

## NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

**1. Name of the proposal (policy, proposition, programme, proposal or initiative):**

Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people 2 years and over

**2. Brief summary of the proposal in a few sentences**

Cystinosis is a rare inherited disease caused by a genetic metabolic disorder where the build-up of a natural chemical called cystine causes damaging crystals to form in areas of the body including the eye, the kidneys and in the muscles. There are 3 different types of cystinosis: nephropathic infantile cystinosis typically present under the age of 2 years; nephropathic juvenile cystinosis usually presenting in people older than 2 years; and non-nephropathic or ocular cystinosis mainly presenting in some teenagers and later in life.

All people with cystinosis have cystine crystals in their corneas. If left untreated the cystine crystals can cause symptoms such as light sensitivity, involuntary closure of the eye, eye pain or diseases of the eye surface. More severe complications such as reduced visual contrast sensitivity (the ability to distinguish between light versus dark; affected especially in situations of low light, fog or glare) can develop as the disease progresses. Complications from poorly managed corneal cystine crystals in older people can lead to permanent visual impairment or blindness.



**3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised**

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A** if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.

| Protected characteristic groups  | Summary explanation of the main potential positive or adverse impact of your proposal  | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact   |
|--|--|--|
| <b>Age:</b> older people; middle years; early years; children and young people.                              | All ages from 2 years and over are affected by this condition so will benefit from the policy.   | The policy considered the evidence in patients the age two years and over as this is the licensed use for mercaptamine. It was noted a randomised control trial is underway in patients under the age of 2 years which will add to the published evidence in due course. |
| <b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions. | The policy may reduce visual impairment due to the effects of cystinosis and is a long-term condition so would potentially benefit any patient with the cystinosis related eye damage. | Centres will be commissioned to support patients with cystinosis and through that mechanism will be able to support access to treatments for patients who have this or other protected characteristics.  |
| <b>Gender Reassignment and/or people who identify as Transgender</b>   | N/A  |  |
| <b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.                           | N/A  |  |
| <b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.                 | N/A  |  |

| Protected characteristic groups   | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|---|---|--|
| <b>Race and ethnicity</b> <sup>1</sup>  | N/A   |  |
| <b>Religion and belief:</b> people with different religions/faiths or beliefs, or none. | N/A   |  |
| <b>Sex:</b> men; women  | N/A   |  |
| <b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.                        | N/A   |  |

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<sup>1</sup> Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travellers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

#### 4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

| Groups who face health inequalities <sup>2</sup>  | Summary explanation of the main potential positive or adverse impact of your proposal   | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact  |
|---|---|---|
| <b>Looked after children and young people</b>   | The new treatment would be easier for older children to use and guardians to oversee as it requires less frequent dosing.   | Centres will be commissioned to support patients with cystinosis and through that mechanism will be able to support access for patients who may face health inequalities. |
| <b>Carers of patients:</b> unpaid, family members.  | The new treatment which is reported as less onerous for carers to give as it requires less frequent dispensing compared to the current treatment which is meant to be used over a 24 hour period. |   |
| <b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&Bs. | The current treatment requires very specific storage parameters. The new product also has some specific storage requirements although less stringent so easier to store.                          |   |
| <b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.      | Proposed treatment is easier to use and oversee which can be an issue where there is turnover of staff support or likely transfer to different locations.   |   |

<sup>2</sup> Please note many groups who share protected characteristics have also been identified as facing health inequalities.

| Groups who face health inequalities <sup>2</sup>  | Summary explanation of the main potential positive or adverse impact of your proposal                        | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|---|--|--|
| <b>People with addictions and/or substance misuse issues</b>  | Proposed treatment is easier to use.   |  |
| <b>People or families on a low income</b>   | Not applicable.  |  |
| <b>People with poor literacy or health</b><br><b>Literacy:</b> (e.g. poor understanding of health services poor language skills). | Proposed treatment is easier to use where understanding complex written instructions may have been an issue. |  |
| <b>People living in deprived areas</b>  | Proposed treatment is easier to use.   |  |
| <b>People living in remote, rural and island locations</b>  | Not applicable.  |  |
| <b>Refugees, asylum seekers or those experiencing modern slavery</b>  | Proposed treatment is easier to use where language barriers may exist.                                       |  |
| <b>Other groups experiencing health inequalities (please describe)</b>  | Not applicable.  |  |

## 5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

|              |           |                    |
|--------------|-----------|--------------------|
| <b>Yes X</b> | <b>No</b> | <b>Do Not Know</b> |
|--------------|-----------|--------------------|

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

| <b>Name of engagement and consultative activities undertaken</b> |                               | <b>Summary note of the engagement or consultative activity undertaken</b>  | <b>Month/Year</b> |
|--|-------------------------------|--|-------------------|
| <b>1</b>   | <b>Stakeholder engagement</b> | Relevant Clinical Reference Groups (CRG): Renal, Specialised Ear and Ophthalmology CRGs engaged as well as professional bodies and a patient organisation. | April 2019        |
| <b>2</b>   | <b>Public Consultation</b>    | Posted on website and contacted groups above. Responses received included those from clinicians from a national charity and patients.                      | Sept 2019         |
| <b>3</b>   | <b>Stakeholder engagement</b> | Relevant CRGS: Renal, Specialised Ear and Ophthalmology Services CRGs engaged as well as professional bodies and a patient organisation.                   | April 2020        |

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

| <b>Evidence Type</b>      | <b>Key sources of available evidence</b>  | <b>Key gaps in evidence</b> |
|---------------------------|---|-----------------------------|
| <b>Published evidence</b> | An evidence review was undertaken of the published evidence in line with NHS England specialised commissioning methods for policy |                             |

| Evidence Type  | Key sources of available evidence   | Key gaps in evidence   |
|--|---|--|
|  | development using the NICE Clinical Support Programme.  |  |
| <b>Consultation and involvement findings</b>   | Supportive of the policy and did not identify equalities issues other than access in under 2 years old. |  |
| <b>Research</b>  | Described in the independent evidence review.   | Use in patients under 2 years old is part of an open Research study. |
| <b>Participant or expert knowledge</b><br>For example, expertise within the team or expertise drawn on external to your team | Policy Working Group included experts in the field as well as patient representatives.                  |  |

**7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty?** Please add an x to the relevant box below.

|  | Tackling discrimination | Advancing equality of opportunity | Fostering good relations |
|--|-------------------------|-----------------------------------|--------------------------|
| The proposal will support?                   |                         | X                                 | X                        |
| The proposal may support?                    | X                       |                                   |                          |
| Uncertain whether the proposal will support? |                         |                                   |                          |

**8. Is your assessment that your proposal will support reducing health inequalities faced by patients?** Please add an x to the relevant box below.

|   | Reducing inequalities in access to health care | Reducing inequalities in health outcomes |
|---|--|--|
| The proposal will support?              | X  | X  |
| The proposal may support?               |  |  |
| Uncertain if the proposal will support? |  |  |

**9. Outstanding key issues/questions that may require further consultation, research or additional evidence.** Please list your top 3 in order of priority or state N/A

| Key issue or question to be answered  | Type of consultation, research or other evidence that would address the issue and/or answer the question                                   |
|---|--|
| 1 The very small cohort of patients with this condition means the evidence base is limited. | If approved, data will be collected on a National Registry (RaDaR) and the outcomes would be available to support future policy decisions. |
| 2   |  |
| 3   |  |

**10. Summary assessment of this EHIA findings**

The findings of this EHIA are that this policy will contribute to reducing health inequalities as it will improve access to a treatment that is beneficial to people with a very rare condition that would otherwise cause sight loss.

Advice from centres with a service is that groups of patients who may face health inequalities can be supported so they have equality of access.



## 11. Contact details re this EHIA

|                                     |                                     |
|-------------------------------------|-------------------------------------|
| Team/Unit name:                     | Internal Medicine Programme of Care |
| Division name:                      | Specialised Commissioning           |
| Directorate name:                   | Finance, Performance and Planning   |
| Date EHIA agreed:                   | 15 June 2020                        |
| Date EHIA published if appropriate: | July 2021                           |