September, 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

There are now 20 European countries where patients 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	Reimbursed access - in line with the label - 5q spinal muscular atrophy (SMA)
Belgium	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA) effective September 1st - inclusion/ exclusion criteria may apply – September 1
Bulgaria	Partner in place; preparing for reimbursement dossier submission
Croatia	Reimbursed Access -Type I, II, III (<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	NICE published its Appraisal Consultation Document (ACD), outlining a 'minded no' for the routine funding of nusinersen. The ACD is an interim decision that does not necessarily reflect the final technology guidance. There was a consultation period during which anyone could respond with their views on the ACD. Additional discussions are ongoing.
Estonia	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	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
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	Negotiations underway
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	Submission of P&R dossier - September 2018
Lithuania	Access through individual reimbursement
Luxembourg	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
Macedonia	Access through a Named Patient Program - September 2018
Montenegro	Access through a Named Patient Program - September 2018
Netherlands	Regular reimbursement for children up to 9·5 years (subject to clinical criteria); involved parties are currently discussing the possibilities of conditional reimbursement for other SMA patients – August 1st 2018
Northern Ireland	Negotiations underway
Norway	Reimbursed access -Types I, II and IIIa (0 to 18 years of age)
Poland	Negotiations underway
Portugal	Negotiations underway
Qatar	Negotiations underway; current access through a named patient programme
Romania	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA) - September 2018
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 - August 1st 2018
Slovenia	Reimbursed access Types I, II and III that are treated in pediatric centers
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

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

Best regards,
The SMA Biogen Team

Adverse events should be reported.
For Ireland, reporting forms and information can be found at www.hpra.ie.
For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Biogen Idec on 1800 812 719 in Ireland and 0800 008 7401 in the UK.