

5.50.029

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|--------------------|-------------------------|------------------------------|----------------|
| <b>Section:</b>    | Prescription Drugs      | <b>Effective Date:</b>       | July 1, 2023   |
| <b>Subsection:</b> | Gastrointestinal Agents | <b>Original Policy Date:</b> | March 12, 2021 |
| <b>Subject:</b>    | Mytesi                  | <b>Page:</b>                 | 1 of 4         |

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**Last Review Date:** June 15, 2023

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## Mytesi

### Description

#### Mytesi (crofelemer)

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#### Background

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

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#### Related policies

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|--------------------|-------------------------|------------------------------|----------------|
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| <b>Subject:</b>    | Mytesi                  | <b>Page:</b>                 | 2 of 4         |

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## 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.

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### 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

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|--------------------|-------------------------|------------------------------|----------------|
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| <b>Subject:</b>    | Mytesi                  | <b>Page:</b>                 | 3 of 4         |

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## Policy Guidelines

### Pre-PA Allowance

None

### Prior-Approval Limits

**Quantity** 180 tablets per 90 days

**Duration** 12 months

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### 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<sup>-</sup>) channel, and the calcium-activated Cl<sup>-</sup> channels (CaCC) at the luminal membrane of enterocytes. The CFTR Cl<sup>-</sup> channel and CaCC regulate Cl<sup>-</sup> and fluid secretion by intestinal epithelial cells. Mytesi acts by blocking Cl<sup>-</sup> secretion and accompanying high volume water loss in diarrhea, normalizing the flow of Cl<sup>-</sup> 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.

# 5.50.029

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| <b>Subject:</b>    | Mytesi                  | <b>Page:</b>                 | 4 of 4         |

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## 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 |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.**