March, 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 Spinal Muscular Atrophy (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**	The Canadian Agency for Drugs and Technologies in Health (CADTH) provided their final assessment recommending to cover SMA patients who: *are pre-symptomatic with two or three copies of SMN2, or have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, or are 12 years of age or younger with symptom onset after six months of age, and never achieved the ability to walk independently. Patient is not currently requiring permanent invasive ventilation* Biogen is negotiating the implementation of this guidance with the provinces (pCPA). INESS/Quebec: 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 and an additional meeting took place on 6th March 2019.
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	The HSE has issued a "minded no" in funding nusinersen at this time. Biogen is responding to the preliminary decision and will continue the dialogue with the Irish authorities.
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	Scottish Medicines Consortium will be broadening 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, expanding to adult patients as of March 7, 2019.
Spain	Reimbursed access - Types I, II and III
Sweden	Reimbursed access – Paediatric (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