March, 2019

Dear Ms Dumitru,

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 of 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. 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 | 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 – 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