Biogen

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:

Access & Reimbursement Details by Country	
Austria	Reimbursement Label varies by Region.
Belgium	Reimbursed access in line with the European label - 5q spinal muscular atrophy (SMA) - inclusion/ exclusion criteria may apply
Bulgaria	Access through individual reimbursement and as of Jan 2020 national access - Types I, II and III (<18 yrs.)
Croatia	Reimbursed Access -Type I, II, III. No age limitations.
Cyprus	Access through individual reimbursement
Czech Republic	Reimbursed access -Types I, II and III. No age limitations.
Denmark	RESTRICTED Reimbursed access – presymptomatic, Type I & II up to app 6 years of age. (Subject to clinical criteria)
England & Wales	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.
Estonia	Negotiations underway
Finland	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
France	Reimbursed access -Types I, II and III. No age limitations
Germany	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
Greece	Reimbursed access for pre-symptomatic, Types I and II; Type III access via exceptional funding and negotiations for Type III for formal access underway
Hungary	Reimbursed access – Pre-symptomatics & Types I, II and III (<18 yrs.)
Iceland	Reimbursed access – Types I, II, III under 18 years old
Ireland	Reimbursed access -Pre-symptomatic & Types I, II and III up to 18 years
Italy	Reimbursed access - Types I, II and III

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