

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

1. **Name of the proposal (policy, proposition, programme, proposal or initiative)**¹: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged older than 2 years

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 such as the kidneys, most of the tissues of the eye, 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 (involving only crystals in the cornea of the eyes and 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.

¹ Proposal: We use the term proposal in the remainder of this document to cover the terms initiative, policy, proposition, proposal or programme.

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

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
Age: older people; middle years; early years; children and young people.	All ages but primarily above the age of 2 years are affected by this condition	The proposal considered the evidence in patients over the age of two years 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.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	The proposal may reduce visual impairment due to long term effects of cystinosis. Cystinosis is a long-term condition so would potentially benefit any patient with the eye related condition.	Clinical criteria reflect the evidence on effectiveness
Gender Reassignment and/or people who identify as Transgender	As above	
Marriage & Civil Partnership: people married or in a civil partnership.	As above	
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	As above	
Race and ethnicity²	As above	

² 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 Travelers, migrants etc.. who experience inequalities so includes addressing the needs of

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
Religion and belief: people with different religions/faiths or beliefs, or none.	Cystinosis is a long-term condition so would potentially benefit any patient with the eye related condition.	
Sex: men; women	As above	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	As above	

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

Groups who face health inequalities ³	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
Looked after children and young people	The new treatment would be easier for older children to use and guardians to oversee	Not Applicable
Carers of patients: unpaid, family members.	The new treatment which is reported as less onerous for carers to give as it requires less frequent dispensing.	

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.

³ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ³	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
Homeless people. 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.	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Proposed treatment is easier to use	
People with addictions and/or substance misuse issues	Proposed treatment is easier to use	
People or families on a low income	Proposed treatment is easier to use	
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	As above	
People living in deprived areas	As above	
People living in remote, rural and island locations	As above	
Refugees, asylum seekers or those experiencing modern slavery	As above	
Other groups experiencing health inequalities (please describe)	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.

Yes: x	No	Do Not Know
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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.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	Stakeholder engagement	Relevant CRGs: Renal, Specialised Ears and Eye CRGs engaged as well as professional bodies and a patient organisation.	April 2019
2	Public Consultation	Posted on website and contacted groups above. Responses received included those from clinicians from a national charity and patients.	Sept 2019
3			

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

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An evidence review was undertaken in line with NHSE specialised commissioning methods for policy development	Use in patients under 2 years old.
Consultation and involvement findings	Supportive of the proposal and did not identify equalities issues other access in under 2year olds	
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team		

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?			
The proposal may support?			
Uncertain whether the proposal will support?	X	X	X

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 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

In summary the proposal has the potential to improve access to healthcare and improve outcomes in this small cohort of patients and as the new product is easier to administer reduces burden on carers and patients.

11. Contact details re this EHIA

Team/Unit name:	Sarah Watson
Division name:	Highly Specialised Team
Directorate name:	Specialised Commissioning
Date EHIA agreed:	
Date EHIA published if appropriate:	