Division of Public Health
Curtis State Office Building
1000 SW Jackson St., Suite 300
Topeka, KS 66612-1368

Kansas Department of Health and Environment

Phone: 785-296-1086
www.kdheks.gov

Lee A. Norman, M.D., Secretary

Laura Kelly, Governor

KDHE TB Prevention and Control

12-Dose Isoniazid-Rifapentine TB Infection Treatment Policy

Purpose: This policy describes the selection criteria for appropriate use of 12-Dose Isoniazid-Rifapentine (3HP) regiment for the treatment of Tuberculosis Infection. Furthermore, the policy outlines the process to be used in administration of the regimen as well as interventions to be conducted prior to, during and at completion of treatment.

Background: On December 9, 2011 the Centers for Disease Control and Prevention (CDC) released recommendations on the use of a new treatment regimen for tuberculosis (TB) infection. This new regimen, referred to as 3HP, represents a major advancement in preventing future cases of TB disease and puts us closer to our goal of TB elimination. The 12-dose regimen is a combination regimen of Isoniazid and Rifapentine given in 12 once-weekly doses under directly observed therapy (DOT). The 12-dose regimen reduces the required treatment for TB infection from 270 daily doses over 9 months to 12 once-weekly doses given over 3 months.

CDC's recommendations are a result of a recent large randomized control trial which found the 12-dose regimen to be as effective for preventing TB as other regimens. The new regimen is also more likely to be completed than the current U.S. standard regimen of 9 months of daily isoniazid given without directly observed therapy. Two additional studies also found the 3HP regimen to be as effective as other regimens in preventing new cases of TB disease. The 3HP regimen does not replace other recommended TB infection treatment regimens; the 3HP regimen is another effective regimen.

The 3HP regimen is NOT recommended for:

- Children younger than 2 years of age,
- People with HIV/AIDS who are taking anti-retroviral therapy,
- Pregnant women or women who expect to become pregnant during treatment, and
- People who are presumed to have been infected with isoniazid-resistant or rifampin-resistant *M. tuberculosis*.

The preferred regimen for children aged 2 to 11 years old is 4 months of daily rifampin.

Medication cost for the new regimen at current Public Health discounted pricing is more than 8 times higher than the most commonly used nine month INH regimen. Cost, however, should not be the only consideration because completion of treatment for TB Infection, especially those at greatest risk for developing TB Disease within their lifetime is the most important factor. Often times, those at greatest risk are also those more likely to not complete treatment under the traditional treatment regimens. The cost of treating an Active TB case which is drug susceptible is estimated to be $17,000 while the cost of treating a multi-drug resistant case of Active TB may be $250,000 or higher.

Policy: Prior to consideration of using any regimen to treat TB Infection, TB Disease must be properly ruled out through use of appropriate diagnostic tools such as Mantoux skin test or IGRA

tests, normal chest radiograph, sputum smear and culture results or other tissue smear and culture results and trained provider diagnosis. Note, IGRAs may be required of some candidates. If unfamiliar, inexperienced or unsure of TB diagnosis criteria, expert consultation should be sought through the Kansas Department of Health and Environment TB Prevention and Control Program.

Highest priority populations for use of the 3HP regimen should be targeted to the following groups:

- Recent contacts of active cases.
- High risk patients who may not be in the same county for 9 months.
- High risk patients who have doubtful compliance for a 9 month program.
- Patients who need to start immune-suppressants as soon as LTBI treatment is completed.
- Patients in whom a medical treatment, surgery, or some other important intervention is dependent on completing LTBI.
- Patients considered high risk who are a flight risk.
- Patients who are abusing alcohol or other substances.

Treatment medications will be provided free of charge from the KDHE through local health departments and other licensed providers who agree to full compliance with this policy. Directly Observed Therapy of EVERY dose of treatment is absolutely required. This must be agreed to by the provider and patient prior to starting treatment.

To use this regimen through the KDHE, complete the *Request for Anti-Tuberculosis Mediations* form located under the forms tab on the KDHE Tuberculosis Control Program Website (https://www.kdheks.gov/tb/forms.html). KDHE reserves the right to deny request for reasons such as: patient not being in the high priority population list, patient not being at risk based on CDC guidelines, unwillingness of provider or patient to comply with DOT requirement or lack of resources to provide the medications.

Once approved for the state supplied regimen, it is expected that the CDC guidelines for best practice be followed. These guidelines are available in the Morbidity and Mortality Weekly published by the CDC on December 9, 2011. For the state supplied regimen, laboratory testing must be taken at baseline (prior to dose one) only if the patient meets high risk criteria as defined by a medical provider or the *Core Curriculum on Tuberculosis: What the Clinician Should Know*, 7th edition as published by the CDC in 2021 and as ordered by a medical provider during treatment. If HIV status is not documented through testing of twelve months prior or less, an HIV test should be completed at baseline.

Patients are to be educated about the potential side effects of the regimen and instructed to seek medical attention upon the first symptom of a possible adverse event. Providers must maintain and submit upon completion of treatment the *KDHE 3HP DOT Log Form* and *KDHE Anti-TB Medication Adverse Event Episode Report* when applicable. Forms should be faxed to 785-559-4224. Programmatic or policy questions may be directed to the TB Controller at 785-296-8893.

12-Dose Isoniazid-Rifapentine Latent TB Infection Treatment - DIRECTLY OBSERVED THERAPY LOG

Epitrax/CMR Number: _____

Patient Name: _____ **Date of Birth:** _____

Initial Weight: _____**kg OR** _____**lbs.** **Dose:** _____ mg **INH** _____ mg **RPT**

Please check symptom boxes only if the client complains of that symptom. Check "No Adverse Reaction" if there are no symptoms.

Please check one of the following upon completion & Fax completed form to 785-559-4224:

Final Disposition: ☐ Completed Treatment ☐ Stopped Treatment ☐ Adverse Event ☐ Lost to f/u ☐ Moved ☐ Other

Treatment Completion Date: _____

Date (MM/DD)												
Dose Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Loss of Appetite	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Nausea or Vomiting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Yellow eyes or skin	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diarrhea	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Rash or Hives	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fever or Chills	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sore muscles	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Numbness or Tingling	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dizziness/Fainting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Abdominal pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other _____	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

No Adverse Reaction												
Rx Stopped or Held (complete Adverse Event Log)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Current Weight												
Blood Pressure												
Provider Initials*												

*Printed name for initial: _____ _____ / _____ _____ / _____ _____

initials Printed name initials Printed name initials Printed name

Clear