

Title: *telithromycin (Ketek)*

Origination: 08/01/07	Revised: 10/21/09	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Ketek is a semisynthetic antibacterial in the ketolide class, and is structurally related to the macrolide family of antibiotics. Ketek blocks protein synthesis by binding to the 23s subunit of the ribosome, and has activity against gram-positive cocci bacteria.
- Ketek is indicated for the treatment of community-acquired pneumonia, of mild to moderate severity, due to *Streptococcus pneumoniae* (including multi-drug resistant isolates of *Streptococcus pneumoniae*), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae* or *Mycoplasma pneumoniae*.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Background Information, continued:

Exclusions

- Member less than 18 years of age.
- Member with a diagnosis or history of Myasthenia Gravis.
- Member with previous history of hepatitis and/or jaundice associated with the use of Ketek or any macrolide antibiotic.
- Member with a history of hypersensitivity to Ketek or any of its excipients, or any macrolide antibiotic.
- Concomitant administration of Ketek with cisapride or pimozide.
- Member with a diagnosis of congenital prolongation of QTc interval, or Member currently receiving Class IA (i.e., disopyramide, quinidine or procainamide) or Class III antiarrhythmic agents (i.e., dofetilide, amiodarone, or sotalol).

Procedure:

- 1.0 Request for Ketek requires documentation from the Member's medical records as maintained by the requesting independent practitioner verifying the following:
 - 1.1 Member has a diagnosis of community-acquired pneumonia of mild to moderate severity due to *Streptococcus pneumoniae* (including multi-drug resistant *Streptococcus pneumoniae*), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae* or *Mycoplasma pneumoniae*:
 - 1.1.1 Multi-drug resistant *Streptococcus pneumoniae* includes isolates known as penicillin-resistant *Streptococcus pneumoniae* and are isolates resistant to two (2) or more of the following antibiotics:
 - 1.1.1.1 Penicillin;
 - 1.1.1.2 Second generation cephalosporins (ex. cefuroxime, cefoxitin, cefotetan, cefaclor, cefprozil, cefpodoxime, loracarbef);
 - 1.1.1.3 Macrolides;
 - 1.1.1.4 Tetracyclines;
 - 1.1.1.5 Trimethoprim/Sulfamethoxazole;
 - AND**
 - 1.2 Culture and sensitivity results indicating bacteria susceptible to Ketek;
 - OR**
 - 1.2 Local epidemiology and susceptibility patterns for initiation of empiric therapy.
- 2.0 If all requirements are met, request may be approved as requested up to a maximum dose of 800mg once daily for 7-10 days.

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References:

1. Ketek (telithromycin) Prescribing Information. Sanofi-aventis U.S. LLC, Bridgewater, NJ. Updated June 2009
2. Clinical Pharmacology Online. 2009. <http://cpip.gsm.com/>.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.