Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Policy: CP100
Elosulfase alfa (Vimizim) for the Management of MPS Type IVA

Document Author:	Assistant Director of Evidence, Evaluation and Effectiveness
Executive Lead:	Acting Medical Director
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Policy Statement

Background	Mucopolysaccharidosis type IVA (Morquio Syndrome) is a very rare inherited lysosomal storage disease. Patients appear normal at birth but, in the early years of life, significant morbidities and multi-systemic clinical impairments develop. This result in increasing pain, fatigue, diminished functional capacity, decreased endurance and impaired quality of life as a patient gets older, leading to increasing dependence on a wheelchair. Patients with MPS IVA usually have early mortality by the age of 30 years. There is currently no approved treatment for MPS IVA other than palliative or supportive care, which does not treat the underlying cause of the disease so it continues to progress. Enzyme replacement therapy is an entirely new treatment option and elosulfase alfa is the first treatment licensed to treat MPS IVA. Elosulfase alfa is the first and only treatment that has the potential to alter the course of the disease.
Summary of Access Criteria	• All patients must have a confirmed diagnosis of MPS IVA as per the diagnosis criteria recommended in Wood et al. (2012): • All patients must have confirmed enzymatic test, elevated urinary Keratan Sulfate and mutation analysis; • In addition patients aged 5 and over can only start once a full set of baseline assessments has been obtained, and they have signed the Managed Access Patient Agreement.
Responsibilities	Referring physicians should: • Inform the patient that this treatment is not funded outside the criteria in this policy and • Refer via the agreed pathway Clinician considering treatment should: • Discuss all the alternative treatment with the patient; • Advise the patient of any side effects and risks of the potential treatment; • Inform the patient that treatment is not funded outside of the criteria in the policy

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1. AIM

1.1 Introduction

The objectives of the document as a whole are to embody a set of auditable measures that will be used to assess the compliance of this "Managed Access Agreement" in England and to ensure that all relevant stakeholders have a common understanding that such measures have the agreement and backing of all involved and will therefore be enforced. This common perspective is aimed to support concerns raised by the NICE Committee in their evaluation; communicated in the second consultation document, and final guidance.

This policy has been based on the Managed Access Agreement has been drawn up by NHS England, BioMarin Europe Limited (the "Market Authorisation Holder" or "MAH"), and patient community experts and clinicians.

For the avoidance of doubt, the parties intend this Managed Access Agreement to be legally enforceable between them.

1.2 Relationship with other Policies and Service Specifications

This document should be read in conjunction with the following documents:

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR).

2. SCOPE

The NICE evaluation has developed positive recommendations conditional on a Managed Access Agreement being developed and agreed by key stakeholders in the use of Elosulfase alfa in the NHS in Wales.

2.1 Definition

Adolescent Paediatric Pain Tool (APPT) is a multidimensional pain assessment tool designed to assess pain location (body outline diagram), intensity (word graphic rating scale) and quality (list of pain descriptors) in hospitalized children eight to 17 years of age.

Six-minute walk test (6MWT) measures the distance an individual is able to walk over a total of six minutes on a hard, flat surface. The goal is for the individual to walk as far as possible in six minutes. The individual is allowed to self-pace and rest as needed as they traverse back and forth along a marked walkway.

European Quality of Life 5 Dimensions (EQ5D) is a widely-used survey instrument for measuring economic preferences for health states. It is one of several such instruments that can be used to determine the quality-adjusted life years associated with a health state. The name is derived from the survey methodology, which measures quality of life in five dimensions and was developed by the EuroQol Research foundation.

Forced vital capacity (FVC) is the total amount of air exhaled during the FEV test. Forced expiratory volume and forced vital capacity are lung function tests that are measured during spirometry.

Forced Expiratory Volume (FEV1) in the first second. The volume of air that can be forced out in one second after taking a deep breath, an important measure of pulmonary function.

Keratan sulphate (KS), also called keratosulfate, is any of several sulfated glycosaminoglycans that have been found especially in the cornea, cartilage, and bone.

Mucopolysaccharidosis type IVA (MPS IVA) (Morquio Syndrome) is a very rare inherited lysosomal storage disease. Patients appear normal at birth but, in the early years of life, significant morbidities and multi-systemic clinical impairments develop. This result in increasing pain, fatigue, diminished functional capacity, decreased endurance and impaired quality of life as a patient gets older, leading to increasing dependence on a wheelchair. Patients with MPS IVA usually have early mortality by the age of 30 years.

2.2 Codes

ICD-10 Codes

Code Category	Code	Description
	E76.2	Other mucopolysaccharidoses

3. ACCESS CRITERIA

3.1 Criteria for Treatment

To receive treatment, patients, parents or guardians must sign up to the 'Managed Access Patient Agreement' included in Appendix A to this Managed Access Agreement, and NHS England and the MAH will use reasonable endeavours to ensure that this requirement and the other eligibility criteria specified in this document are reflected in their contracts with those clinical services providers who purchase Elosulfase alfa from the MAH.

Patients are required to attend their clinics three times a year for assessment.

Children under the age of 5 may not be able to complete all baseline and subsequent assessments. Clinically relevant assessments should be attempted at least once every 12 months until the age of 5, at which point all assessments become compulsory. There may also be other patients i.e. those with cognitive impairments, who are not able to complete a full set of tests at appointed visits. In such cases, clinicians will be expected to make all possible efforts to gather as much of the required data as possible.

Elosulfase alfa must not be started if any of the following apply:

- The patient is diagnosed with an additional progressive life limiting condition where treatment would not provide long term benefit e.g. cancer or multiple sclerosis; or
- The patient has a lung capacity (FVC) of less than 0.3 litres and require ventilator assistance; or
- The patient is unwilling to comply with the associated monitoring criteria:
- All patients are required to attend their clinics three times a year for assessment.
- All patients will sign up to the 'Managed Access Patient Agreement' as seen in the appendix to this Managed Access Agreement.

3.2 Inclusion criteria

All of the following are required before treatment is started:

- All patients must have a confirmed diagnosis of MPSIVA as per the diagnosis criteria recommended in Wood et al. (2012):
- All patients must have confirmed enzymatic test, elevated urinary Keratan Sulfate and mutation analysis;
- In addition patients aged 5 and over can only start once a full set of baseline assessments has been obtained, and they have signed the Managed Access Patient Agreement.

3.3 Exclusion criteria

Any patient not meeting the required pre-testing and diagnostic criteria to confirm a positive diagnosis of MPS IV will not be considered appropriate for initiation of treatment.

3.4 Monitoring and Treatment Continuation

3.4.1 Stopping Criteria

Patients will cease enzyme therapy if any of the following apply:

- The Patient is non-compliant with assessments for continued therapy (non-compliance is defined as fewer than three attendances for assessment in any 14 month period);
- The Patient fails to meet 4 of the 5 criteria as defined below under naïve responder or long term trial patient.
- The Patient is unable to tolerate infusions due to infusion related severe adverse events that cannot be resolved.

Patients who are taken off treatment will continue to be monitored for disease deterioration and supported with other clinical measures. These patients should continue to be assessed to allow gathering of important information.

3.4.2 Treatment of Naïve Responder (for patients who have never received treatment)

NHS Wales and the MAH will use reasonable endeavours to ensure that the requirements detailed in this section and in are reflected in their contracts with those clinical services providers who purchase elosulfase alfa from the MAH.

A responder following the first year of treatment for a treatment naïve patient will demonstrate at least four out of five of the following otherwise they will have to stop treatment with Enzyme Replacement Therapy (ERT):

1. Improvement of 6 minute walking test (6MWT) or 25ft Ambulation Test of at least 10% improvement over baseline, or stabilization after plateauing to a 10% improvement. Baseline will be a single 6MWT test performed according to American Thoracic Society guidelines and applied at a time the patient is in suitable condition that the test is not confounded by other health issues e.g. chest infection, cold etc. If a patient has had any minor surgery in the previous 3 months or major surgery in 6 months they will still take the test but it will repeated. 6MWT will not be performed within 2 hours of respiratory function

testing or any endurance assessments. The following will also be recorded in all patients over the age of 5 at both start and end of 6MWT- heart rate, oxygen saturation, respiratory rate and Borg scale. These values are required to support the validity and effort of 6MWT but only the total distance will be used for determining the stop point.

2. Improvement in FVC or FEV-1 measured with standard spirometry of 5% over baseline in the first year or stabilization after the first year. Both are standard measures and the best values from 3 attempts will be used to determine the stop criterion but improvement in either FVC or FEV-1 will be sufficient as both measure different aspects of respiratory disease. Pulmonary Function Testing should not be done within 2 hours of endurance testing and if the patient is on any inhaler this should be used as appropriate. The other tests should be delayed if the patient is unwell (a respiratory rate higher than normal or a temperature greater than 38 degrees centigrade).

3. Stabilization defined as no adverse change in the numerical value in two of the following three measures:
   a) The score of Quality of Life as measured by utility derived from EQ5D-5L scores OR caregiver burden as measured by MPS HAQ Caregiver Domain,
   b) Beck depression score and
   c) Adolescent Paediatric Pain Tool (APPT) or Brief Pain Inventory (BPI) pain score depending on age.

4. Reduction from baseline in uKSs of 20%

5. A less than 10% reduction in ejection fraction from baseline as measured by echocardiogram.

3.4.3 Patients who are currently on treatment

Patients who are 'currently on treatment' are defined as:

i) clinical trial patients;
ii) patients otherwise already receiving treatment and have become a commissioning responsibility of NHS Wales; and
iii) patients who started on treatment during the term of the Managed Access Agreement and have been receiving treatment for over 12 months. To remain on treatment patients must fulfil four out of five of the response criteria:

   1. 6MWT and 25ft Ambulation Test remains 5% above baseline value at start of treatment with same limitations as for treatment naïve patients;

2. FVC and FEV-1 remain 2% above baseline at start of treatment;

3. uKS levels remain reduced at least 20% from baseline value;

4. Stabilization is defined as no adverse change in the numerical value in two of the following three measures:-
   a) the score of Quality of Life as measured by utility derived from EQ5D-5L scores OR caregiver burden as measured by MPS HAQ Caregiver Domain;
   b) Beck depression score; and
   c) Adolescent Paediatric Pain Tool (APPT) or Brief Pain Inventory (BPI) pain score depending on age.

5. Decline in ejection fraction of less than 10% from baseline as measured by annual echocardiogram

   Patients will also cease to qualify for treatment if they have a lung function (FVC) of less than 0.3L and require ventilator assistance.

   Patients will cease to qualify for treatment if they miss more than 3 infusions in any 14 month period, excluding medical reasons for missing dosages.

3.5 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional grounds for treatment, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the *All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR)*.

If the patient wishes to be referred to a provider out of the agreed pathway and the referring clinician believes that there are exceptional grounds for treatment at an alternative provider, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the *All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR)*.

Guidance on the IPFR process is available at www.whssc.wales.nhs.uk

3.6 Responsibilities

Referrers should:

- Inform the patient that this treatment is not funded outside the criteria in this policy; and
- Refer via the agreed pathway. The agreed pathway includes named physicians, identified by WHSSC, for the purposes of ensuring consistency to this policy and appropriate engagement with the Nationally Designated Centre for advice, opinion and potential genetic testing where considered clinically appropriate. The names physicians are (as of 01.03.16):
    - Dr Duncan Cole, Cardiff and Vale UHB;
    - Dr Graham Shortland, Cardiff and Vale UHB
    - Medical Director, WHSSC;

- Any physician considering management of a patient (paediatric or adult) with confirmed or suspected MPS Type IV is requested to contact the named physicians above before initiating therapy.

Clinicians considering treatment should:

- Discuss all the alternative treatment with the patient;
- Advise the patient of any side effect and risks of the potential treatment;
- Inform the patient that treatment is not routinely funded outside of the criteria in the policy; and
- Confirm that there is contractual agreement with WHSSC for the treatment.

4. QUALITY

Data will be collected from all patients who start during the term of this Managed Access Agreement.

The MAH has been asked by the European Medicines Agency to enrol all patients into a 12 year disease registry to continue to gather information about this ultra-rare condition. The purposes of this registry are to:

i) characterise and describe the MPS IVA population as a whole, including the heterogeneity, progression and
ii) natural history of MPS IVA;
iii) to evaluate the long-term effectiveness and safety of Vimizim (elosulfase alfa):
iv) to help the MPS IVA medical community with the development of recommendations for monitoring subjects and reports on subject outcomes to optimise subject care;
v) to collect data on other treatment paradigms, evaluate the prevalence of their use and their effectiveness;

vi) to characterise the effects of 5 years of elosulfase alfa treatment in subjects under 5 years of age; and
vii) to collect additional data to:
    a) help broaden knowledge of identified and potential risks of elosulfase alfa, as well as increase the size of the safety database and possibly provide new information on use in identified subgroups (pregnancy, hepatic and renal impairment, cardiac impairment); and
    b) to help evaluate long-term effectiveness of elosulfase alfa. The MAH will provide access for NHS England to this database to assist it in assessing the clinical impact of elosulfase alfa on this disease.

4.1 Clinical Outcome and Quality Measures

4.1.1 Outline of Assessment to be made

Assessments	Baseline	Month 4	Month 8	Month 12	Measures	Response
6MWT or 25ft ambulation	x	X		X	Time and Metres /Feet completed	RR, HR, Borg scale and saturations before and after
FVC	x		X		Total value in ML	Best value of 3 attempts
FEV1	x				Total value in ML	Best value of 3 attempts
uKS	x	x		x	% change from baseline Corrected for creatinine	Single lab analysis
EQ5 DL	x			x	Numerical value	Administered by MPS Society
MPS HAQ caregiver	x			x	Numerical value	Administered by MPS Society
Beck score	x		X		Numerical value	Administered by MPS Society
BPI/APTT	x	X	X	x	Random Day before and after infusion	Administered by MPS Society
Cardiac echo	x			x	Ejection fraction as a percentage	Record operator and single operator ideal
Missed infusions		X	X	x	Numerical value Missed Medical reason missed	
Weight	X	X	X	X	Numerical value	
Antibody titres	x		X	x		

4.2 Quality of Life

1. The score of Quality of Life as measured by utility derived from EQ5D-5L scores OR caregiver burden as measured by MPS HAQ Caregiver Domain;
2. Beck depression score and;
3. Adolescent Paediatric Pain Tool (APPT) or Brief Pain Inventory (BPI) pain score depending on age.

4.3 Putting Things Right: Raising a Concern

4.3.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5. EQUALITY IMPACT AND ASSESSMENT

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (welsh).

This policy has been subjected to an Equality Impact Screen.

Enzyme Replacement Therapy (ERT) Elosulfase alfa (Vimizim) for Mucopolysaccharidosis Type IVA Managed Access Patient

AGREEMENT

NICE have approved reimbursement of Elosulfase Alfa, licensed as Vimizim®, subject to the collection of auditable measures that will be used to assess the compliance of a Managed Access Agreement in England and to ensure that all relevant stakeholders have a common understanding that such measures have the agreement and backing of all involved and will therefore be enforced.

The NICE Managed Access Agreement includes:

- A protocol that sets out the clinical criteria for starting and stopping treatment with elosulfase alfa.
- Assurance from BioMarin Europe Limited (the "Marketing Authorisation Holder" or "MAH") that it will collaborate with the MPS Society and NHS England and NHS Wales to collect your anonymized data and continue to support the MPS IVA registry. The data will be used by NICE to inform a review no more than 5 years after publication of the guidance.
- Agreement between the licensed owner of Vimizim and NHS England and NHS Wales to set the total costs of elosulfase alfa during data collection, which is in addition to the discount in the patient access scheme, in order to manage financial risk.

1. Patient Eligibility

The clinical community and MPS Society feel it is appropriate and right that all patients have access to elosulfase alfa (Vimizim) in Wales. The only exception from starting elosulfase alfa in confirmed cases of MPSIVA will be where:

- The patient is diagnosed with an additional progressive life limiting condition where treatment would not provide long term benefit e.g.; cancer or multiple sclerosis
- Patient / Parent are unwilling to comply with the associated monitoring criteria:
- The patient has a lung capacity (FVC) of less than 0.3 litres and require ventilator assistance; or
- The patient is unwilling to comply with the associated monitoring criteria:

All patients are required to attend their clinics three times a year for assessment within a 14 month period.

- All patients will sign up to this 'Managed Access Patient Agreement'.

2. Access to treatment and data collection

The criteria in this Managed Access Patient Agreement have been used because they formed part of the phase III clinical trial and have been the basis on which the European licence for Vimizim was granted.

A distinction has been made between those patients who are naïve to treatment and the cohort of patients who have been on treatment in Wales or those who will be applicable to have commissioning from NHS Wales.

Allowance is also made for children under the age of 5 that may not be able to do some assessments but they should be attempted at least once every 12 months until the age of 5 at which point they become compulsory.

It is expected that all patients, who are appropriate for homecare delivery, will receive infusions via home care delivery. This is expected to follow the clinically appropriate initial hospital infusions at the commencement of treatment.

3. Start Criteria

- Patients must have a confirmed diagnosis of MPSIVA as per the diagnosis criteria recommended in Wood et al. (2012)
- Confirmed enzymatic test, elevated uKS and mutation analysis for all patients
- Patients can only start once a full set of baseline criteria has been obtained.
- Patients / Parents will be expected to attend their clinic three times a year for assessment within a 14 month period.
- Patients / Parents will be informed about the strict requirement for attendance as set out in this patient agreement document, an appendix to the Managed Access Agreement.
- In the event of the patient being unable to maintain the above criteria, the implementation of the stop criteria will be discussed with the Patient / Parent.

4. Stop Criteria

Patients will become ineligible for further treatment where:

- The patient is non-compliant with assessments for continued therapy where non-compliance is defined as fulfilling fewer than three attendances for assessment in any 14 month period.
- The patient fails to meet 4 of the 5 criteria as defined in Appendix B under naïve responder or long term trial patient.

- The patient is unable to tolerate infusions due to infusion related severe adverse events that cannot be resolved.
- Patients who are taken off treatment will continue to be monitored for disease deterioration and supported with other clinical measures. These patients should continue to be assessed to allow gathering of important information.

If you feel that you or your child will be able to comply with the above please fill in your details below and sign for reimbursed treatment to begin.

If you meet the start criteria for elosulfase alfa and choose to receive elosulfase alfa your clinician will be monitoring you or your child for demonstrable benefit, outlined in Appendix B attached.

The Managed Access Agreement (and therefore agreed funding for elosulfase alfa) expires 5 years after NICE's recommendations being published in 2016, or following a further review should this be sooner At year four a comprehensive review will look at the benefits of elosulfase alfa, collectively. Any funding beyond such 5-year term will be conditional on NHS Wales agreeing the terms of such funding with BioMarin, the manufacturer of elosulfase alfa. Accordingly, there are currently no arrangements to enable access to Elosulphase alpha to be available as part of standard NHS care following the expiry of the managed access agreement. Any continued access to Elosulphase alpha beyond this point will be subject to consideration by NICE and publication of further recommendations. If NICE does not recommend Elosulphase Alpha in its further review at that time patients will discontinue NHS treatment with Elosulphase Alpha.

You or the parents of the child must sign this Managed Access Patient Agreement as part of the start criteria for treatment.

Please note. By signing this document you are agreeing to the MPS Society performing the Quality of Life study required as part of this Managed Access Patient Agreement in addition to all collected data from your monitoring visits to hospital to be entered into the MPS IVA registry (MARS registry). This is a commercial registry and if you object to your data being collected into this database your treating clinician may be able to offer an alternative non-commercial registry. Although researchers hope the data collected will lead to better future patient outcomes, it is your right to opt out from the data collection and you will still be offered treatment. By agreeing to your information being entered into the registry you also explicitly consent to that information being used to fulfil the purposes of the registry.

The purposes of the registry are to: (i) characterise and describe the MPS IVA population as a whole, including the heterogeneity, progression and natural

history of MPS IVA; (ii) to evaluate the long-term effectiveness and safety of Vimizim (elosulfase alfa): (iii) to help the MPS IVA medical community with the development of recommendations for monitoring subjects and reports on subject outcomes to optimise subject care; (iv) to collect data on other treatment paradigms, evaluate the prevalence of their use and their effectiveness; (v) to characterise the effects of 5 years of elosulfase alfa treatment in subjects under 5 years of age; and (vi) to collect additional data to: (a) help broaden knowledge of identified and potential risks of elosulfase alfa, as well as increase the size of the safety database and possibly provide new information on use in identified subgroups (pregnancy, hepatic and renal impairment, cardiac impairment); and (b) to help evaluate long-term effectiveness of elosulfase alfa.

Data collected will be shared with NHS Wales, NHS England, NICE and the MAH and may be stored both inside and outside of the EU on static databases and portable devices (including being stored in the United States of America). Research papers and other scientific findings may be developed and published based on information provided in the registry and by signing below you understand and consent to your data being used for such scientific and academic purposes.

*Patient/Parent Name: _____
Signature: _____
Date: _____
Name of Clinician: _____
Signature of Clinician: _____
Date: _____