SUMATRIPTAN  
(ALSUMA®, IMITREX®, SUMAVEL DOSEPRO®, ZECUITY®)  

UTILIZATION MANAGEMENT CRITERIA  

<table>
<thead>
<tr>
<th>DRUG CLASS:</th>
<th>Serotonin 5-HT1 receptor agonists</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND (generic) NAME:</td>
<td>Imitrex (sumatriptan), Alsuma (sumatriptan), Sumavel DosePro (sumatriptan), Zecuity (sumatriptan)</td>
</tr>
</tbody>
</table>

FDA-APPROVED INDICATIONS

Oral, nasal, subcutaneous, and transdermal sumatriptan products are indicated for the acute treatment of migraine with or without aura in adults. Sumatriptan injection is also indicated for the acute treatment of cluster headache episodes. The 5-HT1 agonists are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine.

RESTRICTED ACCESS COVERAGE AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>Restricted Access Triptans</th>
<th>Non-Restricted Access Triptans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alsuma (sumatriptan) auto-injector</td>
<td>Amerge (naratriptan) tablets</td>
</tr>
<tr>
<td>Axert (almotriptan) tablets</td>
<td>Imitrex (sumatriptan) tablets</td>
</tr>
<tr>
<td>Frova (frovatriptan) tablets</td>
<td>Imitrex (sumatriptan) nasal solution</td>
</tr>
<tr>
<td>Relpax (eletriptan) tablets (Restricted Access on Basic Open and Basic Closed Formularies only)</td>
<td>Imitrex (sumatriptan) injection</td>
</tr>
<tr>
<td>Sumavel DosePro (sumatriptan) jet-injector</td>
<td>Imitrex STATdose (sumatriptan) auto-injector</td>
</tr>
<tr>
<td>Treximet (sumatriptan/naproxen) tablets</td>
<td>Maxalt and Maxalt MLT (rizatriptan) tablets</td>
</tr>
<tr>
<td>Zomig (zomtriptan) nasal solution</td>
<td>Zomig and Zomig ZMT (zomtriptan) tablets</td>
</tr>
<tr>
<td>Zecuity (sumatriptan iontophoretic transdermal system)</td>
<td></td>
</tr>
</tbody>
</table>

For members on the Enhanced Formulary, before approval of a restricted access triptan is given, one non-restricted access triptan must be tried.

For members on the Basic Open Formulary, before approval of a restricted access triptan is given, up to two non-restricted access triptans must be tried.

For members on the Basic Closed Formulary, before approval of a non-formulary triptan is given, up to two formulary triptans must be tried.
QUANTITY LIMITATION EXCEPTION CRITERIA:
Coverage is provided if:

1. Patient has the diagnosis of moderate to severe migraine headache. Cluster headache is also an appropriate diagnosis for Imitrex Injection only. (Tension type and chronic daily headaches are **NOT** appropriate diagnoses.) **AND**

2. Patient has tried and failed at least two of the following abortive migraine therapy drug classes:
   - NSAIDS/COX-2 Inhibitor (Ex. ibuprofen, naproxen, diclofenac, celecoxib, etc.)
   - Acetaminophen (Tylenol)
   - Ergotamine-containing products (Ex. Cafergot, Ergomar, etc.)
   - Isomethypentene/dichloralphenazone/acetaminophen (Ex. Midrin, etc.) **AND**

3. If the patient experiences > 4 migraine headaches per month, prophylactic therapy (Ex. Amitriptyline, nortriptyline, topiramate, propranolol, divalproex) should have been given an adequate trial of at least 2 – 3 months, **AND**

4. The possibility of medication-induced, rebound or chronic daily headache has been considered and ruled out.

* Coverage of Imitrex, Alsuma, Sumavel DosePro, or Zecuity is not provided for use in combination with another triptan (e.g. Zomig, Axert, Maxalt, Frova, Relpax) or an ergotamine (e.g. Migranal, Cafergot) due to the possibility of increased blood pressure effect.

### QUANTITY LIMITATIONS

<table>
<thead>
<tr>
<th>EXTENDED SUPPLY</th>
<th>2700 mg per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alsuma injection 6 mg</strong></td>
<td>24 systems</td>
</tr>
<tr>
<td><strong>Sumatriptan tablets 100 mg</strong></td>
<td>27 tablets</td>
</tr>
<tr>
<td><strong>Sumatriptan tablets 50 mg</strong></td>
<td>54 tablets</td>
</tr>
<tr>
<td><strong>Sumatriptan tablets 25 mg</strong></td>
<td>108 tablets</td>
</tr>
<tr>
<td><strong>Sumatriptan inj kits/refills 4 mg (8 mg/ml)</strong></td>
<td>12 kits (24 injections)</td>
</tr>
<tr>
<td><strong>Sumatriptan inj kits/refills 6 mg (12 mg/ml)</strong></td>
<td>12 kits (24 injections)</td>
</tr>
<tr>
<td><strong>Sumatriptan nasal 20 mg</strong></td>
<td>27 devices</td>
</tr>
<tr>
<td><strong>Sumatriptan nasal 5 mg</strong></td>
<td>108 devices</td>
</tr>
<tr>
<td><strong>Sumavel DosePro</strong></td>
<td>24 systems</td>
</tr>
<tr>
<td><strong>Zecuity patch</strong></td>
<td>24 patches</td>
</tr>
</tbody>
</table>

* Tablet equivalents do not imply exact therapeutic equivalents. One injection ~ 20 mg nasal spray ~ 100 mg oral dosage; 5 mg nasal spray ~ 25 mg tablet.

If the patient is requiring amounts in excess of these numbers, please follow the quantity limitations criteria for sumatriptan.
DOSED AND ADMINISTRATION:
The recommended dose is 4 or 6 mg as a subcutaneous injection; 6 mg as a needle-free subcutaneous delivery; 5, 10 or 20 mg as an intranasal solution; or 25, 50, or 100 mg as an oral dose taken with fluids as soon as possible after the onset of symptoms, but can be given anytime during the migraine attack without a change in efficacy. The oral dose used in the majority of the published clinical studies has been 100 mg; however, the manufacturer states there is no evidence that an initial dose of 100 mg provides substantially greater relief than 50 mg. If the patient responds, but satisfactory relief is not obtained within 2 hours, a second dose of up to 100 mg can be given. Treatment can be repeated up to a maximum of two subcutaneous injections (up to 12 mg/day), two intranasal doses (up to 40 mg/day) and two oral doses (up to 200 mg/day) per 24-hour period with a minimum of 1 hour between subcutaneous doses and 2 hours between nasal doses and oral doses. If no relief is experienced after the initial dose, a second dose should not be administered. The first dose of the medication (oral, nasal or subcutaneous injection) should be given in a physician’s office or medical clinic if there is a risk of coronary artery disease (CAD). In recognizing that patients with cluster headaches are predominantly male and over 40 years of age, which are risk factors for CAD, it is recommended that patients who are intermittent users of sumatriptan injection should undergo periodic cardiovascular evaluation.

Zecuity: Single Zecuity transdermal system (TDS) applied to dry, intact, non-irritated skin of upper arm or thigh. No more than two Zecuity should be used in any 24-hour period; second TDS should be used no sooner than 2 hours after activation of first TDS. Zecuity TDS should not be applied to a previous application site until that site remains erythema free for at least 3 days.

WARNINGS AND PRECAUTIONS:
- Do not use with ergotamine-containing or ergot-type products or within 2 weeks of an MAO-A inhibitor.
- Do not use in patients with ischemic heart disease or uncontrolled blood pressure.
- Do not use as a prophylactic agent.
- Give only where diagnosis of migraine (or cluster headache for injection) is clearly established.
- Patient should have a successful trial of sumatriptan in the medical office or emergency room to identify efficacy or possible side effects.
- Contraindications to the use of 5-HT1 agonists: pregnancy, peripheral vascular disease (i.e., thromboangitis, leuetic arteritis, Raynaud's Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, coronary artery disease, or uncontrolled hypertension.

REFERENCES:


REFERENCES SUPPORTING AVERAGE NUMBER OF MIGRAINE ATTACKS PER MONTH:


17. Eur Neurol 1996; 32 (suppl 2): 24-7 (n=606) – 2.9-3.2 per month.


GENERAL REFERENCES:


**POLICY IMPLEMENTATION/UPDATE INFORMATION**

September 2015: Added new to market triptan, Zecuity, to criteria.