DRAFT FOR PUBLIC CONSULTATION

Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	A12X02		
Policy Title	Infliximab for the treatment of hidradenitis suppurativa		
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Section K - Activity Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 The policy proposes **to not routinely commission** the use of infliximab in treating patients with hidradenitis suppurativa (HS) who do not respond to first line treatments.[i] HS has an estimated prevalence rate of 1% of the population,[ii] or approximately 540,000 people in England.[iii] The incidence of HS is estimated at 52 to 67 per million population,[iv] which could indicate approximately 2,820 to 3,640[v] in England in 2014/15.[vi]
	K.1.2 What is the number of patients currently eligible for the treatment	K1.2 The treatment would only target patients with severe to moderate hidradenitis suppurativa who do not respond to first line treatments

	under the proposed policy?	(antibiotics and immunosuppressive treatments).[vii] It is difficult to estimate how many patients would have moderate to severe HS. A study in North America found that 38.1% of newly diagnosed persons with hidradenitis suppurativa had moderate (Hurley Stage II)[viii] and 2.2% had severe (Hurley Stage III)[ix] symptoms.[x] Based on these rates, it is possible that approximately 1,140 to 1,470[xi] patients a year may have moderate to severe symptoms at time of diagnosis across England. It is estimated that circa 100 of these patients per year may be eligible for infliximab having failed first line treatment.[xii]
	K1.3 What age group is the treatment indicated for?	K1.3 The policy relates to patients of all ages.
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 HS usually starts around the age of puberty, but it can appear at any age.[xiii] It is common for HS to appear in adults aged 20 - 40.[xiv] Women are 2 to 5 times as likely to suffer of this condition as men,[xv] the prevalence in women to men has an approximate of 2.7:1.[xvi]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 It is estimated that some patients within the target population may be receiving **infliximab** through individual funding requests (IFRs).[xvii] From April 2014 to September 2015, c. 35 IFRs were submitted.[xviii] For patients with moderate to severe HS for whom first line treatments have failed, **surgical interventions** may be required**.** Based on an extract of SUS data on secondary health care medical activity, in 2014/15 there were c. 500 surgeries relating to excision of sweat gland bearing skin[xix] and c. 500 day cases relating to "unspecified other excisions of lesions of skin."[xx] These figures related to all stages of HS and it is unknown how many of these surgeries relate to the target population.[xxi] This would be in addition to any continuing first line treatments (steroids, antibiotics) being used.

	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	K1.6 While no change in the prevalence rate has been identified (see K2.2), the population with HS is expected to grow with the general population.[xxii] Accordingly, the prevalent population is estimated to be in the region of:[xxiii] • circa 550,000 in 2016/17 • circa 555,000 in 2017/18 • circa 565,000 in 2020/21. Of these, the number with severe HS that could be eligible for the treatment is estimated in the range of 100 per year as set out in K1.2.
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	K1.7 Under a do nothing position (prior to applying the new policy) activity for **infliximab** would remain broadly flat (i.e. current state would be steady state). The number of **surgeries** required for the population would be expected to grow in line with the target population as set out in K1.6.
	K1.8 How is the population currently distributed geographically?	K1.8 Across England – no significant geographical differences in the disease have been identified.
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 The policy is to not routinely commission the use of infliximab for the conditions outlined in K1.1.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence,	K2.2 The exact cause of HS is unclear. HS, particularly moderate to severe HS, is associated with smoking and above-average weight.[xxiv] However, the exact link with HS has not been

	increased survival)	established. There is also evidence that HS is caused by genetic factors,[xxv] and so HS is estimated to grow in line with population (see K1.6).
	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details	K2.3 No evidence of changes was identified.
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	K2.4 The proposed policy establishes a 'not routinely commissioned' proposal for the relevant population (the specific cohort set out in K1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 The current activity has been set out in K1.5; patients in the target population may have episodes in secondary care in addition to the conventional treatments of antibiotics, steroids, and immunosuppressants.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet	K3.2 As the recommendation for infliximab is to not routinely commission for hidradenitis suppurativa, activity would be as set out in K1.7.
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet	K3.3 Under the do nothing scenario, the current level of activity is taken to represent the 'steady state', which is rolled forward in future years. This is likely to be as set out in K1.7.
K4 Existing Pathway	K4.1 If there is a relevant currently	K4.1-K4.3 There is no standard treatment pathway for this condition.

	routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity. K4.2 What are the current treatment access criteria? K4.3 What are the current treatment stopping points?	Current treatment includes antibiotics (erythromycin, metronidazole, minocycline, clindamycin, cephalosporins and penicillins; long term antibiotics: erythromycin or tetracycline), steroids (high-dose oral steroids such as prednisolone; or intralesional corticosteroid injection in the acute phase of the disease), and oestrogens. Retinoids (such as acitretin), dapsone, and TNF-inhibitors (such as infliximab) are usually used in a later stage of the disease.[xxvi]
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. K5.2 2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K 5.1 Surgery may be considered for people with chronic HS to remove the apocrine glands in the affected areas of skin although the disease can reoccur after surgery.[xxvii] K5.2 Not applicable
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy K6.2 Where there are different stopping points on the pathway please	K 6.1 -6.2 Not applicable as position is to not routinely commission.

	indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/Outpatient o Mental Health Provider: Inpatient /Outpatient o Community setting o Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity	K7.1 The treatment is administered in hospital in a day case setting.[xxviii] K7.2 No change anticipated.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.1 Not applicable. K8.2 Not applicable.

K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? K9.2 If this treatment is a drug, what pharmacy monitoring is required? K9.3 What analytical information /monitoring/ reporting is required? K9.4 What contract monitoring is required by supplier managers? What changes need to be in place? K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	K9.1-9.7 Not applicable as position is to not routinely commission.
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision) L1.2 How will the proposed policy	L1.1 Service has a network of expert providers based in designated centres. L1.2 No change anticipated.

	change the way the commissioned service is organised?	
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new policy change / restrict / expand the sources of referral? L2.3 Is the new policy likely to improve equity of access? L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.1 Secondary care dermatologists. L2.2 No change anticipated. L2.3-2.4 The policy standardises the approach to commissioning.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed? L3.2 Is there a change in provider physical infrastructure required? L3.3 Is there a change in provider staffing required? L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place? L3.5 Are there changes in the support services that need to be in place? L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor) L3.7 Is there likely to be either an increase or decrease in the number of	L3.1-3.6 Not applicable as position is to not routinely commission. L3.7 No change anticipated.

	commissioned providers? L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	 L3.8 Publication and notification of new policy.
L4 Collaborative	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 No
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which? M1.2 Is this treatment excluded from national prices? M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services? M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally /	M1.1 No (see M1.2). M1.2 This drug is excluded from national prices as a high cost drug. M1.3 Infliximab would be negotiated under local arrangements. The list price for infliximab is £377.66 for 100mg powder.[xxix] The annual cost per patient (including VAT) is set out in M2.1. M1.4 Not applicable.

	double charged through existing routes.	
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 VAT would be payable as it is envisaged the drug would be administered in a day case setting.[xxx]
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 Not applicable.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 There would be no revenue cost in year one as the policy is to not routinely commission. For reference, the unit cost of the treatment per patient per year is estimated at c. £17,900. This is based on: • A dose of infliximab of 5mg/kg, assuming an average patient weight of 70kg costs c. £1,320 (including 20% VAT, this would be c. £1,600). • This would be administered every 8 weeks,[xxxi] hence about 6.5 times a year. Therefore the cost of the drug per year is estimated at c. £10,300. • A day case episode is required to administer the drug (at a cost of £1,150 per administration).[xxxii] For reference, there can be significant costs associated with elective and non-elective days case and inpatient skin surgery for patients that.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 For patients where infliximab is deemed to be effective, treatment may be continued on an ongoing basis (with administration of the drug every 8 weeks). The yearly cost of the drug is the same as in M2.1.
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	M3.1 Cost neutral, as the position is to not routinely commission.

	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	M4.1 Cost neutral, as the position is to not routinely commission.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2 Cost neutral, as the position is to not routinely commission.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 None identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified e.g. decommissioning less clinically or cost-effective services	M5.1 Not applicable.
M6 Financial	M6.1 What are the material financial risks to implementing this policy?	M6.1 Not applicable.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst	M6.3 Not applicable.

	case and most likely total cost scenarios	
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 To date no studies have been identified which evaluate the cost effectiveness of infliximab in the treatment of HS.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 Not applicable as no studies identified.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 Not applicable.
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

[i] These include oral antibiotics and immunosuppressants.

[ii] NHS Choices, Hidradenitis suppurativa, accessed via: http://www.nhs.uk/conditions/hidradenitis-suppurativa/Pages/Introduction.aspx, last accessed: 11/02/2016.

[iii] This uses ONS population estimates and the prevalence rate stated above. Note that the prevalence is difficult to estimate as some people might be too embarrassed to seek diagnosis and treatment, see NHS Choices, Hidradenitis suppurativa, accessed via: http://www.nhs.uk/conditions/hidradenitis-suppurativa/Pages/Introduction.aspx, last accessed: 12/02/2016.

[iv] Vazquez, B. et al, "Incidence of Hidradenitis Suppurativa and Associated Factors: A Population-Based Study of Olmsted County, Minnesota", http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3541436/, last accessed: 28/01/2016.

[v] This considers the US incidence figure applicable to the English population.

[vi] Figures are rounded. These figures are based on the incidence rates above and use ONS population data for 2014/15.

[vii] Based on discussions with the policy working group.

[viii] For further information on Hurley Stage II, please refer to: British Medical Journal, Best Practice, accessed via: http://bestpractice.bmj.com/best-practice/monograph/1047/basics/classification.html, last accessed: 28/01/2016.

[ix] For further information on Hurley Stage II, please refer to: British Medical Journal, Best Practice, accessed via: http://bestpractice.bmj.com/best-practice/monograph/1047/basics/classification.html, last accessed: 28/01/2016.

[x] Vazquez, B. et al, "Incidence of Hidradenitis Suppurativa and Associated Factors: A Population-Based Study of Olmsted County, Minnesota", accessed via: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3541436/, last accessed: 28/01/2016.

[xi] Figures rounded. These figures are calculated by applying the rates of HS II and HS III to the incidence figures in K1.1.

[xii] Based on discussions with the policy working group. The estimate of 100 patients is based on extrapolation from historic figures and takes into account estimates where data is unavailable; however it is difficult to estimate the level of future demand and figures could vary significantly.

[xiii] NHS Choices, Hidradenitis suppurativa, accessed via: http://www.nhs.uk/conditions/hidradenitis-suppurativa/pages/introduction.aspx, last accessed: 26/11/2015.

[xiv] Average age of onset is 21.8, and average age of patients in the sample was 40.1. Von der Werth JM and Williams HC. (2000) The natural history of hidradenitis suppurativa. J Eur Acad Dermatol Venereol. 14(5). [Online] Available at: http://www.ncbi.nlm.nih.gov/pubmed/11305381 [Accessed 22/01/2016].

[xv] European Medicines Agency, Press release "First medicine recommended for approval for hidradenitis suppurativa", 25th June 2015.

[xvi] Policy Proposition.

[xvii] Some patients may be using infliximab through legacy arrangements.

[xviii] IFR database.

[xix] Includes day cases for OPCS codes: S041 (Excision of sweat gland bearing skin of axilla); S042 (Excision of sweat gland bearing skin of groin); S043 (Excision of sweat gland bearing skin NEC).

[xx] Based on OPCS code S069.

[xxi] Patients eligible under the policy are a subgroup of the wider list of patients included in the SUS data received for Infliximab for HS. SUS data received includes the ICD-10 code L732 (Hidradenitis suppurativa) in the first three positions of the list of ICD-10 codes for every patient.

[xxii] A weighted growth rate has been calculated to account for the higher prevalence in women ONS population data has been used, with a weight on women of 2.7 times the weight on men.

[xxiii] The growth rate set out in endnote xxii is applied to the prevalence estimate set out in K1.1. Figures are rounded to the nearest 1,000.

[xxiv] Patients with these risk factors tend to have more severe consequences. See NHS Choices, Hidradenitis suppurativa, Hidradenitis suppurativa, accessed via: http://www.nhs.uk/conditions/hidradenitis-suppurativa/Pages/Introduction.aspx, last accessed: 12/02/2016.

[xxv] Policy Proposition.

[xxvi] NICE Proposed HTA, "Adalimumab for treating moderate to severe hidradenitis suppurativa", Appendix B, 2015

[xxvii] NICE Proposed HTA, "Adalimumab for treating moderate to severe hidradenitis suppurativa", Appendix B, 2015

[xxviii] Based on discussion with policy working group.

[xxix] Price for Remsima. Dictionary of medicine, http://dmd.medicines.org.uk/DesktopDefault.aspx?AMPP=28803811000001106&toc=nofloat, last accessed: 13/11/2015

[xxx] Based on discussions with policy working group. When can goods being provided on prescription be zero-rated for VAT purposes? [Online] Available at: https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products [Accessed January 18 2016].

[xxxi] Based on discussions with policy working group.

[xxxii] This is based on analysis of the SUS data request. The £1,168 figure represents the cost of a day case, in 2014/15, for adults with hidradenitis suppurativa, who underwent a procedure with OPCS code X892 (Monoclonal antibodies). A factor of -1.6% is applied to account for inflation and efficiency and estimate the 2015/16 cost.