Seysara

Description

Seysara (sarecycline)

Background
Seysara (sarecycline) is a drug in the tetracycline class. The mechanism of action of Seysara in treating acne vulgaris is not known, but it is believed to be due in part to its antibacterial actions. Skin bacteria produce lipase that breaks down triglycerides present in sebum into free fatty acids, which are comedogenic and may be the cause of the inflammatory lesions of acne. Reduction in the number of lipase-producing bacteria or inhibition of lipase production are two possible mechanisms of tetracyclines (1).

Regulatory Status
FDA-approved indication: Seysara is a tetracycline-class drug indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older (1).

Seysara, like other tetracyclines, can cause fetal harm when administered to a pregnant woman. Pregnant patients should be informed of the potential hazard to the fetus and treatment should be stopped immediately (1).

Clostridium difficile associated diarrhea (CDAD) may occur with nearly all antibacterial agents. Treatment with antibacterial agents alters the normal flora of the colon leading to potential overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. CDAD must be considered in all patients who present with diarrhea following antibiotic use (1).
Seysara can also cause central nervous system side effects including light-headedness, dizziness, or vertigo. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery (1).

The safety and effectiveness of Seysara in pediatric patients below the age of 9 years have not been established (1).

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**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.

Seysara may be considered medically necessary in patients 9 years of age and older with moderate to severe acne vulgaris and if the conditions indicated below are met.

Seysara is considered investigational in patients less than 9 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

9 years of age and older

**Diagnosis**

The patient must have the following:

Moderate to severe acne vulgaris

**AND ALL** of the following:

1. Documented baseline evaluation of the condition using the Investigator’s Static Global Assessment (ISGA)
2. Inadequate treatment response, intolerance or contraindication to at least **ONE** medication in **EACH** of the following categories:
   a. Another tetracycline antibiotic
   b. Topical product for acne vulgaris

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**Prior – Approval Renewal Requirements**
Age 9 years of age and older

Diagnosis

The patient must have the following:

Moderate to severe acne vulgaris

1. Decrease from baseline by at least 2 points using the Investigator’s Static Global Assessment (ISGA)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 3 months

Prior – Approval Renewal Limits

Quantity 90 tablets per 90 days

Duration 9 months

Rationale

Summary

Seysara (sarecycline) is a drug in the tetracycline class. The mechanism of action of Seysara in treating acne vulgaris is not known, but it is believed to be due in part to its antibacterial actions. Skin bacteria produce lipase that breaks down triglycerides present in sebum into free fatty acids, which are comedogenic and may be the cause of the inflammatory lesions of acne. Reduction in the number of lipase-producing bacteria or inhibition of lipase production are two possible mechanisms of tetracyclines. The safety and effectiveness of Seysara in pediatric patients below the age of 9 years have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Seysara while maintaining optimal therapeutic outcomes.
Section: Prescription Drugs  
Subsection: Anti-Infective Agents  
Subject: Seysara  
Effective Date: April 1, 2019  
Original Policy Date: April 1, 2019

References

Policy History

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<td>April 2019</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on November 30, 2018 and is effective on January 1, 2019.