OPTIMA HEALTH PLAN

PHARMACY/MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Pretomanid

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Intial Authorization: 26 weeks

- ❑ The provider is an infectious disease specialist or a pulmonologist

AND

- ❑ The patient has a diagnosis of pulmonary extensively drug resistant (XDR), or treatment-intolerant, or nonresponsive multidrug-resistant tuberculosis, NOT due to latent or extra-pulmonary infection due to Mycobacterium tuberculosis **(Please submit chart note notes to include medical history and molecular/phenotypic diagnostics for detection of drug resistance)**

AND

- ❑ The patient had a chest x-ray consistent with pulmonary tuberculosis **(Please submit medical chart note notes)**

AND

- ❑ Patient age ≥ 17 years old

AND

- ❑ The patient's condition has been non-responsive to isoniazid, rifamycins (such as rifampin), pyrazinamide, ethambutol, a fluoroquinolone (such as levofloxacin) AND an injectable (such as amikacin) **(Please submit pertinent medication history and medical chart notes)**

AND

- ❑ The patient been non-responsive to the best available regimen for at least 6 months

OR

- ❑ The patient is intolerant or a contraindication with any of the following: para-amino salicylic acid, ethionamide, aminoglycosides (such as amikacin), or fluoroquinolones (such as levofloxacin)

AND

(Continued on next page)

- ❑ Pretomanid will be taken in combination with bedaquiline (Sirturo®) and linezolid (Zyvox®) as part of the recommended dosing regimen, and will be administered by directly observed therapy (DOT)

AND

- ❑ Prior to initiating combination therapy, the provider will monitor pertinent laboratory measures and assess for signs of liver injury, myelosuppression, and QT prolongation

Reauthorization Approval: 26 Additional Weeks. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ The patient's infection of Mycobacterium tuberculosis requires further treatment (i.e. culture negative status was not observed at 6 months) **(Please submit medical chart notes, culture results after initial 6 months treatment)**

AND

- ❑ Pretomanid will be taken in combination with bedaquiline (Sirturo®) and linezolid (Zyvox®) as part of the recommended dosing regimen - unless linezolid was discontinued after the first 4 weeks of consecutive treatment, then bedaquiline and pretomanid must be continued concomitantly

AND

- ❑ The provider will continue to monitor pertinent laboratory measures and assess for signs of liver injury, myelosuppression, and QT prolongation

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 4/16/2020
REVISED/UPDATED: 6/11/2020;