**Latent Tuberculosis Infection (LTBI) Service Specification**

**For 01 April 2022 – 31 March 2023**

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| **Service** | Latent Tuberculosis Infection (LTBI) – Screening and Treatment Service  |
| **Rationale** | There has been a year-on-year decline in the rate of TB in London. Newham still has the highest numbers and rate in London (48 per 100,000, 2017) though this has reduced substantially in recent years. [[1]](#footnote-1)Screening of individuals from countries with high levels of TB and treatment of those found to have latent TB infections (LTBI) has been identified as one of the 10 key priority areas in PHE’s Collaborative TB Strategy – to systematically implement new entrant Latent TB screening. |
| **Aim** | This service aims to reduce the rate of TB in Newham by:* Offering screening to eligible patients
* Offering counselling and treatment to all patients with LTBI
* Improving the early detection and diagnosis of TB
* Improving the way services are commissioned
* Improving quality of care and value for money

This service also aims to counsel and screen for active TB and other risk factors for those people who already have a positive IGRA.  |
| **Delivery**(please refer to attached LTBI Appendices) | The Primary Care Network will ensure that the service is delivered according to the following standards:1. **New Patients offer of LTBI screening**

Staff undertaking a new patient health check will identify patients meeting the following criteria:* aged 16-35
* not previously been tested or treated for TB
* Come from the list of countries found in appendix 1 and have been in the country less than 5 years

They will explain why the test is being offered and give written information to the patients. Public Health England (PHE) has published LTBI screening and treatment leaflets in English and 11 other languages. These are available at <https://www.gov.uk/government/publications/latent-tb-testing-and-treatment-leaflet> and can be printed for the patients.Patients will be informed that information on their LTBI screening and treatment will be shared with PHE as part of the national programme to enable essential national surveillance and monitoring of programme effectiveness. The practice will ensure that the PHE consent box is ticked on the new patients EMIS template. **IGRA (+HIV) LTBI 2019 test request form V4 (NH)..rtf**. as from April 2019* All LTBI blood samples will be tested for IGRA and HIV.
* The **TWO TUBES** (1x green top and 1x gold top) must be correctly filled and contain at least 6mL of whole blood in each.
* Collect whole blood into the gold top tube, DO NOT mix by inversion and allow to clot.
* Collect whole blood into the Lithium Heparin tube (green top), mix by gentle inversion
* The sample **must** be transported at room temperature (**17°C – 27°C**), a lower temperature may result in indeterminate results. **DO NOT REFRIDGERATE**.
* The samples **must** arrive at SWLP, St Georges within 16 hours of collection

Patients will be informed that they will be called with the result. All patients with a positive IGRA are required to have a chest x-ray and the following blood tests: FBC, U&Es, LFTs, CRP, Hepatitis B Serology (Surface Antigen – HbsAg) and Hepatitis C Serology (anti-HCV).The HCA/Nurse LTBI Lead will be responsible for:* Completing the EMIS LTBI/TB template prior to testing
* Offering IGRA testing to all eligible patients
* Ensuring that all IGRA results (negative and positive) are filed in EMIS
* Communicating all positive results to patients
* Ensuring that all IGRA positive patients attend for additional blood tests and a CXR
* Booking an appointment for all IGRA positive patients with a GP after the above tests and checking the patient has attended.
* Checking that patients who have seen the GP LTBI Lead and agreed to start treatment attend an accredited pharmacy.

The GP LBTI lead will be responsible for:* Seeing all patients who are IGRA positive.
* Checking the CXR result and all blood tests.
* Issue Rifinah and Pyridoxine prescription via EPS only (as a 3-month batch prescription). Please do NOT give prescriptions/tokens to the patient.
* Ensure the patient has nominated an accredited pharmacy for LTBI treatment (see list in EMIS)
* Provide patient with an LTBI appointment card completing the patient and pharmacy details

For more information see “**Latent Tuberculosis Infection Screening Programme Checklist**”. The staff member will provide the patient with the blood form, LTBI information leaflets and information on local phlebotomy services. Pregnant and breastfeeding women should be offered IGRA testing if eligible. If these patients are IGRA positive, they should be seen by a GP to exclude active TB. Please note: CXRs should not be performed in pregnant or breastfeeding women. These patients should be offered a CXR once they have delivered and completed breastfeeding. Results of tests will be sent via lab-in link from the Laboratory and the practice will file the results in patients’ EMIS records. The practice will attempt to contact those who do not attend for a blood test a further 2 times.Those with a positive IGRA and HIV will be invited to the practice for a consultation at which the GP will discuss the result. 1. **Existing Registered patients offer of LTBI screening**

Two searches developed by the Clinical Effectives Group (CEG) will enable practices to identify existing patients who may meet the eligibility criteria for LTBI screening, as for new patients. 1. **Existing Eligible Patients.** This will search based on Age, Country of Birth, date of entry to UK AND not offered or declined LTBI testing. This should identify all patients who ARE eligible for IGRA testing. This group should be contacted and offered testing. Update EMIS accordingly.
2. **Existing Potentially Eligible Patients:** This will search based on Age, Country of Birth BUT not date of entry to UK. This search is important because many potentially eligible patients across Newham do not have a date of entry to the UK coded within their EMIS patient record. This search will provide a list of patients that MAY be eligible for LTBI screening. This group should be contacted and asked for their year of entry and if eligible offered testing. Update EMIS accordingly.

The practice will contact patients by telephone, to verify that they meet screening criteria and encourage them to take the IGRA test. Staff should explain what will happen if the result is negative/positive: they will be called attend for a CXR, additional blood tests (see above) and a GP consultation to discuss treatment if they are IGRA positive. They will reassure the patient that if they have latent TB they are not infective, for example, no one else in their household will need to be screened automatically unless they meet the criteria for LTBI screening anyway. The practice will record if the patient has agreed to take up the offered screening. If the patient is not contactable by phone the practice should send a letter or text with all the relevant information to the patient.A letter should then be posted with information on why it is important to be screened and enclose the relevant blood form with information on the closest phlebotomy service. Alternatively, the patient may wish to pick up all correspondence from the practice receptionist.The practice will attempt to contact the patients if no blood results are received in 2 weeks a further 2 times.**Following the above two pathways if IGRA positive blood test:*** If a patient is also positive for Hepatitis B, C or HIV the patient will be invited for a consultation and the results explained and a relevant referral made to specialist services for Hepatitis B, C or HIV.
* Those with a positive IGRA will be invited to the practice for a consultation.
* All patients with a positive IGRA are required to have a chest x-ray (unless they have had one performed within the 3 months prior to review) and the following blood tests: FBC, U&Es, LFTs, CRP, Hepatitis B Serology (Surface Antigen – HbsAg) and Hepatitis C Serology (anti-HCV).
* The GP will use the EMIS treatment template to record their assessment, taking a history and performing a physical examination of the chest and palpating for lymphadenopathy to exclude active TB. The GP then decides if the patient is suitable for community management or has a risk factor(s) or complicating factor(s) that require referral to secondary care, such as positive HIV serology.
* If the patient has symptoms suggestive of active TB, abnormal results or is high risk for treatment they will be referred to Newham TB Services with all the necessary results using e-Referal service where they will be treated by the TB team.
* If they are low risk for treatment the GP will explain that treatment of their LTBI is recommended and discuss their options. The GP will emphasise that side effects are uncommon and can be managed if they occur.
* When a patient agrees to treatment the GP will:
	+ Offer the patient the list of accredited community pharmacists ([**Appendix 2**](#Appendix2)) and ask them to choose which will provide them with treatment for LTBI.
	+ Issue the patient with an appointment card and write the name of the accredited pharmacy on the card. DO NOT give the patient a green prescription token or form.
	+ Inform the patient that they will have an LFT done 2 weeks after starting treatment and that the GP will share the results with the pharmacy.
	+ The GP will issue a 3-month batch prescription, for Rifinah (Rifampicin and Isoniazid) and Pyridoxine using EPS repeat dispensing (dosages can be found by following the link in [**Appendix 5**)](#Appendix5)
* Once treatment has commenced the pharmacist will document all activities in Webstar Health online. Webstar Health are contracted to inform GP practices when one of their patients has commenced and completed treatment. This must be coded in EMIS. All patients will have an LFT at 2 weeks initiated by the pharmacist who is monitoring treatment and results will go directly to practice.
1. **Patient Treatment**

When a patient starts treatment the pharmacy PharmOutcomes Health system will generate relevant emails/notifications that would be sent to the practice to inform them of treatment outcomes. The emails/notifications will also have the relevant EMIS codes which are listed below:* EMIS NQ TB3- Started Treatment
* EMIS NQ TB2- Declined Treatment
* EMIS NQ TB1- Completed Treatment
* EMIS NQ TB4- Terminated treatment due to side effects
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| **Eligibility and Exclusions** | Eligibility:* Must be registered with a Newham practice, fit the criteria for LTBI screening and have a positive IGRA for treatment.

Exclusions: Not registered with Newham GP. |
| **Workforce Requirements** | The Primary Care Network must ensure that its providers meet the training and competency requirements set out in Schedule 5 Governance including:All staff performing LTBI screening and treatment programme should have completed LTBI E-module for Newham CCG as part of this contract.  |
| **Performance Indicators** |

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| **Activity** | **KPI description** | **Target uptake** |
| **1) Newly Registered Patients** | * Patient identified when they register and test offered with relevant leaflet whether they agree to take the test or not.
* If accepts, and no blood results seen within 2 weeks, then follow up a further 2 times to encourage uptake.
* Demographic data recorded to include – ethnicity and country of origin, date of entry into the UK, Negative or positive results, entered into the treatment template
 | 50% |
| **2) Registered Patients** | * Patient contacted and information given. Patient either accepts or declines.
* If no contact a letter is sent to the patient.
* If accepts and no blood results within 2 weeks then follow up a further 2 times to encourage high level of uptake
* Negative or positive results entered into the treatment template
 | 50% |
| **Consultation and Management of Positive IGRA Patients** |

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| **Activity** | **KPI description** | **Target** **Update** |
| **Management of IGRA positive patient** | * Patient screened for active disease or high risk for treatment complications using EMIS template and diagnostics results. If in any of these categories - refer to secondary care via email attaching all results etc.
* Patients meeting primary care treatment criteria are counselled and offered treatment – GP discuss accredited pharmacy of choice generate 3 monthly electronic prescription and fill out appointment card. GP communicates with accredited pharmacy to ensure patients attends pharmacy appointment
 | 60% |
| **Follow-up Appointment (GP)** | * As above, an extra appointment for face to face discussions for counselling and offering treatment, any concerns, and pharmacy and treatment discussions
 | 30% |
| **Chasing patient regularly (every month where appropriate) for treatment update**  | * Follow up by the practice (any HCP) over telephone or face to face to check if patient is attending the pharmacy to start treatment.
 | 45% |

**Essential requirement for payment**1. CEG Template: LTC and SNS Newham CEG template 2. Sections that must be completed for payment:* Demographic data including ethnicity and country of origin
* Date of first entry into the UK
* Patient offered screening
* Patient accepted screening or not (payment will be made even if patient did not take up the offer)
* Positive or negative IGRA documented
* Documentation of all blood results and x-rays including FBC, U&Es, LFTs, CRP, Hepatitis B Serology (Surface Antigen – HbsAg ) and Hepatitis C Serology (anti-HCV).
* Exclusion of TB and Risk Factors for Treatment section on symptoms, investigations and medication completed with abnormality thn referral made to hospital (completion + abnormality will trigger payment), recording any previous LTBI or TB Treatment
* Record of patient decision to be treated or not to accept treatment (deciding to not be treated will trigger payment)
* 3-month batch prescription on EPS repeat dispensing for Rifinah (Rifampicin and Isoniazid) and Pyridoxine
* Initiation of treatment at pharmacy coded in EMIS - ***this will initiate payment***
* Completion/Discontinuation of treatment at pharmacy coded in EMIS
 |
| **Applicable Standards** | 1. Latent TB Infection : Updated and consolidated guidelines for programmatic management – WHO

<https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/>1. Latent Tuberculosis Infection: A Guide for Primary Health Care Providers

 <https://www.cdc.gov/tb/publications/ltbi/diagnosis.htm> |



**Appendix 2**

**List of pharmacists and contact details**

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| **Pharmacies providing Latent TB service**  |
| No | **Name of Pharmacy**  | **Address** | **Postcode**  | **Telephone Number**  |
| 1 | Akro Pharmacy | 404 Katherine Road Forest Gate London  | E7 8NP | 020 8472 0461 |
| 2 | Beckton Pharmacy  | 11 Mary Rose Mall, Frobisher Road, London | E6 5LX | 020 7476 0243 |
| 3 | Blakeberry | 9 - 11 High Street South Eastham, London | E6 4EN | 020 8472 1943 |
| 4 | Church Rd Pharmacy | 30 Church Road, London | E12 6AQ | 0208 514 5155 |
| 5 | Crailmay | 70 Green St, London  | E7 8JG | 020 8472 2370 |
| 6 | Day Lewis | 17-19 Freemasons Road, Custom House, London | E16 3AR | 020 7476 2254 |
| 7 | Duncans Pharmacy  | 347 High St North, Manor Park, London | E12 6PQ | 020 8472 1555 |
| 8 | Frank Mays Pharmacy  | 30 Barking Road, London | E6 3BP | 020 8472 0601 |
| 9 | Jetsol Pharmacy  | The Hub, 123 Star Lane, Canning Town, London | E16 4PZ | 020 7476 1667 |
| 10 | Kalhan Ltd  | 75 Plashet Rd, London | E13 0QA | 020 8472 2118 |
| 11 | Mansons Chemist  | 15 Woodgrange Road, Forest Gate, London | E7 8BA | 020 8534 3212 |
| 12 | Rohpharm  | Unit 1 Opus studios, 212 Plaistow Road, London | E13 0AL | 020 8471 1040 |
| 13 | Sai Pharmacy  | 150-152 High St North, Eastham, London | E6 2HT | 0208 552 8955 |
| 14 | Vicarage Lane Pharmacy | 10 Vicarage Ln, London  | E15 4ES | 020 8555 1564 |

**Appendix 3**

**Treatment Protocol to be carried out by community pharmacists**

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| **Time (weeks)** | **Action** |
| **1** | Explain Diagnosis and rationale for treatmentCounsel for side effects – ensure those on oral/hormone implant contraceptives have access to alternative (barrier) contraception Issue 1 month of treatment and blood test form for LFTs to be done at 2 weeks |
| **2** | Patient attends for LFTs. |
| **4** | Pharmacist to check adherence and side effects (see [**Appendix 4**](#Appendix4) , the protocol for managing abnormal symptoms and LFT results) and complete the Webstar Health record.If no concerns - issue 1 month of treatment and send to practiceWhere no LFT results are available. Patients must be reminded to attend for blood tests. If the patient is asymptomatic, a full month of treatment may be issued whilst the patient attends for testing.  |
| **8** | Pharmacist to check adherence and side effectsIf no concerns - issue 1 month of treatment and send side-effects form to practice |
| **12** | Pharmacist to check adherence and side effects. If patient fails to attend, pharmacist to contact patient via telephone. Discharge and send side-effects form to practice confirming completion of treatment or incomplete if that is the case. |

**Appendix 4**

**Side Effects Protocol**

**Interactions with TB medications**

**Rifampicin**

Rifampicin is a potent hepatic enzyme inducer which accelerates the metabolism of several drugs, below is a list of interactions:

**Isoniazid**

**Side Effects Management Protocol**

ATT = anti-tuberculosis drugs (rifinah in this case)

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| **Side effects/ADRs** | **Action to take** |
| **Community pharmacists** | **GP** |
| **Pruritus** | Recommend antihistamines. Patient to continue ATT.Pharmacists to communicate this to GP | LFTs to be done. If Normal and itching subsides, patient to continue ATT.If itching continues, patient to be referred to GP for further assessment |
| **Mild Skin rash** | Refer to GP | LFTs to be done. Prescribe antihistamines and assess patient after a few days. If rash continues, reduce dose of ATTs/seek advice from secondary care |
| **Moderate Skin rash** | Refer to GP | Stop ATT, do LFTs and seek secondary care advice |
| **Severe skin rash** | Stop ATT and refer to Newham A&E, inform GP | Follow up A&E attendance |
| **Mild Paraesthesia** | Inform GP | Increase Pyridoxine to 50mg, |
| **Moderate to severe paraesthesia** | Stop ATT, refer to GP for assessment | Do LFTs. Assess patient. Seek secondary care advice |
| **Flu-like symptoms, malaise** | Stop ATT, refer to GP for assessment | Assess for other infections. Do LFTs. Seek secondary care advice |

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| **Gastrointestinal side-effects** |
| **Nausea but no vomiting**  | If nausea is of less than 2 days duration, continue ATT and seek GP advice  | Check LFT’s. Prescribe antiemetics |
| **Vomiting but otherwise well** | Stop ATT and refer to GP  | Prescribe antiemetics |
| **Severe vomiting, evidence of jaundice or dehydration**  | Stop ATT and refer to Newham A&E, inform GP | Follow up A&E attendance |
| **Abdominal pain, diarrhoea** | Stop ATT, refer to GP for assessment | GP to assess and seek advice from secondary care |

**Drug induced liver injury (DILI)**

Before starting anti-tuberculosis treatment (ATT) all patients will have had baseline LFTs and hepatitis B&C serology performed. If the patient has an abnormal baseline ALT, AST or bilirubin, they should be offered repeat LFTs in 2 weeks’ time. If baseline LFTs remain abnormal, patients should be referred to secondary care. Patients with risk factors for DILI should be referred to secondary care. These risk factors include:

1. Hepatitis B or C infection
2. Heavy alcohol use
3. Malnutrition or low serum albumin at baseline
4. Cirrhosis or any other chronic liver disease
5. Other concurrent potentially hepatotoxic medications

During ATT, DILI should be suspected in any patient that vomits, develops itching, develops jaundice or feels unwell after starting treatment. If this is the case LFTs should be checked.

The table below details how patients with elevated AST or ALT levels should be managed:

[http://www.journalofinfection.com/article/S0163-4453(10)00206-9/abstract](http://www.journalofinfection.com/article/S0163-4453%2810%2900206-9/abstract)

Liver Function Tests:

Prior to initiating LTBI therapy, all patients should have baseline LFTs with a repeat at 2 weeks after starting LTBI therapy.

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|  | LFTs(Please refer to Reference Range below) | Recommendations |
| Community Pharmacist | GP |
| LFTs at baseline | If results are abnormal  |  | Repeat LFTsConsider delaying LTBI therapyIf Repeat ALT≥ 82 in Men or ≥ 66 in Women OR bilirubin ≥ 42 (in either sex)Liaise with TB clinician |
| LFTsAfter2 weeks of LTBI Therapy | Normal | Continue with LTBI Therapy |  |
| Mild Elevation (Not Uncommon)If ALT is41-81 in Men33-65 in WomenOr Bilirubin < 42 (in either sex) | Continue with LTBI therapyAND Discuss with GP | Repeat LFTs weekly for two weeks, then two weekly until normal |
| If ALT≥ 82 in Men or ≥ 66 in WomenORbilirubin is ≥ 42 (in either sex) | Do not give LTBI therapyDiscuss with GP | Liaise with TB clinicianEither continue treatment with LFTs weekly for two weeks, then two weekly until normal or stop treatment; |
| If ALT is≥ 123 in Men or≥ 99 in Women | Do not give LTBI therapyDiscuss with GP | Refer to TB clinician urgently |
| If LFTs are not done  | In the absence of ANY side effects of medication, treatment can be continued while reminding patient to attend for LFT testing |  |

Reference Range (from Barts/Royal London Biochemistry Lab)

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| Blood Test | Sex | Normal Range | 2x Upper Limit of Normal (ULN) | 3x Upper Limit of Normal (ULN) |
| Bilirubin (µmol/L) | Women and Men | < 21 |  42 |  63 |
| Alanine Aminotransferase (ALT) (U/L) | Women | < 33 |  66 |  99 |
| Men | < 41 |  82 |  123 |

**Appendix 5**

**Rifinah (Rifampicin and Isoniazid) – dosages**

<http://nww.newhamccg.nhs.uk/primarycare/epc/Documents/LTBI%20protocol%2010020146-Final.doc>

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| **Adult patients <50kg** | **Adult patient >50kg** |
| Rifinah 150, 3 tablets daily(Total dose: Isoniazid 300mg, Rifampicin 450mg daily)Pyridoxine 25mg once daily | Rifinah 300, 2 tablets daily(Total dose: Isoniazid 300mg, Rifampicin 600mg daily)Pyridoxine 25mg once daily |
| **Duration: 3 months** |

**Appendix 6**

**Exclusion of Active TB and Risk factors for treatment**

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| **Symptoms** | **Result** | **Action** |
| Cough | Present/Absent | If any one symptom present for <3 weeksreview as appropriate.If any one symptom present for >3 weeks or more consider urgent referral for possible active TB. |
| Fever | Present/Absent |
| Night Sweats | Present/Absent |
| Weight Loss | Present/Absent |
| **Physical Examination** |
| Chest | Normal/Abnormal |
| Lymphadenopathy | Present/Absent |
| Pulse | Normal/Abnormal |
| **Investigations** |
| CXR | Abnormal/Normal | If abnormal refer as appropriateIf raised/positive refer to secondary care, see below. |
| FBC | Abnormal/Normal |
| CRP | Abnormal/Normal |
| LFTs | Abnormal/Normal |
| U+Es | Abnormal/Normal |
| HIV | Positive/Negative |
| Hepatitis B | Positive/Negative |
| Hepatitis C | Positive/Negative |

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| **Medication and history making patient high risk of drug-induced liver injury (DILI)** |
| Rifinah will lower the concentration of some drugs and increase the concentration of others. Please refer to BNF- interactions.Hepatitis B or C infection.Epilepsy.Malnutrition or low serum albumin at baseline.Cirrhosis or any other chronic liver disease.Other concurrent potentially hepatotoxic medications. | Yes/No | If on any of these medications patient should be referred to secondary care for treatment |
| High alcohol consumption  | Yes/No | Please discuss with secondary care for management advice. |
| **Risk factors for treatment** |
| Any form of contraceptive pill | Yes/No | If yes – this does not affect treatment recommendation but the patient must be counselled on the need for an alternative (barrier) form of contraception during the 3 months’ treatment. |

1. Tuberculosis in London: Annual review (2015 data) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/484927/Annual_review_of_tuberculosis_in_London_2014_data.pdf> [↑](#footnote-ref-1)