

16th March 2018

Dear Board members of SMA Finland,

In response to your request for an update, please find below the information you have requested regarding access to SPINRAZA (nusinersen) in Europe.

Access to reimbursed treatment

We fully understand the devastating impact that SMA has on patients, their families and their communities. We are working tirelessly with health care professionals, government agencies, policy makers and patient advocacy groups across Europe to find solutions so that people who could benefit from nusinersen may receive access to this new treatment option as quickly as possible.

In Europe and across the region, even since the last update in January significant progress has been made in Spain, Norway and Hungary. 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	Reimbursement dossier submitted in March; current access is through a named patient programme
Cyprus	Pricing submission is being evaluated by authorities
Czech Republic	Negotiations underway
Denmark	Negotiations ongoing; Reimbursed access restricted to presymptomatic & Type 1
England & Wales	Access & Reimbursement dossier to be submitted by March 2018
Estonia	Partner in place; preparing for reimbursement dossier submission
Finland	Negotiations ongoing; current access is through individual reimbursement
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 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.
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	Partner in place; negotiations underway for individual reimbursement preparing for reimbursement dossier submission
Luxembourg	Reimbursed access - Types I, II and III
Macedonia	Negotiations underway
Netherlands	Negotiations underway
Northern Ireland	Negotiations underway
Norway	Reimbursed access – Pediatric (initiated below 18 years old) Types I, II and IIIa
Poland	In final stages of HTA assessment; negotiations will follow
Portugal	Negotiations underway
Qatar	Negotiations underway; current access through a named patient programme
Romania	Reimbursement dossier submitted in February
Russia	Partner in place; preparing for reimbursement dossier submission
Saudi Arabia	Negotiations underway; current access through a named patient programme
Scotland	Negotiations underway
Serbia	Negotiations underway; currently patients do not have access in any form
Slovakia	Reimbursement dossier submitted in January 2018
Slovenia	Reimbursed access Types I, II and III treated at a Pediatric clinic
Spain	Reimbursed access agreed - Types I, II and III
Sweden	Reimbursed access – Pediatric (initiated below 18 years old) Types I, II and IIIa
Switzerland	Negotiations underway
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

Biogen is incredibly thankful to the entire SMA community for their continued support, contributing to both the many regulatory approvals within the last year and the ongoing clinical trial programs. We remain a dedicated committed partner to this community and will continue to be available to provide updates in the future, when requested.

Best regards,

The Biogen SMA Team