

September, 2020

Dear members of SMA Europe,

In response to your request, please find an update on access to SPINRAZA (nusinersen).

### **Access to reimbursed treatment**

There are now 29 European countries that have access to nusinersen via regular reimbursement.

Compared to the last report, you can find an updated situation in Switzerland.

As you can see from the table, there is a range of reimbursed access: in line with the label - 5q spinal muscular atrophy (SMA); for Type I, II, III (excluding IV) and in some cases including age restrictions e.g. <18 yrs. Additionally, in certain countries there are rare disease/ medical committees who apply further inclusion and exclusion clinical criteria. For more details, please see the following table:

<b>Access &amp; Reimbursement Details by Country</b>	
<b>Austria</b>	Reimbursement Label varies by Region.
<b>Belgium</b>	Reimbursed access in line with the European label - 5q spinal muscular atrophy (SMA) - inclusion/ exclusion criteria may apply
<b>Bulgaria</b>	Access through individual reimbursement and as of Jan 2020 national access - Types I, II and III (<18 yrs.)
<b>Croatia</b>	Reimbursed Access -Type I, II, III. No age limitations.
<b>Cyprus</b>	Access through individual reimbursement
<b>Czech Republic</b>	Reimbursed access -Types I, II and III. No age limitations.
<b>Denmark</b>	Limited reimbursed access – presymptomatic, Type I & II up to app 6 years of age. (Subject to clinical criteria)
<b>England &amp; Wales</b>	The National Institute for Health and Care Excellence (NICE) has recommended funding for SPINRAZA (nusinersen). The positive recommendation is for the treatment of infants, children and adults with spinal muscular atrophy (SMA), including pre-symptomatic and SMA types 1, 2 and 3, within the terms of the Managed Access Agreement.
<b>Estonia</b>	Negotiations underway
<b>Finland</b>	Reimbursed access - Types I, II and IIIa (<18 yrs.) Diagnosis before two years of age and symptoms started before age 20 months aligned with PALKO positive recommendation
<b>France</b>	Reimbursed access -Types I, II and III. No age limitations
<b>Germany</b>	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
<b>Greece</b>	Reimbursed access for pre-symptomatic, Types I and II; Type III access via exceptional funding and negotiations for Type III for formal access underway
<b>Hungary</b>	Reimbursed access – Pre-symptomatics & Types I, II and III (<18 yrs.)
<b>Iceland</b>	Reimbursed access – Types I, II, III under 18 years old
<b>Ireland</b>	Reimbursed access -Pre-symptomatic & Types I, II and III up to 18 years
<b>Italy</b>	Reimbursed access - Types I, II and III

<b>Latvia</b>	Reimbursed access - Pre-symptomatic (2-3 SMN2 copies), TI (2 copies ≤6mo, 3 copies ≤8mo), II & III (≤12 years)
<b>Lithuania</b>	Access through individual reimbursement
<b>Luxembourg</b>	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
<b>North Macedonia</b>	Access through a named patient programme
<b>Montenegro</b>	Access through a named patient programme
<b>Netherlands</b>	Regular reimbursement for children up to 9.5 years (subject to clinical criteria) and conditional reimbursement for SMA patients older than 9.5 years as of January 2020 for at least 7 years.
<b>Northern Ireland</b>	Northern Ireland follows NICE's recommendation.
<b>Norway</b>	Reimbursed access -Types I, II and IIIa (<18 yrs.)
<b>Poland</b>	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
<b>Portugal</b>	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
<b>Romania</b>	Reimbursed access in line with the European label - 5q spinal muscular atrophy (SMA)
<b>Russia</b>	Marketing authorization was granted. Negotiation for Federal Access as of 2021 underway.
<b>Scotland</b>	SMC has broadened Spinraza's reimbursement, from Type 1 currently, to cover Types 2 & 3 (later onset)
<b>Serbia</b>	Access through a named patient programme
<b>Slovakia</b>	Reimbursed access -Types I, II and IIIa
<b>Slovenia</b>	Reimbursed access Types I, II and III
<b>Spain</b>	Reimbursed access - Types I, II and III
<b>Sweden</b>	Reimbursed access – Pediatric (initiated below 18 years old) Types I, II and IIIa
<b>Switzerland</b>	Reimbursed access - pre-symptomatic and Type I, II, III
<b>Turkey</b>	Access through a named patient programme (Type I, II, III without age limitation)
<b>Ukraine</b>	Marketing authorization received on January 11, 2020. Negotiations expected in H2

We will continue to be available to provide updates in the future, when requested.

Best regards,  
The SMA Biogen Team