

CONTRACT VARIATION AGREEMENT No.4

Contract/Variation Reference: NHS England, Biogen, Spinal Muscular Atrophy UK, TreatSMA, Muscular Dystrophy UK, SMA REACH UK and NICE entered into a Managed Access Agreement dated 03 July 2019, as varied, relating to the agreed terms and conditions according to which patients will be entitled to access the drug called nusinersen (Spinraza®) for treatment for 5q Spinal Muscular Atrophy (SMA) NICE TA588 (the “**MAA**”).

Contract documentation and documents relied upon	
MAA	Signed: 03 July 2019
Contract Variation 1	Signed: 18 May 2021
Contract Variation 2	Signed: 12 January 2022
Contract Variation 3	Signed: 28 November 2022
Relevant guidance (“Guidance”)	
Nusinersen for treating spinal muscular atrophy Technology appraisal guidance (TA588)	24 July 2019

Date of this Variation Agreement (Variation Agreement No.4 Effective Date):
20 MARCH 2025

This variation agreement relates to the variation of the MAA as set out below (the “Variation Agreement No.4”).

Capitalised words and phrases in this Variation Agreement No.4 have the meanings given to them in the MAA.

1. In consideration of their respective obligations under the MAA (as varied by this Variation Agreement No.4) the Parties have agreed to the following variation to the MAA:

1.1. Clause 3.1 will be deleted and replaced with the following:

3.1. This MAA shall take effect on 3rd July 2019 it will remain in force until the earlier of: (i) publication of a NICE reappraisal of nusinersen; or (ii) the expiry or termination of the MAA. Data collection will be in place for a minimum of three (3) years. For the avoidance of doubt, this MAA shall expire automatically on 30 September 2026 if it has not expired earlier as a result of the publication of the NICE reappraisal of nusinersen. NICE will reissue guidance to the NHS in England based on a review of the data by the end of the sixth year of this MAA. For the purposes of

this clause, "Guidance" means the guidance published by the National Institute for Health and Care Excellence in 2019 in relation to the use of nusinersen ID1069.

2. All other definitions terms and conditions contained in the MAA shall continue to apply in full force and effect.
3. The variations set out in this Variation Agreement No.4 take effect on the Variation Agreement No.4 Effective Date

IN WITNESS OF WHICH the Parties have signed this Variation Agreement No.4 on the date(s) shown below

<p>NHS England</p> <p>Ed Waller</p>	<p>..... Signature</p> <p>Deputy Chief Finance Officer NHS England</p> <p>..... Date</p>
<p>Biogen</p> <p>Jonathan Randell</p>	<p>..... Signature</p> <p>Head of Value & Access, UK & Ireland</p> <p>..... Date</p>
<p>Clinical Lead (SMA REACH UK)</p> <p>..... Name</p>	<p>..... Signature</p> <p>..... Title</p> <p>..... Date</p>
<p>Patient Organisation: Spinal Muscular Atrophy UK</p> <p>..... Name</p>	<p>..... Signature</p> <p>..... Title</p> <p>.....</p>

	Date
Patient Organisation: TreatSMA Name Signature Title Date
Patient Organisation: Muscular Dystrophy UK Name Signature Title Date
NICE Name Signature Title Date