SPECIALTY GUIDELINE MANAGEMENT

ZECUITY (sumatriptan iontophoretic transdermal system)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Zecuity is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

- Use only if a clear diagnosis of migraine has been established.
- If a patient has no response to the first migraine attack treated with Zecuity reconsider the diagnosis of migraine before Zecuity is administered to treat any subsequent attacks.
- Zecuity is not intended for the prevention of migraine attacks.

All other indications are considered experimental/investigational and are not a covered benefit.

B. EXCLUSIONS

- Confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension
- Medication overuse headache

C. CRITERIA FOR APPROVAL

Authorization of 1 month may be granted for members who are prescribed Zecuity for the acute treatment of migraine headache (with or without aura) when ALL of the following criteria are met:

1. A clear diagnosis of migraine has been established
2. The member has had an inadequate treatment response after at least a 30 day trial of or is intolerant to at least TWO of the following generic oral triptan medications:
    a. naratriptan (Amerge)
    b. sumatriptan (Imitrex)
    c. rizatriptan (Maxalt)
    d. zolmitriptan (Zomig)
3. The member has had an inadequate treatment response after at least a 30 day trial of or is intolerant to BOTH of the following:
    a. sumatriptan (Imitrex) nasal spray
    b. sumatriptan (Imitrex) subcutaneous injection
4. The member is 18 years or age or older

D. CONTINUATION OF THERAPY

Authorization for 3 months may be granted to members (including new members) who are requesting authorization for continuation of therapy when the following criteria are met:

1. Member meets ALL initial authorization criteria listed in Section C.
2. Member has had a clinical response with Zecuity in the treatment of acute migraine

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. Dosing Limits

The following dosing limits apply:

- Four (4) Zecuity iontophoretic transdermal systems per 28 days

REFERENCES

1. Zecuity [package insert]. Malvern, PA: NuPathe Inc.; March 2014.
2. Snow V, Weiss K, Wall E, et al. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. *Ann Intern Med*. 2002;137(10):840-849.
3. Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine--revised report of an EFNS task force. *Eur J Neurol*. 2009;16(9):968-981.