Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1610		
Policy Title	Trientine for Wilson Disease Proposal Choose an item. (ref A3.1)		
Lead Commissioner	Joan Ward	**Clinical Lead**	James Dooley
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Integrated Impact Assessment – Index

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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Wilson's disease is an autosomal recessive condition with a prevalence of approximately 1 in 30,000 of the population (Weiss KH. Wilson disease. Gene Reviews; last updated 2013). At present, however, the number of patients with Wilson's disease in England is not known but is estimated to be c1,854 (based on the England population of c56 million). If all patients are started on d-penicillamine, the first line treatment, then estimates from the European Association for the Study of the Liver (EASL) suggest that c30-35% could not be treated with this agent. Thus approximately 556 patients could benefit from trientine dihydrochloride. The experience of the clinical community is that in England the number of patients receiving trientine dihydrochloride is likely to be much lower than this, estimated to be c100 patients. *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	**100** *Source: required* Please specify Policy Proposition section 6
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** Please specify Click here to enter text.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	**70% adult, 30% paediatric** *Source:* Please specify

<table>
<tr><td></td><td>Policy Working Group</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>unknown</u>
If unevenly, estimate regional distribution by %:
<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table>Source: Policy Proposition section 6
Please specify
Click here to enter text.</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Constant</u>

If other, Click here to enter text.
Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Please specify
Click here to enter text.
Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed</td><td><table><tr><td>YR2 +/-</td><td>+1</td></tr><tr><td>YR3 +/-</td><td>+2</td></tr></table></td></tr>
</table>

<table>
<tr><td>service specification commissioning criteria, per year in years 2-5 and 10?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR4 +/-</td><td>+3</td></tr><tr><td>YR5 +/-</td><td>+4</td></tr><tr><td>YR10 +/-</td><td>+7</td></tr></table>Source: Service specification proposition section 3.1

<u>Yes</u></td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u>
Please specify
Trientine is currently funded for the patients who were in receipt of the drug in April 2017.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>100
Source: required
Please specify
Policy Proposition section 6</td></tr>
<tr><td>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</td><td>100
Source: required
Please specify
Policy Proposition section 6</td></tr>
</table>

A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	**NA** *Source: required* Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Trientine is not a new treatment. It has been established as effective for this disease for over 50 years. It is an oral therapy. Patients may be treated by a liver specialist, a neurologist or a metabolic physician and there is usually an MDT approach to their care as patents can develop both liver and neurological symptoms. The associated activity relating to its use has not changed and will not be changed through this policy. The drug was in tariff until the end of 2016/17 with patient drug costs being met by hospitals and/or CCGs. As Wilson disease is a long-term condition, it is likely that some patients are still being funded by CCGs in the absence of a policy and hence why the current NHS England drug spend is much lower than expected. *Source:* NCDR
A4.2. What are the current treatment access and stopping criteria?	New patients are not able to access this treatment unless via IFR. In relation to stopping criteria, Wilson disease is a lifelong condition; Patients who, after being prescribed trientine hydrochloride (or a combination of trientine and zinc), are on follow up without symptoms and have satisfactory parameters thought to reflect stable disease stable patients may be considered for transfer to zinc. Some patients for whom the treatment is not effective and liver disease progresses may need a liver transplant. In relation to the policy there are clear access criteria which define intolerance to penicillamine which is the first line treatment. .

	Source: *Policy Proposition section 8*
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Click here to enter text. a) 100, based on the assumption that CCGs are funding some patients b) 0 c) 100 based on the assumption that CCGs are funding some patients d) 100 based on the assumption that CCGs are funding some patients e) Treatment is lifelong *Source:* *r Policy Proposition section 6*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** If yes, Click here to enter text. *Source:* *required*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment	Total estimated eligible **NA** a) enter % b) enter % c) enter % d) enter %

e) Complete treatment?	e) enter % *Source: required*
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Click here to enter text. a) 100 , based on the assumption that CCGs are funding some patients b) 0 c) 100 , based on the assumption that CCGs are funding some patients d) 100, based on the assumption that CCGs are funding some patients e) Treatment is for life *Source:*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long** Click here to enter text. *Source: required*
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	*Select all that apply:* Emergency/Urgent care attendance ☐ Acute Trust: inpatient ☒

	<table><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table> Please specify: Click here to enter text.
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>number</td></tr><tr><td>MIDLANDS & EAST</td><td>number</td></tr><tr><td>LONDON</td><td>number</td></tr><tr><td>SOUTH</td><td>number</td></tr></table> No providers are specifically commissioned to treat Wilson disease. The disease can affect patients in relation to neurological or liver function or both. Patients are seen in a range of services, metabolic, neurological and hepatological. Some patients are treated in specialist centres, some in DGHs through shared care.

A7.3 Does the proposition requires a change of delivery setting or capacity requirements?	**No** Please specify: Click here to enter text. *Source: required*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☒ Patient level contract monitoring ☐ Patient level drugs dataset ☒ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☐ Mental Health Services DataSet (MHSDS) ☐ National Return** ☐ Clinical Database** ☐ Other** ☐ **If National Return, Clinical database or other selected, please specify: Click here to enter text.
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:*

	<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☐</td></tr><tr><td>Treatment function code</td><td>☒</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table>
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<u>Already specified in current NHS England Drugs List document</u>** If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication: **Trientine for Wilson Disease**
A8.4 **Identification Rules for Devices:** How are device costs captured?	**<u>Not applicable</u>**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**<u>Not applicable</u>** The drug is dispensed at existing routine OP appointments which may be contracted and paid for by NHS England or CCGs depending on the specialty code used. The policy will have no impact on the contracting/payment responsibility of the associated activity.
A9 Monitoring	

<table>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u>
Please specify
Click here to enter text.</td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:
<table><tr><td>Drugs or Device MDS</td><td>☐</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table>Please specify: Click here to enter text.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
To be included in the routine drug minimum data set (MDS)</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>
If yes, specify how routine performance monitoring data will be used for dashboard reporting.
Click here to enter text.
If no, will one be developed?
No</td></tr>
<tr><td>A9.6 NICE reporting
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new</td><td><u>No</u>
If yes, specify how performance monitoring data will be used for this purpose.</td></tr>
</table>

policy?	Click here to enter text.
Section B – Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	There are no providers specifically commissioned to treat Wilson disease. The disease can affect patients in relation to neurological or liver function or both. Patients are seen in a range of services including metabolic, neurological and hepatological. Some patients are treated in specialist centres and some in DGHs as part of shared care arrangements. *Source: required*
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: Click here to enter text. *Source: required*
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care** Please specify:
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☐ Secondary care ☒

	Tertiary care ☒ Other ☐ Please specify: Click here to enter text.
B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: Click here to enter text.
B2.3 Is the new policy likely to improve equity of access?	**Increase** Please specify: **Newly presenting patients are unable to access treatment other than through the IFR process** *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** Please specify: **Newly presenting patients will be able to access treatment** *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Click here to enter text.

B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No – go to B3.4** If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	**No** Please specify: Click here to enter text.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**Yes** Please specify: **Centres must have expertise in hepatobiliary, neurology and metabolic or networked arrangements for these services**
B3.7 Are there changes in the support services that need to be in place?	**No** Please specify: Click here to enter text.
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No** Please specify:

B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region

No change

Please complete table:

Region	Current no. of providers	Future State expected range	Provisional or confirmed
North	4	4	P
Midlands & East	4	4	P
London	4	4	P
South	4	4	P
Total	16	16	P

Please specify:

There are a relatively small number of expert centres so the policy will not affect the provider profile

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

Publication and notification of new policy	☒
Market intervention required	☐
Competitive selection process to secure increase or decrease provider configuration	☐
Price-based selection process to maximise cost effectiveness	☐
Any qualified provider	☐
National Commercial Agreements e.g. drugs, devices	☐
Procurement	☐

	Other ☐ Please specify
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:*

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☒
	Paid entirely by Local Tariffs	☐

<table>
<tr><td></td><td><table>
<tr><td></td><td>Partially paid by National Tariffs</td><td>☐</td></tr>
<tr><td></td><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table></td></tr>
<tr><td>C1.2 Drug Costs
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>The list price is £3,090 ex-VAT per packet of 100 capsules (300mg).
Source : NICE
The estimated number of capsules required per day is between 2-5 for paediatric patients and 4-8 for adults.</td></tr>
<tr><td>C1.3 Device Costs
Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information.
NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>N/A</td></tr>
<tr><td>C1.4 Activity Costs covered by National Tariffs
List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</td><td>N/A
As the drug is dispensed during routine OP appointments, there is no difference to the associated activity cost whether the drug is routinely available or not. Routine OP appointments are likely to be covered by national tariffs.</td></tr>
<tr><td>C1.5 Activity Costs covered by Local Tariff
List all the HRGs (if applicable), HRG or local description, estimated</td><td>N/A</td></tr>
</table>

<table>
<tr><td>average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</td><td></td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>N/A</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>Yes</u>
Please specify: Prior approval on annual basis</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td>
<table>
<tr><td>YR1</td><td>£65,125</td></tr>
<tr><td>YR2</td><td>£65,125</td></tr>
<tr><td>YR3</td><td>£65,125</td></tr>
<tr><td>YR4</td><td>£65,125</td></tr>
<tr><td>YR5</td><td>£65,125</td></tr>
</table>

This is the cost of 1 patient receiving the drug continuously for all 5 years and is based on:
• the list price of £3,090 for 100 capsules
• VAT applicable for 50% of drugs dispensed
• 30% of patients are paediatric

No</td></tr>
</table>

C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost pressure** Year 1: £4,008.1k Year 2: £4,008.1k Year 5: £4,203.5k Trientine dihydrochloride is not a new treatment. During 2015/16, the cost of the drug increased significantly and as a consequence, the drug was excluded from tariff at the start of 2017/18. The drug continued to be funded by providers and/or CCGs (via GP prescribing) until March 2017 when NHS England took over the funding responsibility. In April 2017, NHS England agreed to fund patients already in receipt of this treatment whilst the policy was in development. Patient access since April 2017 has been directed through the individual funding requests (IFR) process. Existing patient numbers are unknown and it is likely that some patients have continue to be funded by CCGs in 17/18 and into 18/19 and hence why the total cost recorded by NHS England is only equivalent of c39 patients per year. Please specify: Click here to enter text.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	N/A
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Whilst a number of patients have been funded by CCGs during 17/18 and 18/19 during transition, the responsibility for funding the drug was established as NHS England once it was excluded from tariff at the start of

	17/18. Therefore it is not appropriate to transfer funding from CCGs.
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost saving** CCGs have continued to fund some existing patients. Following the publication of a policy, it is likely that the cost will transfer to NHS England. Budget impact for providers: **Cost neutral** There may be a cost saving if providers have not realised the drug was excluded from tariff and therefore chargeable from 2017/18.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Year 1: £455.9k Year 2: £651.3k Year 5: £1,432.7k Due to the drug historically being included in tariff and the likelihood that a number of patients have continued to be funded by CCGs and providers, there is a lack of information about the current number of patients. The above impact assumes that only patients already receiving the drug would have continued to be funded by the system from 2017/18 with a natural annual reduction of c3 patients per year and an increase of c3 plus generic growth.

C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	**N/A**
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	This policy will be considered for investment at the November CPAG
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	The number of patients requiring the drug has been under estimated due to the lack of historic information.
C6.2 How can these risks be mitigated?	Close monitoring of actual patient numbers following the implementation of the policy will be required. The overall cost may reduce following a commercial in confidence review of the drug price.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	**N/A –** the cost impact only relates to the drug as all other costs remain unchanged.

<table>
<tr><td>C6.4 What scenario has been approved and why?</td><td>N/A – the number of patients expected to receive the drug has been based on clinical consensus due to the lack of historic patient numbers.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☒</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr>
</table>Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2"></td></tr>
</table>

C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	**NA**