January 7th, 2019

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 24 European countries where SMA 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
Bulgaria	Partner in place; preparing for reimbursement dossier submission
Canada **INESSS and the Government of Quebec**	Interim agreement with pCPA. The Provinces will cover limited number of Type 1 SMA patients (according to the current HTA recommendations) and Biogen Canada will cover the most urgent Type 2 and 3 patients – defined as those with the highest risk of losing motor function. Final reimbursement criteria to be defined in January 2019, once the Canadian Agency for Drugs and Technologies in Health (CADTH) provide their final assessment, following Biogen's resubmission in September 2018. Reimbursed Access - pre-symptomatic and symptomatic patients with Type 1, 2 and 3 of all ages
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 in August 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 has been a public consultation period and NICE committee meeting took place on 23 October to review the feedback. Ongoing discussions are underway with all stakeholders
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	Reimbursed access – Types I, II, III under 18 years old - November 2018
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; negotiations underway
Lithuania	Access through individual reimbursement
Luxembourg	Reimbursed access in line with the label - 5q spinal muscular atrophy (SMA)
Macedonia	Negotiations underway
Montenegro	Negotiations underway
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	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)
Qatar	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
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	Reimbursed access - in line with the label - 5q spinal muscular atrophy (SMA)

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

Best regards,
The SMA Biogen Team