Purpose:

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

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored, as indicated, via individual departmental audit process(es).

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

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, Chlamydophila pneumoniae or Mycoplasma pneumoniae.
Background Information, continued:

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.

Coverage Guidelines

- 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.

Exclusion Criteria

- 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).

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians are licensed by the State of Florida.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization  Number: 07.049

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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 pneumonia), Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae or Mycoplasma pneumoniae:

1.1.1 Multi-drug resistant Streptococcus pneumonia includes isolates known as penicillin-resistant Streptococcus pneumonia 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, cefpodoxine, 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;

1.3 If criteria are met, request may be approved as requested up to a maximum dose of 800mg once daily for 7-10 days.

References:
