SUMATRIPTAN (IMITREX®, ALSUMA® and SUMAVEL DOSEPRO®) UTILIZATION MANAGEMENT CRITERIA

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

**FDA INDICATIONS:**
- Oral, nasal, and subcutaneous 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.

For members on the Basic Open Formulary, before approval of a nonpreferred agent is given, up to two preferred agents must be tried. Please consult the formulary list as these agents may change over time.

<table>
<thead>
<tr>
<th>QUANTITY LIMITATIONS</th>
<th>SHORT TERM (<em>Tablet or Tablet Equivalent</em>)</th>
<th>EXTENDED SUPPLY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>900 mg per 30 days</td>
<td>2700 mg per 90 days</td>
</tr>
<tr>
<td>Sumatriptan tablets 100 mg</td>
<td>9 tablets</td>
<td>27 tablets</td>
</tr>
<tr>
<td>Sumatriptan tablets 50 mg</td>
<td>18 tablets</td>
<td>54 tablets</td>
</tr>
<tr>
<td>Sumatriptan tablets 25 mg</td>
<td>36 tablets</td>
<td>108 tablets</td>
</tr>
<tr>
<td>Sumatriptan inj kits/refills 4 mg (8 mg/ml)</td>
<td>4 kits (8 injections)</td>
<td>12 kits (24 injections)</td>
</tr>
<tr>
<td>Sumatriptan inj kits/refills 6 mg (12 mg/ml)</td>
<td>4 kits (8 injections)</td>
<td>12 kits (24 injections)</td>
</tr>
<tr>
<td>Sumatriptan nasal 20 mg</td>
<td>9 devices</td>
<td>27 devices</td>
</tr>
<tr>
<td>Sumatriptan nasal 5 mg</td>
<td>36 devices</td>
<td>108 devices</td>
</tr>
<tr>
<td>Sumavel DosePro</td>
<td>8 systems</td>
<td>24 systems</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.
QUANTITY LIMIT 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 other abortive migraine therapies.
   Examples of medications used for abortive therapy include:
   a. Diclofenac (Voltaren®)
   b. Ergotamine-containing products (Cafergot, Wigraine, Ergomar, etc.)
   c. Flurbiprofen (Ansaid®)
   d. Ibuprofen (Motrin®)
   e. Isometheptene/Dichloralphenazone/Acetaminophen (Midrin,etc.), **AND**
3. If the patient experiences > 4 migraine headaches per month, prophylactic therapy should have been given an adequate trial, **AND**
4. The possibility of medication-induced, rebound or chronic daily headache should be considered.

* Coverage of Imitrex, Alsuma, or Sumavel DosePro 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.

DOSAGE 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 12mg/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.

WARNINGS AND PRECAUTIONS:

- Do not use with ergotamine-containing or ergot-type products or within 2 weeks of an MAO-A inhibitors.
- 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, leucitic arteritis, Raynaud’s Syndrome, thrombophlebitis, arteriosclerosis), hepatic or renal impairment, coronary artery disease, or uncontrolled hypertension.

DRUG INTERACTIONS:

- Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because there is a theoretical basis that these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine) and 5-HT1 agonists within 24 hours of each other should be avoided.
- MAO-A inhibitors increase the systemic exposure of the 5-HT1 agonists and concomitant use is contraindicated.
- Concomitant use of more than one 5-HT1 agonist within 24 hours of each other is not recommended.
- Selective serotonin reuptake inhibitors (SSRIs) have been reported to cause weakness, hyperreflexia, and incoordination when coadministered with 5-HT1 agonists.

REFERENCES:


REFERENCES SUPPORTING AVERAGE NUMBER OF MIGRAINE ATTACKS PER MONTH:


GENERAL REFERENCES: