RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Aemcolo belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. Aemcolo is used for the treatment of travelers’ diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E.coli*) in adults (1).

Regulatory Status
FDA-approved indication: Aemcolo is a rifamycin antibacterial indicated for the treatment of travelers’ diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults (1).

Limitations of Use:
Aemcolo is not indicated in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of *E. coli* (1).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Aemcolo and other antibacterial drugs, Aemcolo should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria (1).

The safety and effectiveness of Aemcolo in pediatric patients less than 18 years of age have not been established (1).

Summary
Aemcolo belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. Aemcolo is used for the treatment of travelers’ diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E.coli*) in adults. The safety and effectiveness of Aemcolo in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Aemcolo while maintaining optimal therapeutic outcomes.

References