BlueCross BlueShield Federal Employee Program

MYTESI
(crofelemer)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Mytesi (crofelemer) is an inhibitor of both the cyclic adenosine monophosphate (cAMP)-stimulated cystic fibrosis transmembrane conductance regulator (CFTR) chloride ion (Cl^-) channel, and the calcium-activated Cl^- channels (CaCC) at the luminal membrane of enterocytes. The CFTR Cl^- channel and CaCC regulate Cl^- and fluid secretion by intestinal epithelial cells. Mytesi acts by blocking Cl^- secretion and accompanying high volume water loss in diarrhea, normalizing the flow of Cl^- and water in the gastrointestinal tract (1).

Regulatory Status

FDA-approved indication: Mytesi is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy (1).

Other infectious etiologies of diarrhea should be ruled out prior to starting treatment with Mytesi to reduce the risk of inappropriate therapy and worsening of disease (1).

Women with HIV-1 should be instructed not to breastfeed due to the potential for HIV transmission (1).

The safety and effectiveness of Mytesi in pediatric patients have not been established (1).

Summary

Mytesi (Crofelemer) is an inhibitor of both the cyclic adenosine monophosphate (cAMP)-stimulated cystic fibrosis transmembrane conductance regulator (CFTR) chloride ion (Cl^-) channel, and the calcium-activated Cl^- channels (CaCC) at the luminal membrane of enterocytes. The CFTR Cl^- channel and CaCC regulate Cl^- and fluid secretion by intestinal epithelial cells. Mytesi acts by blocking Cl^- secretion and accompanying high volume water loss in diarrhea, normalizing the flow of Cl^- and water in the gastrointestinal tract. Other infectious etiologies of diarrhea should be ruled out prior to starting treatment with Mytesi to reduce the risk of inappropriate therapy and worsening of disease. The safety and effectiveness of Mytesi in pediatric patients have not been established (1).

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

References

1. Mytesi [package insert]. San Francisco, CA. Napo Pharmaceuticals, Inc. November 2020.