Zecuity

Description

Zecuity (sumatriptan iontophoretic transdermal system)

Background

The selective serotonin receptor agonists, or “triptans”, are a class of medications that have the ability to stop a migraine headache at its earliest signs. Triptans work by binding to serotonin receptors in the brain. By mimicking the actions of serotonin, triptans cause the blood vessels to constrict and prevent some nerves from transmitting signals to the brain, effectively blocking the pain associated with migraine headaches. Each triptan medication affects a slightly different number of serotonin receptors, but all work in a similar fashion (1). Zecuity is a battery-powered sumatriptan patch that uses an electrical current to transport the drug through the skin over four hours (2).

Regulatory Status

FDA-approved indication: Zecuity is a serotonin (5HT) 1b/1d receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults (2).

Limitations of Use: (2)

1. Use only after a clear diagnosis of migraine has been established.
2. Not intended for the prevention of migraine attacks

Zecuity has several contraindications, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as cerebrovascular stroke (2).
Excessive use of triptans can lead to medication overuse headache (MOH) (2).

Safety and effectiveness in pediatric patients have not been established (2).

**Related policies**
Amerge, Axert, Frova, Maxalt, Relpax, Sumatriptan, Zomig

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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.*

Zecuity may be considered *medically necessary* in patients 18 years of age or older for the treatment of migraines with aura (classic or classical) or without aura (common), that have inadequate response or are intolerant to nasal, and injected sumatriptan; inadequate response or intolerant to generic oral triptan; prescriber agrees to limit use to treatment of migraines that cannot be managed with patients primary medication; and none of the following: hemiplegic migraine, basilar migraine, cardiovascular disease, cerebrovascular disease and uncontrolled hypertension.

Zecuity is considered *investigational* in patients below 18 years of age and for all other indications.

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**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnoses**
Patient must have **ONE** of the following
1. Migraine, with aura (classic or classical)
2. Migraine, without aura (common)

AND **ALL** of the following:
1. Inadequate response or intolerant to nasal and injected sumatriptan
2. Inadequate response or intolerant to generic oral triptan
3. Physician agrees to limit use to treatment of migraines that cannot be managed with patients primary medication
**Section:** Prescription Drugs  
**Effective Date:** October 1, 2016  
**Subsection:** Analgesics and Anesthetics  
**Original Policy Date:** October 2, 2015  
**Subject:** Zecuity  
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AND NONE of the following:
- a. Hemiplegic migraine
- b. Basilar migraine

**Prior – Approval Renewal Requirements**

**Diagnoses**

Patient must have **ONE** of the following

1. Migraine, with aura (classic or classical)
2. Migraine, without aura (common)

AND ALL of the following:

1. Physician agrees to limit use to treatment of migraines that cannot be managed with patients primary medication

AND NONE of the following:
- a. Hemiplegic migraine
- b. Basilar migraine

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity** 4 patches per 90 days

**Duration** 6 months

**Prior – Approval Renewal Limits**

**Quantity** 4 patches per 90 days

**Duration** 6 months

**Rationale**
Summary
Zecuity is indicated for the acute treatment of migraine attacks with or without aura in adults. This medication is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar headaches. This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke (3).

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

References

Policy History

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<tbody>
<tr>
<td>October 2015</td>
<td>Addition to PA</td>
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<tr>
<td>March 2016</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>September 2016</td>
<td>Policy number changed from 5.02.46 to 5.70.46</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2016 and is effective October 1, 2016.

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