9th September 2019

Dear Board members of SMA Europe,

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

Access to reimbursed treatment

There are now 28 European that have access to nusinersen via regular reimbursement. 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 label - 5q spinal muscular atrophy (SMA) effective September 1st - inclusion/ exclusion criteria may apply
Bulgaria	Pricing & Reimbursement dossier submission in Apr 2019. Negotiations underway. Access through individual reimbursement
Canada	The following provinces have reimbursed access: - Quebec: pre-symptomatic and symptomatic patients with Type 1, 2 and 3 of all ages - Saskatchewan, Ontario, Alberta and the federal plan of noninsured health benefits: pre-symptomatic and symptomatic patients with Type 1, 2 and 3 under 18 years.
Croatia	Reimbursed Access -Type I, II, III , expanded to adult patients in August 3, 2019.
Cyprus	Access through individual reimbursement
Czech Republic	Reimbursed access -Types I, II and IIIa (subject to clinical criteria)
Denmark	Reimbursed access – presymptomatic, Type I & II (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 for Type I (<16 months), Type II (<10 years) and Type III (<18 years)
Iceland	Reimbursed access – Types I, II, III under 18 years old - November 2018
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) as of July 30, 2019
Lithuania	Access through individual reimbursement
Luxembourg	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
Macedonia	Negotiations underway
Montenegro	Access through a named patient programme
Netherlands	Regular reimbursement for children up to 9·5 years (subject to clinical criteria); The Healthcare Institute recommended conditionally reimbursement for patients over 9.5 years of age.
Northern Ireland	Northern Ireland will follow 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 label - 5q spinal muscular atrophy (SMA)
Russia	Partner in place; Registration dossier was submitted in November 2018. EAP opened on 23rd of April 2019 and will close when the MAA is granted.
Scotland	SMC has broadened Spinraza's reimbursement, from Type 1 currently, to cover Types 2 & 3 (later onset) starting April 2019
Serbia	Access through a named patient programme
Slovakia	Reimbursed access -Types I, II and IIIa - August 1st 2018
Slovenia	Reimbursed access Types I, II and III, expanded to adult patients in March 7, 2019.
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) up to 20 years old; Individual reimbursement for patients above 20
Turkey	Access through a named patient programme (Type I, II, III without age limitation)
Ukraine	Partner in place; preparing for submission of registration dossier in Q3 2019

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

Best regards,
The SMA Biogen Team