Pharmacy Medical Necessity Guidelines

Sirturo™ (bedaquiline)

Effective: 8/27/14

Clinical Documentation and Prior Authorization Required | ✓ | Type of Review – Case Management
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Not Covered | | Type of Review – Clinical Review
Fax: 617-673-0988 | ✓ |
Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review
RxFUM

OVERVIEW

FDA-APPROVED INDICATIONS

Sirturo (bedaquiline) is indicated as part of combination therapy in adult patients (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo should be reserved for use when an effective treatment regimen cannot otherwise be provided.

MDR-TB is a form of TB that is resistant to at least two of the primary drugs (isoniazid and rifampin) used for the treatment of TB. Resistance to one or more several forms of treatment occurs when the bacteria develops the ability to withstand antibiotic attack and relays that ability to its offspring. Resistance can spread from one person to another since the entire strain of bacteria inherits the capacity to resist the effects of the various treatments. Inadequate treatment or improper use of the anti-TB medications remains an important cause of MDR-TB in HIV-infected patients is extremely concerning since immunosuppressed individuals have higher susceptibility to not only acquiring MDR-TB but also to rapid disease progression, which may lead to rapid disease progression, which may lead to rapid transmission to other immunosuppressed patients.

Currently, there are ten drugs approved by FDA for treating TB in addition to Sirturo (Capastat, Isoniazid, Myambutol, Paser, Priftin, Pyrazinamide, Rifadin [rifampin], Rifamate, Rifater, Seromycin [no longer marketed in US], Streptomycin, Trecator). Of the approved drugs, isoniazid, rifampin, Myambutol, and pyrazinamide are considered first-line anti-TB agents and form the core of initial treatment regimens for active TB. Priftin (rifapentine) may also be considered first-line agent under specific situations. Additionally, there are two combination products, Rifamate (isoniazid/rifampin) and Rifater (isoniazid/pyrazinamide/rifampin) which are also approved for the treatment of TB.

World Health Organization (WHO) guidelines for the management of MDR-TB recommend that treatment regimens should be based on the history of drugs taken by the patients, taking into account the drugs and regimens commonly used in the country and the prevalence of resistance to first-line and second-line drugs. Drug regimens should consist of at least four drugs with either certain or almost certain effectiveness, based on drug susceptibility testing. Often, more than four drugs may be started if the susceptibility pattern is unknown, if effectiveness is questionable or if extensive, bilateral, pulmonary disease is present.

Sirturo should be administered under directly observed therapy (DOT). Sirturo should only be used in combination with at least three other drugs to which the patient’s MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four other drugs to which the patient’s MDR-TB isolate is likely to be susceptible.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Sirturo™ (bedaquiline) for members when all of the following criteria for a particular regimen are met and limitations do not apply:

1. Documented diagnosis of pulmonary multi-drug resistant tuberculosis AND
2. The member is at least 18 years of age AND
3. Sirturo should only be used in combination with at least three other drugs to which the patient’s MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four other drugs to which the patient’s MDR-TB isolate is likely to be susceptible.
LIMITATIONS
None

CODES
None

REFERENCES

APPROVAL HISTORY
- June 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee
BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.