Clinical Pharmacy Program Guidelines for Triptans- ARIZONA

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Triptans</td>
</tr>
<tr>
<td>Markets in Scope</td>
<td>Arizona</td>
</tr>
</tbody>
</table>

1. Background:

FDA Approved Indications:

a. Amerge (naratriptan), Frova (frovatriptan), Imitrex/Imitrex Nasal Spray (sumatriptan), Relpax (eletriptan), Zomig/Zomig Nasal Spray (zolmitriptan), Zomig-ZMT (zolmitriptan orally-disintegrating tablet), Sumachip (sumatriptan and capsaicin-menthol), Zembrace SymTouch (sumatriptan injection), Onzetra Xsail (sumatriptan nasal powder), Sumavel DosePro (sumatriptan injection):

- **Migraine Headaches:** Indicated for the acute treatment of migraine with or without aura in adults. Not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness have not been established for cluster headache, which is present in an older, predominantly male population.

b. Axert (almotriptan):

- **Migraine Headaches for adults:** Approved for the acute treatment of migraine with or without aura in adults.
- **Migraine Headaches for adolescents:** Indicated for adolescents, age 12 to 17 years, for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated) [2]. Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

c. Maxalt (rizatriptan), Maxalt-MLT (rizatriptan orally-disintegrating tablet):

- **Migraine headaches:** Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: “Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first...
migraine attack treated with MAXALT, the diagnosis of migraine should be reconsidered before MAXALT is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of MAXALT have not been established for cluster headache.

d. **Treximet (sumatriptan/naproxen)**
   - **Migraine Headaches:** Indicated for the acute treatment of migraine attacks with or without aura in adults. Carefully consider the potential benefits and risks of Treximet and other treatment options when deciding to use Treximet. Treximet is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Treximet have not been established for cluster headache.

2. **Coverage Criteria:**

   A. **Requests Above the Quantity Limit –See Section 4 for Quantity Limits** (Brand Amerge, Axert, Frova, Brand Imitrex, Brand Maxalt/Maxalt MLT, Generic naratriptan, Relpax, Generic rizatriptan/rizatriptan ODT, Generic sumatriptan, Treximet, Brand Zomit/Zomig ZMT, or Generic zolmitriptan/zolmitriptan ODT, SumaChip, Zembrance SymTouch, Onzetra Xsail, Sumavel DosePro)

   **NOTE:** This criterion applies to requests above the quantity limit only. Non-preferred products are addressed in Section C.

   1. Diagnosis of migraine headaches with or without aura
     -AND-
   2. Prescribed by or in consultation with one of the following:
      - Neurologist
      - Pain management specialist
     -AND-
   3. Patient is experiencing two or more headaches monthly
     -AND-
   4. Currently receiving prophylactic therapy with at least one of the following:
• Antidepressants [eg, Elavil (amitriptyline)*, Effexor (venlafaxine)] [A]
• Antihistamines (eg, cyproheptadine*) [B]
• Antiepileptics [eg, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)]
• ACE Inhibitors [eg, Zestril (lisinopril)]
• Angiotensin receptor blockers [eg, Atacand (candesartan)]
• Alpha-agonists (eg, clonidine*, guanfacine*) [C]
• Beta-blockers [eg, Inderal (propranolol), timolol, Toprol XL (metoprolol)]

-AND-

5. **One** of the following:

   a. Higher dose or quantity is supported in the dosage and administration section of the manufacturer’s prescribing information

   -OR-

   b. Higher dose or quantity is supported by one of the following compendia:
      • American Hospital Formulary Service Drug Information
      • Micromedex DRUGDEX System
      • Clinical Pharmacology

   -OR-

   c. Physician provides evidence to support safety and additional efficacy at higher than maximum doses as documented in published biomedical literature demonstrating safety and efficacy of doses/quantities greater than those approved by the FDA for the diagnosis indicated

   -AND-

6. Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

**Authorization will be issued for 12 months.**

**NOTES:** *Amitriptyline, clonidine, cyproheptadine, and guanfacine are recommended only for patients < 65 years old. [A, B, C]*

**NOTE TO PRESCRIBER:** A common cause of chronic daily headaches is excessive use of the following medications: analgesics (such as acetaminophen or ibuprofen), narcotics, triptans, or ergotamines.
B. **Non-Preferred Products**

1. Diagnosis of migraine headaches with or without aura

   -AND-

2. Patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products (document drugs, duration, and date of trials).

   **Authorization will be issued for 12 months.**

3. **Endnotes**

   **A:** Amitriptyline, a tricyclic antidepressant (TCA), is part of the Beer’s Criteria for potentially inappropriate medication use in older adults (independent of diagnoses or condition) because of its strong anticholinergic and sedation properties. [13] However, amitriptyline has been more frequently studied than the other agents, and is the only antidepressant with fairly consistent support for efficacy in migraine prevention. Other TCAs are clinically efficacious based on consensus and clinical experience, but lack scientific evidence of efficacy.

   **B:** Cyproheptadine is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old).

   **C:** Central alpha-blockers are part of the Beer's Criteria for potentially inappropriate medication use in older adults because of the high risk of adverse CNS effects.

4. **Quantity Limits:** Brand Amerge, Axert, Frova, Brand Imitrex, Brand Maxalt/Maxalt MLT, Generic naratriptan, Relpax, Generic rizatriptan/rizatriptan ODT, Generic sumatriptan, Treximet, Brand Zomig/Zomig ZMT, or Generic zolmitriptan/zolmitriptan ODT, SumaChip, Zembrace SymTouch, Onzeta Xsail, Sumavel DosePro

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Strength</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Brand Amerge</td>
<td>1mg, 2.5mg</td>
<td>9 tabs/month</td>
</tr>
<tr>
<td>generic naratriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frova</td>
<td>2.5mg</td>
<td>9 tabs/month</td>
</tr>
<tr>
<td>Brand Imitrex</td>
<td>25mg, 50mg, 100mg</td>
<td>9 tabs/month</td>
</tr>
<tr>
<td>generic sumatriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand Maxalt</td>
<td>5mg, 10mg</td>
<td>9 tabs/month</td>
</tr>
<tr>
<td>Generic rizatriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand Maxalt MLT</td>
<td>5mg, 10mg</td>
<td>9 tabs/month</td>
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<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Generic Form</th>
<th>Dosage</th>
<th>Monthly Supply</th>
</tr>
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<tbody>
<tr>
<td>Generic rizatriptan ODT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axert</td>
<td>6.25mg, 12.5mg</td>
<td>6 tabs/month</td>
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<tr>
<td>Relpax</td>
<td>20mg, 40mg</td>
<td>6 tabs/month</td>
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</tr>
<tr>
<td>Brand Zomig</td>
<td>2.5mg</td>
<td>6 tabs/month</td>
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</tr>
<tr>
<td>Generic zolmitriptan</td>
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<td></td>
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</tr>
<tr>
<td>Brand Zomig ZMT</td>
<td>2.5mg</td>
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<tr>
<td>Generic zolmitriptan ODT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand Imitrex Nasal Spray</td>
<td>5mg, 20mg</td>
<td>6 spray devices/month</td>
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</tr>
<tr>
<td>Generic sumatriptan nasal spray</td>
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<tr>
<td>Treximet</td>
<td>85mg/500 mg, 10mg/60mg</td>
<td>9 tabs/month</td>
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</tr>
<tr>
<td>Brand Zomig</td>
<td>5mg</td>
<td>6 tabs/month</td>
<td></td>
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<tr>
<td>Generic zolmitriptan</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Brand Zomig ZMT</td>
<td>5mg</td>
<td>6 tabs/month</td>
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<tr>
<td>Generic zolmitriptan ODT</td>
<td></td>
<td></td>
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<tr>
<td>SumaChip</td>
<td>100mg tablets and capsaicin-menthol 0.0375%</td>
<td>1 box (39 units)/month</td>
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<tr>
<td>Onzetra Xsail</td>
<td>11mg</td>
<td>1 box (8 units)/month</td>
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<td>Zembrace SymTouch</td>
<td>3mg</td>
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<tr>
<td>Brand Imitrex</td>
<td>4mg, 6mg</td>
<td>2 devices per month</td>
<td></td>
</tr>
<tr>
<td>Generic sumatriptan injection</td>
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</tbody>
</table>

5. **References:**


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<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization- Triptans- ARIZONA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Control</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>6/2018</td>
<td>New Policy specific to AZ, no naratriptan section</td>
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