


9/10/2020




**SPINRAZA**  
(nusinersen) injection  
12 mg/5 mL

# SPINRAZA: Global Pricing and Reimbursement (P&R) Status Update Report

Global Value & Access

August 3, 2020



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## Executive Summary

Updated: 03 August 2020

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**Guidance:** For external 'high-level' communications, please see the following bullet points on the overview of reimbursement across major regions/geographies:

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**A. Licensed countries (i.e. countries with regulatory approval):**

- 29 countries with formal reimbursement in Europe
- 41 countries with formal reimbursement at Global level

**B. NPP and/or individual patient reimbursed countries:**

- 6 countries in Europe
- 17 countries at Global level

**C. Total Access (Global)**

- 58 countries world-wide where we have achieved formal reimbursement, individual reimbursement, or a named-patient sales program
  - Formal reimbursement: 41 countries
  - Individual patient request reimbursement: 7 countries
  - Named-patient sales program (NPP): 10 countries

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## SPINRAZA – Summary of Reimbursement Status

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| P&R | Reimbursement Status   | Countries (71)  |
|-----|--|---|
|     | Full reimbursement<br><i>(as per label)</i>                              | [22] Germany, Italy, Luxembourg, Israel, Japan, Spain, Belgium, Romania, Hong Kong, Portugal, Poland, Scotland, Slovenia, France, UK (England/Wales), UK (N. Ireland), Qatar, UAE, Croatia, Brazil, Netherlands <sup>2</sup> , Czech Republic |
|     | Broad reimbursement <i>(in line or broader than clinical trial data)</i> | [16] USA, Greece, Sweden, Norway, Hungary, Switzerland, Finland, Australia, Slovakia, Iceland, S. Korea, Argentina <sup>9</sup> , Austria, Canada <sup>3</sup> , Ireland, Bulgaria  |
|     | Restricted Reimbursement<br><i>(whilst negotiations ongoing)</i>         | [3] Denmark <sup>1</sup> , Latvia <sup>5</sup> , Taiwan <sup>8</sup>  |
|     | Individual Reimbursement   | [7] Chile, Cyprus, Lithuania, Uruguay, Mexico <i>(private insurance)</i> <sup>6</sup> , Colombia, Russia <sup>7</sup>   |
|     | Named Patient Sales Program (NPP)  | [10] Turkey, S. Arabia, Kuwait, Serbia, Macau, Montenegro, Egypt, Oman, North Macedonia, Costa Rica   |
|     | Negotiations underway  | [5] Estonia, New Zealand, Bahrain, Singapore, China <sup>4</sup>  |
|     | Preparations underway  | [8] Ukraine, Algeria, Malaysia, Iraq, Ecuador, Guatemala, Panama, Peru  |

<sup>1</sup>Pre-symptomatic, Type I and Type II (≤4yrs disease duration); <sup>2</sup>Conditional reimbursement agreement for patients >9.5yo over 7-year period beginning Jan 2020; <sup>3</sup>See Slide Notes; <sup>4</sup>Available via Self-Pay Patient Assistance Program in conjunction with China Primary Health Care Foundation; <sup>5</sup>Pre-symptomatic (2 or 3 SMN2 copies), Type I (2 SMN2 copies up to 6 months, 3 SMN2 copies up to 8 months), II & III (up to 12 years); <sup>6</sup>Preparations underway for reimbursement through public health system; <sup>7</sup>Access via individual reimbursement at the regional level (~25% of regions have made purchases as of Q2 2020), negotiations for national reimbursement ongoing; <sup>8</sup>SMA patient Type 1, 2a OR pre-symptomatic of SMN 2 two copies, starting treatment before turning 7; <sup>9</sup>July 2020: Argentina regulatory label restricted to Type 1 & 2 SMA. Reimbursement for Type 1, 2 and 3a (already on treatment). Restriction for new Type 3a & Type 4. Negotiations ongoing.

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## SPINRAZA – Europe MAP of Reimbursement Status

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