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

1. Name of the proposal (policy, proposition, programme, proposal or initiative)[1]: Lanreotide as a monotherapy for the treatment of symptomatic non-localised autosomal dominant polycystic liver disease (adults) [2422]

2. Brief summary of the proposal in a few sentences

Polycystic liver disease (PLD) is a rare genetic disease that exists in two forms, in isolation as autosomal dominant polycystic liver disease (ADPLD) or as part of autosomal dominant polycystic kidney disease (ADPKD). It is characterised by the formation of multiple cysts that cause progressive liver enlargement. Abnormal liver function and liver failure are rare in PLD. Most people with PLD have few to no symptoms and therefore do not require any treatment. However, for those otherwise defined as experiencing symptomatic PLD, symptoms can be broadly classified into two categories: mass effect resulting from the enlarged liver and those which are complications of the cysts (such as infection, torsion, rupture, and haemorrhage). Mass effect can result in symptoms including abdominal distention, early satiety, postprandial fullness, gastro-oesophageal reflux, malnutrition dyspnoea, hepatic venous-outflow obstruction (Budd-Chiari syndrome), inferior vena cava syndrome, portal-vein compression and bile-duct compression.

Injectable lanreotide as monotherapy is proposed as an alternative first-line treatment option for adult patients with symptomatic non-localised autosomal dominant PLD where individuals decline, are unsuitable for, or show incomplete response to aspiration sclerotherapy, fenestration, surgical resection or transplantation.

Though limited by a lack of a comprehensive established registry with national coverage, literature suggests that PLD has an estimate prevalence of 10 per 100,000 people, equating to around 5,000 in England. However, many people with PLD do not have significant symptoms and only around 5% would have the combination of both diffuse non-dominant cystic distribution and significant symptoms that would warrant lanreotide. This would estimate approximately 250 people would have the characteristics suggesting benefit from

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

lanreotide. Due to the action of oestrogen in the development of cysts, women are disproportionately affected by PLD by a ratio of 6 to 1, experiencing greater symptoms and more severe disease (Masyuk et al, 2017).

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
Age: older people; middle years; early years; children and young people.	Polycystic liver disease is rare in childhood and more common with age. Although many people with the condition do not have any symptoms, the age at which symptoms begin to occur can vary with individuals but is usually after 30 years old.	The clinical commissioning policy will ensure that lanreotide is available to all patients who meet the criteria outlined. Post-pubescent children can access under the Commissioning Medicines for Children Policy [LINK]. Pre-pubescent children are not covered by this policy given the unavailability of safety data in this age group and children not being included in the drug's marketing authorisation.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	People with symptoms of polycystic liver disease may consider themselves to have a disability and the condition is likely to affect daily living activities, especially those requiring bending and mobility.	The clinical commissioning policy should be delivered against the NHS Standard contract, which includes Service Conditions (SC)12 and SC13 which state that commissioned services are expected to support accessibility of services through delivery of services in appropriate estates which support access for individuals with disability related needs, such as the use of step free access, mobility aids and hearing loops. All NHS providers should ensure access to interpreter and communication guides at each appointment for

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
		patients requiring this support, and that recording processes are in place to capture patient communication needs in line with the NHS Accessible information standard.
Gender Reassignment and/or people who identify as Transgender	There is no published evidence to provide a credible estimate of the rate of polycystic liver disease in this population. However, transgender men who maintain oestrogen levels may still be physiologically at an increased risk of polycystic liver disease. Additionally transgender women are likely to take exogenous oestrogen as part of their feminising medicines. Presently, the exclusion criteria state the use of exogenous hormones should be considered regarding risk benefit by the MDT prior to initiating.	No specific mitigations are required. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation. With regards to the use of exogenous oestrogen, the multidisciplinary team should consider whether individual clinical circumstances would limit the ability of the patient to gain benefit over risk from lanreotide as stated in the policy.
Marriage & Civil Partnership: people married or in a civil partnership.	The clinical commissioning policy is not considered to have any positive or adverse impact on this protected characteristic group.	No specific mitigations are required. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Most patients with symptoms and with severe disease are women, and pre-menopausal women are at greatest risk. Because the cause of this difference is considered to be driven by female sex hormones, such as oestrogen, which	Lanreotide is only clinically appropriate in pregnancy if the benefits are considered to outweigh the potential harms. It is therefore unlikely, but possible, that pregnant people could be receiving lanreotide covered by this policy and, if

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
	contributes to the growth of liver cysts, people who have been pregnant are at greater risk of developing the disease sooner and experiencing more severe disease.	so, this policy will ensure that it is available, when clinically appropriate.
Race and ethnicity[2]	The clinical commissioning policy is not considered to have any positive or adverse impact on this protected characteristic group.	No specific mitigations are required. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.
Religion and belief: people with different religions/faiths or beliefs, or none.	The clinical commissioning policy is not considered to have any positive or adverse impact on this protected characteristic group.	No specific mitigations are required. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.
Sex: men; women	Males and females are affected by polycystic liver disease in equal numbers, but most patients with symptoms and with severe disease are women. The cause of this difference is considered to be driven by female sex hormones, such as oestrogen, contributing to the growth of liver cysts. Oral contraceptives and	The clinical commissioning policy will ensure that lanreotide is available to all patients for who meet the criteria outlined in the policy, irrespective of sex.

[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 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.

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
	oestrogen replacement therapy are also associated with more severe disease.	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	The clinical commissioning policy is not considered to have any positive or adverse impact on this protected characteristic group.	No specific mitigations are required. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

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[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	Not applicable. The patient population is highly unlikely to include children.	No specific mitigations are required. Post-pubescent children can access under the NHS England Commissioning Medicines for Children in Specialised Services Policy [LINK]. Pre-pubescent children are not covered by this policy given the unavailability of safety data in this age group and children not being included in the drug's marketing authorisation.
Carers of patients: unpaid, family members.	The clinical commissioning policy will have a mild positive impact on this group	The clinical commissioning policy has been developed with patient and public voice

[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
	of people who experience health inequalities.	representatives as part of the stakeholder engagement activity. Specialised Hepatobiliary & Pancreas services will continue to signpost patients and their carers/family members to support groups, Charities and other third sector organisations following diagnosis to ensure they are aware of the support available.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	There is no published evidence reporting that homeless people are at greater risk of polycystic liver disease. However, lanreotide can be self-administered provided they are educated in injecting and have access to a fridge as well as a safe sharps disposal. For those with no fixed abode, this may be difficult to achieve. People experiencing homelessness can find it challenging to access healthcare may therefore enter the treatment pathway when their disease has progressed. People experiencing homelessness may have poor health literacy and agency and face stigma and discrimination when trying to access health and care services and arrange follow-up appointments.	The clinical commissioning policy will ensure that lanreotide is available for all patients who meet the criteria outlined in the policy, irrespective of their housing status. Commissioned providers should ensure that their services are accessible and attractive to all patients and delivered in a manner that is free from judgement and welcoming to all. Commissioners should ensure services are available as close to patients as possible for ease of access, particularly where there is sufficient local demand. Information should be available to patients in a style and format that enables patients to understand and retain the content. All providers should have non-attendance policies that include flexibility for groups that may be disproportionately disadvantaged, such as those experiencing homelessness, where contacting patients consistently may be more challenging. All providers should use multiple forms of contacting

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
		patient by letter, phone call or via a referring agency where consent has been provided, agreed prior to discharging such individuals for non-attendance. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation. Where required, clinicians should consider an individual's living arrangements in order to decide whether administration at the clinic or at home would be appropriate.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	There is no published evidence reporting that people involved with the criminal justice system are at greater risk of polycystic liver disease. People involved in the criminal justice system may find it challenging to access healthcare if they experience stigma, discrimination and social exclusion and may therefore enter the treatment pathway when their disease has progressed. People involved in the criminal justice system may have poor literacy, health literacy and agency which may make accessing health and care services and arranging follow-up appointments difficult.	The clinical commissioning policy will ensure that lanreotide is available to all patients who meet the criteria outlined in the policy, irrespective of their offending status and history. Commissioned providers should ensure that their services are accessible and attractive to all patients and delivered in a manner that is free from judgement and welcoming to all. Information should be available to patients in a style and format that enables patients to understand and retain the content. Commissioners should ensure that there is continuity of care for people leaving prison and that patients are transferred to services as close to home as possible for ease of access so that they are retained in treatment.

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
		Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.
People with addictions and/or substance misuse issues	There is no published evidence reporting that people with addictions and/or substance misuse issues are at greater risk of polycystic liver disease. People with addictions or substance misuse issues can find it challenging to access healthcare and may therefore enter the treatment pathway when their disease has progressed. People experiencing addictions and substance misuse issues may have poor health literacy and agency and face stigma and discrimination when trying to access health and care services and arrange follow-up appointments.	The clinical commissioning policy will ensure lanreotide is available to all patients who meet the criteria outlined in the policy, irrespective of addiction or other substance misuse issues. Commissioned providers should ensure that their services are accessible and attractive to all patients and delivered in a manner that is free from judgement and welcoming to all. Information should be available to patients in a style and format that enables patients to understand and retain the content. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.
People or families on a low income	People or families on a low income may face challenges in arranging and attending appointments if they have competing priorities and/or inflexible working patterns without paid time off work to attend appointments. This may result in people or families on a low	The clinical commissioning policy will ensure lanreotide is available to all patients who meet the criteria outlined in the policy, irrespective of income. Services should be mindful of the need to arrange appointments flexibly and using a digital first approach where appropriate to minimize travel times and maximise convenience for patients.

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
	income entering the treatment pathway later, when their disease has progressed. Further, lanreotide can be self-administered provided they are educated in injecting and have access to a fridge as well as a safe sharps disposal. For those with no fixed abode, this may be difficult to achieve.	Where face to face appointments are essential, services should also consider if it is possible to arrange this so that the number of visits patients need to make can be minimized (e.g. investigations and consultations scheduled on the same day). This will make for more efficient treatment planning as well as having a positive environmental impact. Services should signpost to support services and information, as applicable, to support patient access. This includes information about relevant public transport links and access to support with cost of prescription medicines, including the NHS Prescription Prepayment Certificate. Patients and families may be directed to the Healthcare Travel Costs Scheme for support with costs for attending specialised centres, where eligible. Providers need to ensure eligible patients and carers are aware of the NHS Healthcare Travel Costs Scheme. Data collection and quality monitoring should include recording and monitoring of any disparities in access and outcomes on basis of deprivation decile to support engagement with ongoing

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
		national, regional and local work to address health inequalities across all NHS services. Where required, clinicians should consider an individual's living arrangements in order to decide whether administration at the clinic or at home would be appropriate.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	People with poor literacy or health literacy may find it challenging to access healthcare and may be less likely to seek help early in their disease progression. In addition, people with poor literacy or health literacy may face difficulties in arranging or attending follow-up appointments if they are unused to prioritising their health care needs.	The clinical commissioning policy will ensure lanreotide is available for all patients who meet the criteria outlined in the policy, irrespective of literacy or health literacy levels. Services should be mindful to communicate with patients in a style and format that maximises patients' ability to understand and retain the content.
People living in deprived areas	There is no published evidence to suggest that people living in deprived areas are at greater risk of polycystic liver disease. However, lanreotide can be self-administered provided they are educated in injecting and have access to a fridge as well as a safe sharps disposal. For those with no fixed abode, this may be difficult to achieve. Deprivation is not evenly distributed across England, with the South East being the least deprived Region (IMD 2019 score of 15.5) and the North East	The clinical commissioning policy ensures that lanreotide will be available to all patients who meet the criteria outlined in the policy, irrespective of the deprivation in the geographical area in which they live. Where face to face appointments are essential, services should consider if it is possible to arrange this so that the number of visits patients need to make can be minimized (e.g. investigations and consultations scheduled on the same day). This will make for more efficient treatment planning as well as having a positive environmental impact.

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
	being the most deprived Region (IMD 2019 score 28)[15].	Services should signpost to support services and information, as applicable, to support patient access. This includes information about relevant public transport links and access to support with cost of prescription medicines, including the NHS Prescription Prepayment Certificate. Data collection and quality monitoring should include recording and monitoring of any disparities in access and outcomes on basis of deprivation decile to support engagement with ongoing national, regional and local work to address health inequalities across all NHS services. Where required, clinicians should consider an individual's living arrangements in order to decide whether administration at the clinic or at home would be appropriate.
People living in remote, rural and island locations	People living in remote, rural and island locations may face challenges in arranging and attending appointments if they have to travel long distances to attend appointments. This may result in people living in remote, rural and island locations entering the treatment pathway later, when their disease has progressed	The clinical commissioning policy ensures that lanreotide is available to all patients who meet the criteria outlined in the policy, irrespective of the population density where they live. Services should be mindful of the need to arrange appointments flexibly and using a digital first approach where appropriate (and technology supports this) to minimize travel times and maximise convenience for patients.

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
		Where face to face appointments are essential, services should also consider if it is possible to arrange this so that the number of visits patients need to make can be minimized (e.g. investigations and consultations scheduled on the same day). This will make for more efficient treatment planning as well as having a positive environmental impact.
Refugees, asylum seekers or those experiencing modern slavery	Refugees and asylum seekers are legally entitled to free primary and secondary NHS care. However, refugees, asylum seekers and those experiencing modern slavery may face difficulties in accessing primary care if they have no recourse to public funds, are unable to prioritise their health needs or have poorer literacy and health literacy. This may be compounded by language and other cultural barriers and exacerbated by any additional vulnerabilities including safeguarding issues. Further, lanreotide can be self-administered provided they are educated in injecting and have access to a fridge as well as a safe sharps disposal. For those with no fixed abode, this may be difficult to achieve.	Commissioned providers will require all their staff to have completed their mandatory Safeguarding and Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation. Where required, clinicians should consider an individual's living arrangements in order to decide whether administration at the clinic or at home would be appropriate.
Other groups experiencing health inequalities (please describe)	None.	

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**

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 testing**	Two weeks stakeholder testing with registered stakeholders from the Internal medicine Programme of Care CRGs. 4 responses were received.	**October 2025**
2	**Assurance from PPVAG**	The policy received assurance from PPVAG	**January 2026**
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	Two evidence reviews were undertaken to inform this policy.	The PWG acknowledge that further evidence may be required to understand the possibility of treating pregnant patients with lanreotide.
Consultation and involvement findings	Planned	N/A
Research	As above	N/A
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A PWG including Consultant Hepatologists, specialist pharmacists and patient voice was assembled and contributed to this policy and impact assessment.	N/A

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	
The proposal may support?	x		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	Clinical safety and efficacy of lanreotide use in pregnant individuals.	Requires additional publication of high quality research, likely retrospective studies. Exclusion criteria based on current SmPC guidance.
2		N/A
3		N/A

10. Summary assessment of this EHIA findings

The policy may make a contribution to advancing equality of opportunity particularly for pre-menopausal women and trans-men with raised oestrogen levels. More information is required to understand the possibility of treating pregnant patients with lanreotide. As with all services, providers and health care workers must ensure access to information through appropriate communication methods and support health literacy for patients.

11. Contact details re this EHIA

Team/Unit name:	Internal Medicine Programme of Care
Division name:	Specialised Commissioning
Directorate name:	System Development Group
Date EHIA agreed:	
Date EHIA published if appropriate:	