

16th June, 2018

Dear SMA Community,

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

Access to reimbursed treatment

In Europe and across the region, since the last update in May, significant progress has been made in Croatia, the Czech Republic, Denmark, Romania and Slovakia. For full details, please see the following table:

Access & Reimbursement Details By Country	
Austria	Reimbursed access - Types I, II and III
Belgium	Negotiations underway
Bulgaria	Partner in place; preparing for reimbursement dossier submission
Croatia	Reimbursed Access -Type I, II, IIIa (<18 yrs)
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	Access & Reimbursement dossier submitted March 2018
Estonia	Partner in place; Negotiations underway
Finland	Reimbursed access for patients up to, and including, 17 years old, aligned with PALKO positive recommendation.
France	Negotiations underway; current reimbursed access given to Types I, II and III through post ATU
Germany	Negotiations underway; reimbursed access given to Types I, II and III
Greece	Reimbursed access for pre-symptomatic, Types I and II; negotiations for Type III underway
Hungary	Biogen & NEAK agreement signed. Final access decisions will be made by NEAK as per the Rare Disease Committee criteria in response to all individual applications.
Iceland	Partner in place; preparing for reimbursement dossier submission
Ireland	Negotiations underway
Israel	Reimbursed access - Types I, II and III
Italy	Reimbursed access - Types I, II and III
Kuwait	Negotiations underway; current access through a named patient programme
Latvia	Partner in place; preparing for reimbursement dossier submission
Lithuania	Access through individual reimbursement
Luxembourg	Reimbursed access - Types I, II and III
Macedonia	Negotiations underway

Netherlands	Negotiations underway
Northern Ireland	Negotiations underway
Norway	Reimbursed access -Types I, II and III (0 to 18 years of age)
Poland	Positive recommendation for broad patient population by President of Transparency Commission - negotiations underway
Portugal	Negotiations underway
Qatar	Negotiations underway; current access through a named patient programme
Romania	Positive HTA report published, Spinraza included in the national list of reimbursed medicines and therapeutic protocol published (Types I,II and III)
Russia	Partner in place; preparing for reimbursement dossier submission
Saudi Arabia	Negotiations underway; current access through a named patient programme
Scotland	Reimbursed Access Type I (later-onset patients funded via the Individual Treatment Fund); negotiations for Type II and III in preparation
Serbia	Access through a named patient programme
Slovakia	Reimbursed access -Types I, II and IIIa as of August 1 st 2018
Slovenia	Reimbursed access Types I, II and III pediatric patients
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	Negotiations ongoing; current access through a named patient programme
Ukraine	Partner in place; preparing for reimbursement dossier submission
UAE	Negotiations underway; current access through a named patient programme

Thank you for the support we consistently receive from the entire SMA community. We would not have made such progress without you, the families living with SMA, the physicians, health systems and government agencies who have supported the nusinersen program. We still have much work to do and we will continue to work tirelessly to ensure that patients who may benefit from nusinersen will receive access as quickly as possible.

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

Best regards,
The SMA Biogen Team