Information statement regarding the impact of COVID-19 (coronavirus) on the nusinersen (Spinraza) Managed Access Agreement

NICE and NHS England and NHS Improvement have taken advice from clinical experts and consulted with patient advisory groups (Treat SMA, MDUK and SMA UK) to review the potential impact of COVID-19 on the delivery of the Managed Access Agreement (MAA) for nusinersen (Spinraza) for treating Spinal Muscular Atrophy (SMA) [NICE TA588]. This statement sets out considerations for patients (and/or their carers) who are already receiving treatment and those patients (and/or their carers) who have not yet started treatment. We have considered the unprecedented demand on the NHS in the coming months and that some patients may want to self-isolate or have been advised to shield.

While we would like to provide general information about likely access to treatment and suggested adjustments to clinical monitoring, some hospitals may have to take additional local decisions to further prioritise resources to tackle COVID-19. For questions about your individual circumstances and to understand what is available at your usual treatment centre, please contact the team who manage your treatment.

For existing managed access patients

1. Patients who are already receiving treatment as part of the MAA

1.1 Where safe and appropriate to do so nusinersen will continue to be delivered in hospital (including loading doses). However, patients attending face-to-face appointments are advised to follow the UK Government advice on social distancing and shielding where applicable.

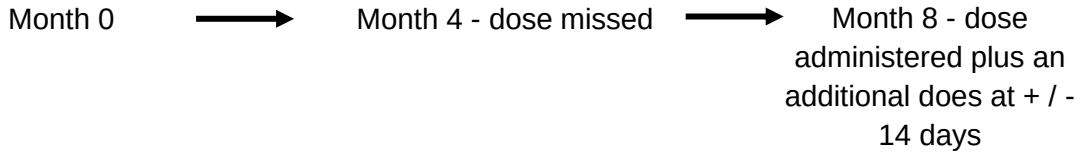
1.2 In consultation with their treating clinician, the patient and their family should assess whether the benefits of treatment with nusinersen outweigh the risks of attending a treatment centre to receive treatment and take part in ongoing managed access assessments (also see section 2 below).

1.3 It is recognised that during this period there may be circumstances where a treatment dose is missed or delayed. The advice outlined in 1.3.1 and 1.3.2 has been developed by clinical advisors with the aim of maintaining a steady concentration of the drug in the Cerebral Spinal Fluid and to ensure that during these extenuating circumstances patients on treatment are not disadvantaged by missed or delayed nusinersen doses.

1.3.1 In the case of a delayed dose, these clinical advisors recommend that nusinersen be administered as soon as possible within 1-2 months of the scheduled treatment date, and that subsequent doses are maintained at 4-monthly intervals, e.g.

Month 0 → Month 4 - dose delayed → Month 5-6 - dose administered → Month 8 - dose administered

1.3.2 In the case of missed dose, these clinical advisors recommend that nusinersen be administered at the next 4-monthly interval followed by an additional dose at + / - 14 days, e.g.



1.4 For patients who do not receive their scheduled treatments because they have self-isolated or have been advised to shield, NICE and NHS England and NHS Improvement are reviewing what this will mean for restarting nusinersen within the MAA. We will continue to review the situation for these patients and provide an update as soon as we are able.

2. Ongoing monitoring of existing managed access patients

2.1 If it is not possible for patients to attend hospital for managed access monitoring, it is recommended that assessments be completed via video consultation (where feasible and appropriate) with highest priority placed on completion of the following motor function assessments:

- HINE
- WHO MOTOR SCALE
- Fracture record
- Ventilation record
- Respiratory events (e.g. Infections)

2.2 Clinical teams must record when assessments have been conducted via video or telephone consultation within data uploads to SMA REACH UK.

2.3 If patients are unable to complete ongoing assessments as required by the MAA (e.g. because it is unsafe, or circumstances do not allow), these should be deferred until they can be undertaken safely, under valid, standardised conditions (unless clinically urgent). With these measures we aim to ensure that no patient will be disadvantaged if they are unable to complete monitoring assessments as a direct result of COVID-19.

2.4 Spinal posture should continue to be assessed when patients attend hospital for nusinersen treatment.

For new patients starting treatment under the MAA

3. Adjustments to baseline assessments and treatment initiation

3.1 In line with the NHS England and NHS Improvement statement describing access to treatment, priority will be given to: patients who have Type 1 SMA, patients who have Type 2 SMA diagnosed in the previous three months; and all eligible patients (in line with the managed access entry criteria) in whom there has been a rapid deterioration (in the preceding month).

3.2 In consultation with their treating clinician, the patient and their family should assess whether the benefits of treatment with nusinersen outweigh the risks of attending a treatment centre to receive treatment and take part in ongoing managed access assessments.

3.3 The NHS Genomic Medicine Services will prioritise rapid genetic testing which will inform clinical treatment or decision making. Genetic test results for SMA may be disrupted during this period. Clinical teams, via the genetic testing labs, will be able to provide their patients with the most up to date information concerning genetic testing.

3.4 Changes to the dosing schedule during the loading phase are not advised.

3.5 If in consultation with the patient and their family, a clinical decision is made to start a new patient on treatment within the MAA, completion of the following motor baseline tests should be a prioritised:

- RHS
- WHO MOTOR SCALE
- RULM
- HINE
- CHOP-INTEND
- summary of contractures

If any of these assessments have been recorded in the 3 months prior to treatment initiation, these results can be used as a baseline if a new measure cannot be collected.

3.6 Patients in other groups not listed in 3.1 who already have appointments booked to start treatment are likely to have to wait to start treatment.

3.7 It is recognised that some treatment centres may need to defer treatment initiation during this period because of the limited availability of clinical staff and patients being unable to safely attend hospital.

3.8 For patients who have not yet been assessed prior to starting treatment, this may mean that arrangements to book these assessments could be deferred. Treatment centres have received this patient information and processes for contacting adult patients will resume once the current restrictions associated with the COVID-19 pandemic are lifted.

Patients and their families should contact their clinical team if they have any concerns about their treatment while these measures are in place.

We will regularly review this information and share updates as these become available.