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5.50.029

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	March 12, 2021
Subject:	Mytesi	**Page:**	1 of 4

Last Review Date: June 13, 2024

Mytesi

Description

Mytesi (crofelemer)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Mytesi may be considered **medically necessary** if the conditions below are met.

Mytesi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Non-infectious diarrhea associated with HIV/AIDS

AND ALL of the following:

1. Patient is on anti-retroviral therapy (ART)
2. Other infectious etiologies of diarrhea have been ruled out
3. Patient has had an inadequate treatment response, intolerance, or contraindication to at least one anti-diarrheal medication such as diphenoxylate/atropine, loperamide, bismuth subsalicylate, etc.

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Non-infectious diarrhea associated with HIV/AIDS

AND ALL of the following:

1. Patient is on anti-retroviral therapy (ART)
2. Patient has experienced symptomatic relief since starting Mytesi

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 180 tablets per 90 days

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

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).

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.

Policy History

Date	Action
March 2021	Addition to PA
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.50.029
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.