

**Integrated Impact Assessment Report for Clinical Commissioning Policies**

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| <b>Policy Reference Number</b>  | F05X02  |                        |                      |
| <b>Policy Title</b>             | Treatment of iron overload for transfused and non transfused patients with chronic inherited anaemias |                        |                      |
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**Section A - Activity Impact**

| <b>Theme</b>  | <b>Questions</b>                                      | <b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)  |
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| A1 Current Patient Population & Demography / Growth | A1.1 What is the prevalence of the disease/condition? | <p>A1. 1 In the UK, about 12,500 people have Sickle Cell Disease (SCD). 1 in 2,400 babies born in England have SCD, but rates are much higher in some urban areas - about 1 in 300 in some places.</p> <p>It is estimated to affect about 12 per 100,000 of the UK population, although the prevalence in some ethnic groups is substantially greater and the prevalence in any locality will be affected by the proportion of the population that are genetically linked to susceptible populations.</p> <p>According to data from the NHR, distribution in the UK is different from SCD with a greater proportion</p> |

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|  | <p>A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p> <p>A1.3 What age group is the treatment indicated for?</p> | <p>of thalassaemia patients being treated outside London. There are an estimated 1500 patients in the UK of whom 947 are on the NHR (October 2014).</p> <p>There are also an unknown number of patients with rare inherited forms of anaemia who may require transfusion and/or iron chelation (estimated less than 500). These diseases are not population specific and are encountered across the UK. Clinical management is the same as for thalassaemia patients.</p> <p>A1.2 Whilst there is a national registry, there is under reporting of patients with and treated for rare anaemias. According to the NHR annual report for 2014, approximately 9% of patients with SCD are on long term transfusion programs and about 40% of those transfused are currently receiving iron chelation. It is recognised that this data may be incomplete and underestimate the numbers on transfusion and on iron chelation. Approximately 50% people with thalassaemia are on lifelong transfusions and around 60% of thalassaemia patients receive iron chelation, the difference being patients with non-transfusion dependent thalassaemia (NTDT) can still develop complications due to iron overload and may need chelation.</p> <p>A1.3 Adults and children</p> |
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A1.4 Describe the age distribution of the patient population taking up treatment?

A1.4 In SCD, the majority of patients are under the age of 25 although there are patients reported on the NHR up to 75+

In thalassaemia, there is a higher proportion of patients aged 25 – 55 than in sickle cell, and fewer over the age of 55.

A1.5 What is the current activity associated with currently routinely commissioned care for this group?

A1.5 It is not possible to use SUS / HES data to reliably identify activity based on diagnosis and intervention (e.g. iron chelation). In addition, not all activity relating to haemoglobinopathy is funded by specialised commissioning (haematology outpatients is likely to be CCG commissioned) although all iron chelation drug spend for diseases defined as specialised, is the responsibility of NHS England. In the absence of national HES / SUS data, activity assumptions are based on

- a) The National Haemoglobinopathy Registry which collects and cleans individual patient data from providers but there is known under reporting,
- b) Provider reported data submitted as part of the West Midlands Quality Review Service 2014/16 peer review programme of health services for people with haemoglobin disorders. This includes reports of total numbers submitted as part of an assessment of delivery against quality standards
- c) Regional pharmacy data on aggregate reported spend on the drugs included in this policy. This is not a patient level.

Patients eligible for chelation have commissioned access to treatment already but anecdotal evidence suggests there is not equal access to all regimens included in the policy proposition:

- Deferasirox (DFX) – this is a newer oral agent
- Deferiprone (DFP) – this is an older oral agent
- Deferoxamine (DFO) – this is administered via subcutaneous infusion.
- Combination of DFO and DFP
- Combinations with DFX are excluded from the policy.

Patients on chelation require MRIs to monitor iron levels. Monitoring can be for liver and cardiac iron. Different MRI modalities are used for this.

According to the 2014/16 Peer Review programme, at least 800 adults and children were on long term red cell transfusions. However it is understood that there is under reporting and actual numbers are likely to be higher and therefore as assumption of 1000 patients on chelation has been made.

Identifying current MRI activity is affected by the same issues outlined above. This policy does not recommend an increase in MRIs.

A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new

A1.6 Projected growth is assumed to be in line with population growth, although it is noted that this may be a conservative estimate as the following factors may also impact:

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|  | <p>policy) in 2, 5, and 10 years?</p> <p>A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?</p> <p>A1.8 How is the population currently distributed geographically?</p> | <ul style="list-style-type: none"> <li>• Changes in life-expectancy and improving survival</li> <li>• Changes in fertility and birth rate in affected population subgroups</li> <li>• Changes in migration</li> </ul> <p>A1.7 Changes in prevalence will translate into changes in activity. Where patients require transfusion and this leads to iron loading, then chelation will be required. The use of alternatives to transfusion such as hydroxycarbamide where it is indicated and the use of automated exchange transfusion can impact on the levels of chelation required but is not the primary focus of this policy.</p> <p>A1.8 Data from the National Haemoglobinopathy Registry (NHR) shows that about 80% of people with SCD are cared for at London centres with the remainder being largely confined to major cities such as Birmingham and Manchester. According to data from the NHR, distribution of people with thalassaemia in the UK is different from SCD with a greater proportion of thalassaemia patients being treated outside London.</p> |
| <p>A2 Future Patient Population &amp; Demography</p> | <p>A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing</p>  | <p>A2.1 Other: Iron chelation and access to MRI monitoring is routinely commissioned however the CRG reports inconsistent access to the different therapeutic regimens and monitoring across the country.</p>   |

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|             | <p>treatment threshold / add an additional line / stage of treatment / other?</p> <p>A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p> <p>A 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.</p> <p>A2.4 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?</p> | <p>A2.2 Projected growth in absolute numbers requiring chelation and the amount required may be impacted by the following factors:</p> <ul style="list-style-type: none"> <li>• Changes in life-expectancy and improving survival</li> <li>• Changes in fertility and birth rate in affected population subgroups</li> <li>• Changes in migration</li> <li>• Access to automated red cell exchange</li> </ul> <p>A2.3 Data from new-born screening shows fewer births of babies with sickle cell disease in London with stable numbers outside the UK. Anecdotal data shows larger increase in patient numbers outside London due to relocation from London.</p> <p>A2.4 This policy will not increase or decrease the number of patients eligible for iron chelation or monitoring. The policy may impact on the proportion of different chelation regimens used to treat iron overload</p> <p>This policy will not increase the current volume of MRI activity.</p> |
| A3 Activity | A3.1 What is the current annual activity for the target population covered under the new policy? Please provide   | <p>A3.1 Given the limitations of available data the following assumptions have been made</p> <ul style="list-style-type: none"> <li>• 1000 patients on chelation,</li> </ul>  |

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|  | <p>details in accompanying excel sheet.</p> <p>A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.</p> <p>A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted?</p> | <p>73% adults, 27% children</p> <ul style="list-style-type: none"> <li>• Almost half (42.5%) of adults and over 70% (71.6%) of children are already estimated to be on DFX</li> <li>• Those on chelation are likely to attend outpatient care monthly for monitoring and have annual MRI monitoring</li> <li>• There is regional variation in uptake of DFX and areas with lower uptake have been used to calculate the potential maximum impact of the policy recommendation.</li> </ul> <p>A3.2 No new activity is expected as a result of this policy. It is expected that the policy will not change</p> <ul style="list-style-type: none"> <li>• the total number of patients accessing chelation as this is clinically indicated and routinely commissioned</li> <li>• the total number of patients accessing MRI as this is clinically indicated and routinely commissioned.</li> </ul> <p>The policy is expected to result in some changes in the proportions of uptake <i>between</i> different regimens. Scenario modelling has assumed shifts of up to 100% although unlikely due to the clinical utility of DFO and DFP where clinically indicated.</p> <p>A3.3 Not applicable. Iron chelation is routinely commissioned as a treatment for managing iron overload and MRI scanning is available for this indication. Without the policy, reported inconsistent</p> |
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|   | Please details in accompanying excel sheet.   | access to routinely commissioned iron chelation treatments / MRI will remain   |
| A4 Existing Patient Pathway                                     | <p>A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p> | <p>A4.1 The oversight of iron chelation therapy is a responsibility of specialist haemoglobinopathy centres (SHC); this includes decisions about starting, monitoring, changing and stopping therapy. Provision of chelation may be provided at either the SHC or a local haemoglobinopathy centre or accredited local Haemoglobinopathy centre as part of network arrangements and agreed by the local commissioner.</p> <p>A4.2 The policy does not change the access criteria which remain as at present: patients with iron overload as a result of transfusions for SCD, thalassaemia or non transfusion dependent anaemias are treated with iron chelation where iron overload is indicated. MRI is used to monitor iron levels.</p> <p>A4.3 Where transfusions are stopped, chelation therapy will continue until the iron burden returns to safe levels. Patients with normal iron burden but continuing transfusions will require doses commensurate with iron loading.</p> |
| A5 Comparator (next best alternative treatment) Patient Pathway | A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to  | A5.1 There is no 'next best' alternative. This policy ensures equal access to routinely commissioned treatment and monitoring based on individual patient clinical need.   |



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|                               | <p>outline associated activity.</p> <p>A5.2 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.</p> | <p>A5.2 Not applicable for the scope of this policy. However, patients moving to automated red cell exchange will be able to reduce or stop iron chelation over time.</p>   |
| <p>A6 New Patient Pathway</p> | <p>A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p> <p>A6.2 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</p>                                      | <p>A6.1 The policy does not propose a new pathway.</p> <p>A6.2 Not applicable. Iron overload indicates treatment start and the aim of chelation is to return iron levels to normal when treatment will be reduced or discontinued as indicated.</p> |

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|                      | <p>after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>  |  |
| A7 Treatment Setting | <p>A7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> <li>○ Acute Trust: Inpatient/Daycase/ Outpatient</li> <li>○ Mental Health Provider: Inpatient/Outpatient</li> <li>○ Community setting</li> <li>○ Homecare delivery</li> </ul> <p>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what?<br/><i>e.g. service capacity</i></p> | <p>A7.1 Specialist haemoglobinopathy centres (SHC) provide oversight about starting, monitoring, changing and stopping therapy. Provision may be at SHC or a local haemoglobinopathy centre or accredited local Haemoglobinopathy centre as part of network arrangements and agreed by the local commissioner. Treatments are either delivered via a pump or are oral medicines. Generally they are prescribed during outpatient (day case) attendances. Drugs may be dispensed by home delivery.</p> <p>A7.2 No change from the policy recommendations.</p> |
| A8 Coding            | <p>A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure</p>   | <p>A8.1 There is no new patient pathway associated with this policy. Drugs spend via drugs MDS where they are excluded drugs.</p> <p>A8.2 No new activity. Changes in selection of chelator to be tracked via drugs MDS</p>  |

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| A9 Monitoring | <p>A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>A9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>A9.3 What analytical information /monitoring/ reporting is required?</p> <p>A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>A9.6 Are there any directly applicable NICE quality standards</p> | <p>A9.1 No</p> <p>A9.2 Drugs MDS will demonstrate changes in regimens. Assurance required that Deferasirox (DFX) not used in combination as such a combination is an exclusion to this policy</p> <p>A9.3 Drugs MDS will demonstrate changes in regimens. Assurance required that Deferasirox (DFX) not used in combination as outside policy</p> <p>A9.4 Assurance required that Deferasirox (DFX) not used in combination as outside policy</p> <p>A9.5 Monitoring of iron levels is already included in the haemoglobinopathy dashboard. The National Haemoglobinopathy Registry collects data on transfusion programmes and chelation therapy and reporting to the registry is a requirement.</p> <p>A9.6 No NICE quality standards apply to treatment of iron overload. A proposed guidance on 'Chronic</p> |

|                            | <p>that need to be monitored in association with the new policy?</p> <p>A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i></p> | <p>iron overload (in people with thalassaemia) - desferrioxamine, deferiprone and deferasirox [ID350]' was suspended in 2010.</p> <p>A9.7 No</p>   |
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| Section B - Service Impact |  |  |
| Theme                      | Questions  | Comments (Include source of information and details of assumptions made and any issues with the data)  |
| B1 Service Organisation    | B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)   | B1.1 Specialist haemoglobinopathy centres (SHC) provide oversight about starting, monitoring, changing and stopping chelation therapy. Provision may be at SHC or a local haemoglobinopathy centre or accredited local Haemoglobinopathy centre as part of network arrangements and agreed by the local commissioner. Treatments are either delivered via a pump or are oral medicines. Generally they are prescribed as part of outpatient (day case) attendances. This policy makes no change to this. |
|                            | B1.2 How will the proposed policy change the way the commissioned service is organised?  | B1.2 The proposed policy does not change the way the service is commissioned or organised.   |
| B2 Geography &             | B2.1 Where do current  | B2.1 Currently referrals come from   |

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| <p>Access</p>            | <p>referrals come from?</p> <p>B2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>B2.3 Is the new policy likely to improve equity of access?</p> <p>B2.4 Is the new policy likely to improve equality of access / outcomes?</p>  | <p>haematology services.</p> <p>B2.2 The new policy does not change the pathway for referrals.</p> <p>B2.3 The new policy intends to improve equity of access.</p> <p>B2.4 The new policy intends to improve equality of access / outcomes.</p>  |
| <p>B3 Implementation</p> | <p>B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> <p>B3.2 Is there a change in provider physical infrastructure required?</p> <p>B3.3 Is there a change in provider staffing required?</p> <p>B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> | <p>B3.1 No lead in time is required prior to implementation as these are routinely used drugs and monitoring.</p> <p>B3.2 No. The new policy does not require a change in provider physical infrastructure</p> <p>B3.3 No. The new policy does not require a change in provider staffing</p> <p>B3.4 No. The new policy does not require new clinical dependency / adjacency</p> |

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|                                | <p>B3.5 Are there changes in the support services that need to be in place?</p> <p>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>B3.8 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)</p> | <p>B3.5 No. The new policy does not require changes in support arrangements.</p> <p>B3.6 No. The new policy does not require a change in provider / inter provider governance</p> <p>B3.7 No. The new policy does not require an increase or decrease in the number of commissioned providers</p> <p>B3.8 NHS England will notify providers and commissioners of the policy</p> |
| B4 Collaborative Commissioning | B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)   | B4.1 The pathway is already a shared commissioning responsibility of NHS England and CCGs in terms of attendances and MRI. NHS England is the commissioner of chelation drugs   |

**Section C - Finance Impact**

| <b>Theme</b> | <b>Questions</b>   | <b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)  |
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| C1 Tariff    | <p>C1.1 Is this treatment paid under a national prices*, and if so which?</p> <p>C1.2 Is this treatment excluded from national prices?</p> <p>C1.3 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?</p> <p>C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?</p> <p>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>C1.6 Do you envisage a prior approval /</p> | <p>C1.1 Yes. MRI is unbundled for outpatient attendances</p> <p>C1.2 Yes. Drugs are excluded. MRI is unbundled for outpatient attendances</p> <p>C1.3 Chelators are funded as excluded drugs. MRI is unbundled for outpatient attendances</p> <p>C1.4 Not applicable</p> <p>C1.5 Modelling has assumed that VAT is payable where drugs are infused and not for orals. Use of home delivery of these treatments is appropriate and thought to be widely used</p> <p>C1.6 No. It is not envisaged that prior approval / funding</p> |

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|                                    | <p>funding authorisation being required to support implementation of the new policy?</p>  | <p>authorisation is required to support implementation of the policy.</p>  |
| <p>C2 Average Cost per Patient</p> | <p>C2.1 What is the revenue cost per patient in year 1?</p> <p>C2.2 What is the revenue cost per patient in future years (including follow up)?</p> | <p>C2.1 Based on the assumptions set out in K3.1,</p> <ul style="list-style-type: none"> <li>• The current baseline revenue cost per patient of treating iron overload with chelation and MRI monitoring is £16,902. This assumes 42.5% of adults and 71.6% of children on chelation are already estimated to be on DFX.</li> <li>• If the policy increases the overall proportion on DFX (the highest cost of treatments) to 75%, the revenue cost is £17,905 pp in Yr 1</li> <li>• If the policy increases the overall proportion on DFX (the highest cost of treatments) to 100%, the revenue cost is £18,616 pp in Yr 1</li> <li>• These costs are only impacted by the used of drug as MRI and attendances remain constant whatever the treatment</li> </ul> <p>C2.2 The revenue cost per patient in subsequent years is constant affected only by the following:</p> <ul style="list-style-type: none"> <li>• The overall proportion treated with DFX</li> <li>• The effect of DFX becoming available as a generic</li> <li>• If the policy increases the</li> </ul> |



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|  |  | <p>overall proportion on DFX (the highest cost of treatments) to 75%, the revenue cost is £18,881 in Yr 2; £19,910 in Yr 3; £12,635 in Yr 4 when DFX becomes generic</p> <ul style="list-style-type: none"> <li>• If the policy increases the overall proportion on DFX (the highest cost of treatments) to 100%, the revenue cost is £20,329 in Yr 2; £22,042 in Yr 3; £13,271 in Yr 4 when DFX becomes generic</li> </ul> <p>These costs are only impacted by the used of drug as MRI and attendances remain constant whatever the treatment</p> |
| <p>C3 Overall Cost Impact of this Policy to NHS England</p>        | <p>C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>C3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>                             | <p>C3.1 The impact of this policy on NHS England is a cost pressure if the policy results in a shift in the proportion on DFX.</p> <p>C3.2 Not applicable</p>  |
| <p>C4 Overall cost impact of this policy to the NHS as a whole</p> | <p>C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).</p> <p>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as</p> | <p>C4.1 The policy is expected to be cost neutral for other parts of the NHS.</p> <p>C4.2 The impact of this policy on NHS England is a cost pressure if the policy results in a shift in the proportion on DFX.</p>   |

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|   | <p>a whole.</p> <p>C4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p> | <p>C4.3 Not applicable</p> <p>C4.4 The policy is expected to be cost neutral for other parts of the NHS as no recommendations are made for increasing the number of eligible patients treated or changing the current treatment and monitoring pathway.<br/>Maximising the effectiveness of chelation may result in further cost savings to all commissioners as the consequences of iron overload are avoided but there is insufficient data to model this.</p> |
| C5 Funding  | C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning less clinically or cost-effective services</i>   | C5.1 New NICE guidance estimates that greater use of automated red cell exchange for transfusion could result in long term savings for NHS England. This is outside the scope of this policy but is a priority area for work in 2016//17. Automated red cell exchange is considered to reduce frequency and time taken to complete manual exchanges and is considered to reduce iron chelation requirements.   |
| C6 Financial Risks Associated with Implementing this Policy | <p>C6.1 What are the material financial risks to implementing this policy?</p> <p>C6.2 Can these be</p>   | <p>C6.1 The material risk to the policy is ensuring combinations with DFX which are excluded from this policy are not used and reimbursed</p> <p>C6.2 Mitigation requires monitoring</p>   |

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|                    | <p>mitigated, if so how?</p> <p>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>   | <p>of drugs MDS and audit to ensure criteria of policy are followed.</p> <p>C6.3 Scenario modelling has assumed increased proportion using most expensive oral treatment increasing to 75 and 100%.</p>  |
| C7 Value for Money | <p>C7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>C7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p> | <p>C7.1 An evidence review has been conducted of the published literature. This concluded cost effectiveness is affected by</p> <ul style="list-style-type: none"> <li>• The fact that intravenous drugs incur additional preparation and delivery costs</li> <li>• Adherence is a key requirement for any treatment to work and this is reported as being lower with non oral options</li> </ul> <p>C7.2 Published cost effectiveness data was from company sponsored studies in a number of cases.</p> |
| C8 Cost Profile    | <p>C8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>C8.2 If so, confirm the source of funds to meet</p>  | <p>C8.1 No. There are no non-recurrent capital or revenue costs associated with the policy.</p> <p>C8.2 Not applicable</p>   |

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For public consultation