

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):** 2267: Parenteral nutrition for the treatment of adults and children with type 2 and type 3 intestinal failure requiring home parenteral nutrition
- 2. Brief summary of the proposal in a few sentences**

This commissioning statement is designed to prioritise use of licenced generic multi-chamber bags of parenteral nutrition (PN), and thereby maximise the best use of limited compounding capacity. The commissioning statement proposes a stepwise assessment such that compounded parenteral nutrition is only used for patients who are unable to maintain nutritional stability when utilising multi-chamber bags for all, or some, of their nutritional intake.

Intestinal failure (IF) is not a condition which affects any particular group of people disproportionately, including taking all protected characteristics into consideration. This proposal is not considered to adversely impact on any sub-groups positively or negatively, so there are no specific equality issues identified to address. People with type 3 IF have a permanent, potentially life limiting condition, and some may consider that they have a disability. To date within the UK, through inclusion of pharmacy and dietetics input to Multi-Disciplinary Teams (MDTs), PN prescriptions have been designed bespoke to the patient, and the majority of patients have received an individually compounded product. This is not the model in place across the majority of Europe, and North America. Latterly, with restrictions in available capacity for aseptically compounded products, and with the availability of a wide range of generic Multi-chamber bags (MCBs), clinicians have increasingly explored use of this product. This commissioning statement suggests standardising that approach. This commissioning statement does not propose any material changes to the clinical and nursing care that patients already receive, but asks clinicians to check whether a MCB would meet patients' needs before investigating a more bespoke prescription.

The proposal is considered to promote fair and equitable national coverage for patients with IF and for those requiring home PN, through protecting limited compounding resource for those with the greatest clinical need. Generic multi-chamber bags are end-

sterilised, and do not, in the main, require refrigeration, which makes delivery and storage less problematic. Patients who have received compounded products in the past have been offered MCBs when they have wanted to travel away on holiday, or when compounding availability has necessitated moving patients to contingency prescriptions.

There is a service specification for adult patients, but no equivalent at this point in time for children, although one is under consideration. This commissioning statement will cover both adults and children.

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.	This commissioning statement relates to both adults and children. Given that the policy aims to manage demand by encouraging use of available licensed product in line with the evidence, the expected impact on both adults and children is positive. There is a smaller range of MCBs that would meet the needs of younger children, who are more likely to require a compounded product.	N/A
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Severe IF does not disproportionately impact those with other disabilities, although patients with severe IF may consider the condition a disability in itself. Some patients / carers might not have the	Clinical teams will take into consideration a patient / carer's dexterity and ability to manipulate the feed, or multiple lines when determining the optimal prescription for their patient. The commissioning statement also highlights that each prescription should be decided by multi-

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
	dexterity to manage multiple infusions, or blending MCBs.	disciplinary team on an individual patient basis, taking into account clinical and nutritional factors, burden of treatment regimen and risk assessment of treatment regimen, including home environmental and social factors. In addition, patients will be monitored to ensure that the PN provided meets the patients' clinical and nutritional needs and the stopping criteria outlined in the commissioning statement will be applied where appropriate.
Gender Reassignment and/or people who identify as Transgender	Severe IF does not disproportionately impact those undergoing gender reassignment and/or people who identify as transgender positively or negatively.	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	Severe IF does not disproportionately impact people who are married or in a civil partnership positively or negatively.	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Severe IF does not disproportionately impact positively or negatively people before and after childbirth and who are breastfeeding, although they may have additional clinical and nutritional needs that their medical team would take into consideration for the patients prescription.	The commissioning statement highlights that each prescription should be decided by a multi-disciplinary team on an individual patient basis, taking into account clinical and nutritional factors, burden of treatment regimen and risk assessment of treatment regimen, including home environmental and social factors

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
Race and ethnicity ¹	Severe IF does not disproportionately impact people from different racial and ethnic backgrounds positively or negatively.	N/A
Religion and belief: people with different religions/faiths or beliefs, or none.	Severe IF does not disproportionately impact people with different religious/faiths or beliefs positively or negatively although they may express preferences that their medical team would need to consider regardless of this proposal.	N/A
Sex: men; women	Severe IF does not disproportionately impact men or women positively or negatively.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Severe IF does not disproportionately impact people depending on their sexual orientation positively or negatively.	N/A

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.**

¹ 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.

Groups who face health inequalities ²	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	Severe IF does not disproportionately impact looked after children and young people positively or negatively. However, people from these groups may experience difficulties in general accessing services and accessing follow up.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group
Carers of patients: unpaid, family members.	Severe IF does not disproportionately impact carers of patients positively or negatively. Because this commissioning statement applies to children, family members will play a key role in accessing services, treatments and follow up.	The commissioning statement highlights that each prescription should be decided by a multi-disciplinary team on an individual patient basis, taking into account clinical and nutritional factors, burden of treatment regimen and risk assessment of treatment regimen, including home environmental and social factors for example, family situation.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	Severe IF does not disproportionately impact homeless people positively or negatively. However, people from this group may experience difficulties in general accessing services and accessing follow up. The cold-chain delivery requirements needed when patients are being treated with compounded PN may be difficult for this group, so there is likely to be a positive impact with increasing use of generic product as outlined in this commissioning	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group

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

Groups who face health inequalities ²	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
	statement, because it does not require cold-chain delivery.	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Severe IF does not disproportionately impact people involved in the criminal justice system positively or negatively.	N/A
People with addictions and/or substance misuse issues	Severe IF does not disproportionately impact people with addictions and/or substance misuse issues positively or negatively.	N/A
People or families on a low income	Severe IF does not disproportionately impact people or families on a low income positively or negatively. However, the cold-chain delivery requirements needed when patients are being treated with compounded PN may be difficult for this group, so there is likely to be a positive impact with increasing use of generic product as outlined in this commissioning statement, because it does not require cold-chain delivery.	N/A
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Severe IF does not disproportionately impact people with poor literacy or health Literacy positively or negatively, however, a patient / carer's ability to understand the type of infusion prescribed for them will be considered by the clinical team looking after them.	The commissioning statement highlights that each prescription should be decided by a multi-disciplinary team on an individual patient basis, taking into account clinical and nutritional factors, burden of treatment regimen and risk assessment of treatment regimen, including home environmental and social factors for example, language and

Groups who face health inequalities ²	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
		literacy. Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks.
People living in deprived areas	Severe IF does not disproportionately impact people living in deprived areas positively or negatively.	N/A
People living in remote, rural and island locations	Severe IF does not disproportionately impact people living in remote, rural and island locations positively or negatively. The need for cold-chain delivery to people living in remote areas, may be helped with increasing use of generic product. However, people from this group may experience difficulties in general accessing services and accessing follow up.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.
Refugees, asylum seekers or those experiencing modern slavery	Severe IF does not disproportionately impact Refugees, asylum seekers or those experiencing modern slavery positively or negatively. However, people from this group may experience difficulties in general accessing services and accessing follow up.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.
Other groups experiencing health inequalities (please describe)	Not applicable	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.

No		
-----------	--	--

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

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
<p>Published evidence</p>	<p>Cogle SV, Martindale RG, Ramos M, Roberti GJ, Roberts PR, Taylor K, Sacks GS. Multicenter prospective evaluation of parenteral nutrition preparation time and resource utilization: 3-chamber bags compared with hospital pharmacy-compounded bags. <i>Journal of Parenteral and Enteral Nutrition</i> 2021;45(7):1552-1558. Available from https://pubmed.ncbi.nlm.nih.gov/33188572/</p> <p>Crooks B, Harrison S, Millward G, Hall K, Taylor M, Farrer K, Abraham A, Teubner A, Lal S. Catheter-related infection rates in patients receiving customized home parenteral nutrition compared with multichamber bags. <i>Journal of Parenteral and Enteral Nutrition</i> 2022;46(1):254-257. Available from https://pubmed.ncbi.nlm.nih.gov/34287965/</p> <p>Nagelkerke SCJ, Jonkers-Schuitema CF, Kastelijn WLM, Gerards ALE, Benninga M. A, de Koning BAE, Tabbers MM. Standardized and individualized parenteral nutrition mixtures in a pediatric home parenteral nutrition population. <i>Journal of Pediatric Gastroenterology and Nutrition</i> 2020;70(2):269-274. Available from https://pubmed.ncbi.nlm.nih.gov/31978031</p> <p>Harrison S, Kopczynska M, Leahy G, Taylor M, Farrer K, Barrett M, Mallawaarachchi P, Abraham A, Teubner A, Lal S (2022). Hybrid model of compounded and multichamber bag parenteral nutrition for adults with chronic intestinal failure. <i>JPEN Journal of Parenteral and Enteral Nutrition</i>, 46(7):1632-1638.</p> <p>Pironi, L., Boeykens, K., Bozzetti, F., Joly, F., Klek, S., Lal, S., Lichota, M., Mühlebach, S., van Gossum, A., Wanten, G.,</p>	

Evidence Type	Key sources of available evidence	Key gaps in evidence
	<p>Wheatley, C., & Bischoff, S. C. (2020). ESPEN guideline on home parenteral nutrition. <i>Clinical Nutrition</i>, 39(6). https://doi.org/10.1016/j.clnu.2020.03.005</p> <p>https://www.espen.org/files/ESPEN-Guidelines/ESPEN_guideline_on_home_parenteral_nutrition.pdf</p> <p>NICE guidance on nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition: https://www.nice.org.uk/guidance/cg32/evidence/full-guideline-194889853</p> <p>ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Standard versus individualized parenteral nutrition - PubMed (nih.gov)</p>	
Consultation and involvement findings	Not applicable	
Research	Not applicable	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The Policy Working Group (PWG) was made up of leading severe intestinal failure clinicians including doctors, nurses, dietician, public health and pharmacists, covering both adult and paediatric patients. It included patient representation from Patients on Intravenous and Nasogastric Nutrition Therapy (PINNT)	

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?	Yes	Yes	Yes

The proposal may support?			
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?	Yes	Yes
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	None	
2		
3		

10. Summary assessment of this EHIA findings

This change is intended to make best use of licenced product in the first instance, which is less challenging to store and to distribute. The intention is to preserve the challenged compounding capacity, which will be better available for those patients that are unable to thrive on any of the generic products. This will ensure that all patients have access to the appropriate parenteral support to meet their individual needs.

11. Contact details re this EHIA

Team/Unit name:	Specialised Colorectal Clinical Reference Group
Division name:	Internal Medicine
Directorate name:	Specialised Commissioning
Date EHIA agreed:	
Date EHIA published if appropriate:	