcare provider based on your goals and preferences. Building on a decade of clinical data and real-world experience supporting the **Low Dose Regimen of SPINRAZA (12 mg)**, we are excited to bring the High Dose Regimen to people living with SMA, which reflects our shared commitment to the SMA community.

What is new:
The High Dose Regimen of SPINRAZA is now approved, offering higher loading and maintenance doses. The FDA's approval is based on data from the DEVOTE study, which investigated the efficacy and safety of High Dose SPINRAZA in people of various ages who had not been treated before, as well as those who had prior treatment with the Low Dose Regimen.

How the High Dose Regimen of SPINRAZA is administered:
SPINRAZA is an intrathecal injection, or an injection into the fluid of the spine, by a healthcare professional experienced in performing lumbar punctures. For those new to SPINRAZA treatment, the High Dose Regimen begins with two loading doses of 50 mg given 14 days apart, followed by a maintenance dose of 28 mg every four months thereafter. For those already taking the Low Dose Regimen of SPINRAZA, you will receive one 50 mg dose in place of your next 12 mg dose, followed by a maintenance dose of 28 mg every four months, without any change to your treatment schedule. Additional clinical benefit in patients who transition from the Low Dose Regimen (12 mg) to the High Dose Regimen has not been established in a controlled study.

What is the same:
High Dose SPINRAZA is composed of the same drug (nusinersen) as the 12 mg regimen. The volume of medicine in each vial will be the same across all dosages – 5 mL – with the higher doses including a more concentrated amount of nusinersen.

Availability:
The High Dose Regimen of SPINRAZA is now available in the United States.

Talking with your care team:
Treatment decisions are personal, and your care team is the best partner in helping you determine whether High Dose SPINRAZA aligns with your needs. If you have questions about access, coverage or available resources, please reach out to your Family Access Manager (FAM). If you do not have a FAM, please call 1-844-477-4672 to speak with a Lead Case Manager, available Monday – Friday, 8:30 a.m. – 8:00 p.m. ET.

For more information, please visit www.spinraza.com.

Our gratitude:
Since its approval in the U.S. in 2016, SPINRAZA has helped to set a new standard in care and has been used by thousands of people living with SMA worldwide. The approval of High Dose SPINRAZA would not have been possible without the support and contributions of the SMA community, for which we are deeply grateful. From the earliest SPINRAZA studies to today's approval, your involvement and advocacy have played a critical role in pushing science forward. We are honored to continue this work alongside you, and we look ahead with optimism about what we can achieve together.

WHAT IS SPINRAZA?

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

IMPORTANT SAFETY INFORMATION

Increased risk of bleeding complications has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

The most common side effects of SPINRAZA in the Low Dose Regimen in infantile- and later-onset SMA include lower respiratory infection, constipation, fever, headache, vomiting, back pain, and post-lumbar puncture syndrome.

The most common side effects of SPINRAZA in the High Dose Regimen in infantile-onset SMA include pneumonia, COVID-19, pneumonia aspiration, and malnutrition. COVID-19 was not discovered at the time of the studies for the Low Dose Regimen.

These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

Please see full Prescribing Information.

This information is not intended to replace discussions with your healthcare provider.

With appreciation,
Your Biogen Team