Triptan Step Therapy and Quantity Limit Program Summary

Program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace, FocusRx and KeyRx.

FlexRx standard and GenRx standard quantity limit program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

### FDA APPROVED INDICATIONS AND DOSAGE 1-13,14,19,20,23

<table>
<thead>
<tr>
<th>Agents</th>
<th>Acute treatment, migraine attacks with/without aura (adults)</th>
<th>Acute treatment, migraine headaches (pediatrics)</th>
<th>Acute treatment, cluster headache episodes (adults)</th>
<th>Dosage and Administration Schedule (^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amerge® (naratriptan) tablet</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 1 mg or 2.5 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min time before repeat dose: 4 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Max dose/24 hours: 5 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The safety of treating an average of more</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>than 4 migraine attacks in a 30-day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>period has not been established</td>
</tr>
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<td><strong>Axert® (almotriptan) tablet</strong></td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>Initial dose: 6.25 mg or 12.5 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Min time before repeat dose: 2 hours</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Max dose/24 hours: 25 mg</td>
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<td><strong>Frova® (frovatriptan) tablet</strong></td>
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<td></td>
<td></td>
<td>Initial dose: 2.5 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min time before repeat dose: 2 hours</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Max dose/24 hours: 7.5 mg</td>
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<td><strong>Imitrex®, Sumatriptan tablet</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 25 mg to 100 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min time before repeat dose: 2 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Max dose/24 hours: 200 mg</td>
</tr>
<tr>
<td><strong>Imitrex® (sumatriptan) nasal spray</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 5 mg or 10 mg (1-2 sprays)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>or 20 mg (1 spray)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min time before repeat dose: 2 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Max dose/24 hours: 40 mg</td>
</tr>
<tr>
<td>Agents</td>
<td>Acute treatment, migraine attacks with/without aura (adults)</td>
<td>Acute treatment, migraine headaches (pediatrics)</td>
<td>Acute treatment, cluster headache episodes (adults)</td>
<td>Dosage and Administration Schedule&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Imitrex®, Sumavel™, Sumatriptan subcutaneous injection</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>Initial dose: 4 mg or 6 mg SC  Min time before repeat dose: 1 hour  Max dose/24 hours: 12 mg</td>
</tr>
<tr>
<td>Maxalt®, Maxalt MLT® (rizatriptan) tablet</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>Initial dose: 5 mg or 10 mg  Min time before repeat dose: 2 hours  Max dose/24 hours: 30 mg</td>
</tr>
<tr>
<td>Onzetra Xsail™ (sumatriptan nasal powder) nosepiece</td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 22 mg  Min time before repeat dose: 2 hours  Max dose/24 hours: 44 mg</td>
</tr>
<tr>
<td>Relpax® (eletriptan) tablet</td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 20 mg or 40 mg  Min time before repeat dose: 2 hours  Max dose/24 hours: 80 mg</td>
</tr>
<tr>
<td>Tosymra™ (sumatriptan) nasal spray</td>
<td>✓</td>
<td></td>
<td></td>
<td>Initial dose: 10 mg  Minimum time before repeat dose: 1 hour  Maximum dose/24 hours: 30 mg</td>
</tr>
<tr>
<td>Treximet™ (sumatriptan/naproxen) tablet</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>Adults:  Initial dose: One 85/500 mg tablet  Min time before repeat dose: 2 hours  Max Dose/24 hours: Two 85/500 mg tablets  Pediatric:  Recommended dose: 10/60 mg  Maximum dose: 85/500 mg</td>
</tr>
</tbody>
</table>
### Agents

<table>
<thead>
<tr>
<th>Agents</th>
<th>Acute treatment, migraine attacks with/without aura (adults)</th>
<th>Acute treatment, migraine headaches (pediatrics)</th>
<th>Acute treatment, cluster headache episodes (adults)</th>
<th>Dosage and Administration Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zembrace SymTouch™ (sumatriptan) injection</td>
<td>✓</td>
<td></td>
<td></td>
<td>The recommended dose of Zembrace SymTouch is 3 mg injected subcutaneously. The maximum cumulative dose that may be given in 24 hours is 12 mg; one 3 mg injection may be given up to four times a day with each injection at least 1 hour apart.</td>
</tr>
<tr>
<td>Zomig®, Zomig ZMT® (zolmitriptan) tablet</td>
<td>✓</td>
<td></td>
<td>Initial dose: 1.25 mg or 5 mg Min time before repeat dose: 2 hours Max dose/24 hours: 10 mg</td>
<td></td>
</tr>
<tr>
<td>Zomig® (zolmitriptan) nasal spray</td>
<td>✓ ✓</td>
<td></td>
<td>Initial dose: 2.5 mg; Maximum single dose: 5 mg Min time before repeat dose: 2 hours Max dose/24 hours: 10 mg</td>
<td></td>
</tr>
</tbody>
</table>

All products in the above chart are indicated for the acute treatment of migraine attacks with or without aura in adults.¹⁻¹³,¹⁴,¹⁹,²⁰,²³

- Use only after a clear diagnosis of migraine has been established
- These products are not intended for prophylactic therapy of migraine attacks, or for management of hemiplegic or basilar migraine.

While the incidence is rare, the triptans have been associated with angina, myocardial infarction (MI), cardiac arrhythmias, hypertension, or stroke, particularly when they were used in patients with vascular risk factors. Triptans should be used with extreme caution in these patients or those with a suspected history of coronary artery disease. Triptans should not be used in patients with uncontrolled hypertension, ischemic heart disease, peripheral vascular disease, or cerebrovascular disease. Triptans should not be used within 24 hours of treatment with another 5-HT1 agonist, or an ergotamine-containing or ergot-type medication like dihydroergotamine or methylergide.¹⁻¹³,¹⁴,¹⁹,²⁰,²³

### CLINICAL RATIONALE

The Medical Letter Treatment Guidelines (2017) – Drugs for Migraine states that a triptan is the drug of choice for moderate to severe migraine. The short-acting oral serotonin (5-HT1B/1D) receptor agonists (triptans) sumatriptan (Imitrex, and others), almotriptan (Axert, and generics), eletriptan (Relpax), rizatriptan (Maxalt, and generics), and zolmitriptan (Zomig, and generics) are similar in efficacy. Onset of pain relief generally occurs 30-60 minutes after administration. The longer-acting oral triptans naratriptan (Amerge, and generics) and
frovatriptan (Frova, and generics) have a slower onset of action and lower initial response rate than other triptans, but they are better tolerated. Patients with migraine who have nausea or vomiting may not be able to take an oral triptan. Intranasal triptan formulations have a more rapid onset of action than oral tablets, but their efficacy is partially dependent on GI absorption of the portion of the dose that is swallowed. Use of sumatriptan nasal powder (Onzeta Xsail) results in a faster rise in sumatriptan plasma concentrations and higher peak concentrations than use of a similar dose of sumatriptan nasal spray, suggesting that a larger portion of the dose is absorbed intranasally with the powder. Subcutaneously administered sumatriptan relieves pain faster (in about 10 minutes) and more effectively than other triptan formulations, but it causes more adverse effects.17

The American Academy of Neurology and the American Headache Society guidelines (2012, reaffirmed 2015) on pharmacologic treatment for episodic migraine prevention in adults state that frovatriptan is established as effective and should be offered for short-term mensturally associated migraine (MAMs) prevention (Strong Evidence). Naratriptan and zolmitriptan are probably effective and should be considered for short-term MAMs prevention (Moderate Evidence).15

The Institute for Clinical Systems Improvement Guideline Diagnosis and Treatment of Migraine Headache states that triptans are considered to have equal efficacy and are more effective at halting migraine pain at mild levels than if the headache is more severe. Clinicians should consider using subcutaneous sumatriptan or intranasal zolmitriptan as a first line option for the treatment of cluster headaches.16

The American Academy of Neurology 2010 Guideline: Acute and preventive pharmacologic treatment of cluster headache state that sumatriptan subcutaneous injection and zolmitriptan nasal spray are recommended for acute treatment of cluster headaches.14

American Headache Society (2015): The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies: The specific medications – triptans (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan [oral, nasal spray, injectable, transcutaneous patch], zolmitriptan [oral and nasal spray]) are effective (Level A). The evidence base for medication efficacy should be considered along with potential medication side effects, potential adverse events, patient-specific contraindications to use of a particular medication, and drug-to-drug interactions when deciding which medication to prescribe for acute therapy of a migraine attack.18

American Headache Society (2016): Treatment of Cluster Headaches: Since the publication of the 2010 American Academy of Neurology review, there are no new data from randomized, double-blind, controlled trials that contribute to determining the efficacy or safety for a number of acute treatments, including specifically sumatriptan and zolmitriptan. For acute treatment, sumatriptan subcutaneous, zolmitriptan nasal spray, and high flow oxygen remain the treatments with a Level A recommendation.21

The American Headache Society (AHS) and the American Academy of Neurology (AAN) suggest the following agents for the prevention of migraine:9

- Established as effective (Level A)
  - Antiepileptic drugs (AEDs)
    - Divalproex
    - Valproate
    - Topiramate
  - Beta blockers
    - Metoprolol
    - Propranolol
    - Timolol
  - Triptans
- Frovatriptan for short term menstrually associated migraines (MAMs) prevention
- Probably effective (Level B)
  - Antidepressants
    - Amitriptyline
    - Venlafaxine
  - Beta blockers
    - Atenolol
    - Nadolol
  - Triptans
    - Naratriptan, zolmitriptan for short term MAMs prevention

For additional clinical information see Prime Therapeutics Formulary Chapter 10.4A: Migraine Products: Triptans.

The European Headache Federation and WHO consensus article (2019) states the following:

- Individuals with migraine headaches should almost always be managed in primary care. The exception being chronic migraine, which likely requires specialist management.
- Any headache not responding satisfactorily in primary care should be referred to a specialist
- In adults and children, regular high frequency use (>2 day/week) of acute medication risks the development of medication-overuse headache
- Treatment of episodic acute migraine headaches should be approached in a step wise manner and should treat three attacks at each step before moving to the next step if needed:
  - Step 1:
    - Use non-opioid analgesics, plus an antiemetic when needed.
  - Step 2 for adults:
    - Use triptan products.
    - Triptans should not be used regularly on ≥10 days/month to avoid the risk of medication overuse headaches.
    - Triptan efficacy is highly variable between individuals, so patients should try different triptans and formulations. Sumatriptan subcutaneous injection should be considered when all other triptans are ineffective.
    - When nausea is present, zolmitriptan nasal spray or sumatriptan subcutaneous injection may be preferred.
  - Step 2 for children and adolescents:
    - Failure of Step 1 in children should lead to specialist referral. No specific anti-migraine drugs have shown efficacy in children under 12 years of age
    - Failure of Step 2 in adolescents (12-17 years of age), the following have shown efficacy and are approved:
      - Sumatriptan nasal spray
      - Zolmitriptan nasal spray
- For episodic migraine prophylaxis:
  - Indication for migraine prophylaxis include:
    - Attacks cause disability on two or more days per month
    - And acute therapy has been optimized but does not prevent this, or is poorly tolerated, or there is a risk of over-frequent use of acute therapy, even when it is effective
    - And the patient is willing to take daily medication.
    - Failure of acute therapy is an indication for migraine prophylaxis.
    - For children: frequent absence from school.
  - Migraine prophylaxis agents may take 2-3 months to show efficacy.
  - Children requiring prophylactic medication should be referred to a specialist.
  - Medications which are effective in adult prophylaxis of episodic migraine include:
    - Beta blockers:
- Atenolol, bisoprolol, metoprolol, propranolol
  - Amitriptyline
  - Topiramate
  - Candesartan
  - Sodium valproate
  - Flunarizine
  - CGRP

  - Onabotulinum toxin A is not effective in episodic migraine.
  - When prophylaxis therapy fails:
    - Failure may be due to subtherapeutic dosage or duration of therapy.
    - Failure of one therapy does not predict the failure of another therapy.
    - Review of the following are recommended:
      - Diagnosis
      - Adherence
      - Other medications, especially for medication overuse headache causes
    - The prophylaxis therapy should be discontinued if it fails to show clear benefit.
    - If all prophylaxis therapies fail, a specialist should be referred.

- Chronic migraine management:
  - Chronic migraine patients should be referred to a specialist.
  - Medications with efficacy in chronic migraine include:
    - Topiramate
    - Onabotulinum A
    - CGRP

- Cluster headache patients should be referred to specialists.
  - Acute therapies include:
    - Triptans:
      - Sumatriptan subcutaneous injection
      - Sumatriptan nasal spray
      - Zolmitriptan nasal spray
    - Oxygen
  - Transition and maintenance therapies include:
    - Prednisone
    - Greater occipital nerve blockade
    - Verapamil
    - Lithium carbonate
    - Topiramate
  - Neuromodulation is another treatment option.
  - Failure of one prophylactic therapy does not predict the failure of other therapies
  - Combination prophylaxis therapy can be considered though the potential for toxicity is high.
  - For chronic cluster headache patients, long-term prophylaxis therapy may be needed.

- Medication overuse headache (MOH)
  - Prevention is preferred.
  - The four objectives of management are:
    - Stop the overused medication.
    - Recovery from MOH.
    - Review and reassess the underlying headache disorder
    - Prevent relapse while allowing acceptable use of medications
  - Comorbidities may also require management

The European Headache Federation guideline states the following on combining migraine prophylaxis therapy:25
- In episodic migraine, it’s suggested to stop oral prophylaxis migraine agents before
starting CGRPs, unless the patient previously had chronic migraine prior to prophylaxis. In such patients, the suggestion is to add CGRP to the ongoing oral prophylaxis therapy.

- In chronic migraine, it’s suggested to add CGRP to ongoing oral prophylaxis therapy.
- In chronic migraine patients on onabotulinum A therapy and are receiving inadequate treatment response, it’s suggested to stop onabotulinum A therapy before starting CGRPs.
- In patients with chronic migraine who are on treatment with CGRP and may benefit from additional prevention, it’s suggested to add on oral preventative agents.
- In patients with medication overuse, it’s suggested to use CGRPs before or after withdrawal of acute medications.

Based on published data from a 1989 survey the median frequency of migraine attacks is 1.5 per month, and the median duration of an attack is 24 hours; at least 10% of patients have weekly attacks, and 20% have attacks lasting two to three days. Additional surveys from the mid to late 1990’s have confirmed these data. Survey results continue to report a median attack duration of 24 hours; 54% to 63% of patients report monthly attacks and 13% to 25% report weekly attacks.

REFERENCES – Clinical Rationale

Triptan Quantity Limit

Objective
The intent of the Triptans Quantity Limit (QL) program is to provide automatic approval for up to six headache days per month, as packaging allows. The program requires prior authorization for use which exceeds this limit.

QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Quantity Limit per Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amerge® (naratriptan) Tablets</td>
<td>67406050100310</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>1 mga</td>
<td>67406050100320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>Axert® (almotriptan) Tablets</td>
<td>67406010100320</td>
<td>12 tablets (2 packages of 6)</td>
</tr>
<tr>
<td>6.25 mga</td>
<td>67406010100330</td>
<td>12 tablets (1 package of 12)</td>
</tr>
<tr>
<td>12.5 mga</td>
<td>67406010100310</td>
<td>18 tablets (2 packages of 9)</td>
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<tr>
<td>Frova® (frovatriptan) Tablets</td>
<td>67406030100300</td>
<td>20 tablets (2 packages of 9)</td>
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<tr>
<td>2.5 mga</td>
<td>67406030100320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>Imitrex® (sumatriptan) Injection</td>
<td>67406070101003</td>
<td>12 doses (6 packages)</td>
</tr>
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<td>4 mg STATDose® systema</td>
<td>67406070100310</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>4 mg STATDose® refilla</td>
<td>67406070100320</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6 mg STATDose® systema</td>
<td>67406070100330</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6 mg STATDose® refilla</td>
<td>67406070100340</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6mg/0.5mL single dose vial (5 x 0.5 mL/package)</td>
<td>67406070102010</td>
<td>5 mL (2 packages)</td>
</tr>
<tr>
<td>Sumatriptan Injection</td>
<td>67406070100320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>6 mg/0.5 mL syringe</td>
<td>67406070100330</td>
<td>18 tablets (2 packages of 9)</td>
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<tr>
<td>Imitrex®, Sumatriptan (sumatriptan) Nasal Spray</td>
<td>67406070100340</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>5 mga</td>
<td>67406070002010</td>
<td>12 units (2 packages of 6)</td>
</tr>
<tr>
<td>4 mg STATDose® systema</td>
<td>67406070002020</td>
<td>12 units (2 packages of 6)</td>
</tr>
<tr>
<td>Imitrex® (sumatriptan) Tablets</td>
<td>67406070100310</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>25 mga</td>
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<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>50 mga</td>
<td>67406070100330</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>100 mga</td>
<td>67406070100340</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>Maxalt® (rizatriptan) MLT Tablets</td>
<td>67406060100310</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>5 mga</td>
<td>67406060100320</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>10 mga</td>
<td>67406060100330</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>Maxalt® (rizatriptan) Tablets</td>
<td>67406060100340</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>5 mga</td>
<td>67406060100310</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>10 mga</td>
<td>67406060100320</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>Onzetra Xsail™ (sumatriptan) nasal powder</td>
<td>67406060100330</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>11 mg nosepiece</td>
<td>67406060100340</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>Relpax® (eletriptan) Tablets</td>
<td>67406060100350</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>20 mga</td>
<td>67406060100360</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>40 mga</td>
<td>67406060100370</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>Sumatriptan Injection</td>
<td>67406070100380</td>
<td>12 doses (6 packages of 2)</td>
</tr>
<tr>
<td>6 mg/0.5 mL single dose injection devicea</td>
<td>67406070100390</td>
<td>12 doses (6 packages of 2)</td>
</tr>
<tr>
<td>Sumavel™ DosePro™ (sumatriptan) Injection</td>
<td>67406070100400</td>
<td>12 doses (6 packages of 2)</td>
</tr>
<tr>
<td>6 mg/0.5 mL single dose injection device</td>
<td>67406070100410</td>
<td>12 doses (6 packages of 2)</td>
</tr>
<tr>
<td>Tosymra™ (sumatriptan) nasal spray</td>
<td>67406070002010</td>
<td>18 sprays</td>
</tr>
</tbody>
</table>
### Brand (generic) | GPI | Quantity Limit per Month
--- | --- | ---
**Treximet™ (sumatriptan/naproxen) Tablets**
10/60 mg | 67992002600305 | 9 tablets (1 package of 9)
85/500 mg<sup>a</sup> | 67992002600320 | 18 tablets (2 packages of 9)

**Zembrace SymTouch™ (sumatriptan injection)**
3 mg/0.5 ml pens | 6740607010D505 | 24 pens (12 ml)

**Zomig® (zolmitriptan) Nasal Spray**
2.5 mg/100 microliters | 67406080002010 | 12 units (2 packages of 6)
5 mg/100 microliters | 67406080002020 | 12 units (2 packages of 6)

**Zomig® (zolmitriptan) Tablets**
2.5 mg<sup>a</sup> | 6740608000320 | 12 tablets (2 packages of 6)
5 mg<sup>a</sup> | 6740608000330 | 12 tablets (4 packages of 3)

**Zomig® (zolmitriptan) ZMT Tablets**
2.5 mg<sup>a</sup> | 67406080007220 | 12 tablets (2 packages of 6)
5 mg<sup>a</sup> | 67406080007230 | 12 tablets (4 packages of 3)

<sup>a</sup>- available as a generic, included in quantity limit program
<sup>b</sup> – available as generic only, included in quantity limit program

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**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
Quantities above the program quantity limit for **target agents** will be approved when ONE of the following is met:

1. **ALL** of the following:
   a. The patient has a diagnosis of migraine headache
   **AND**
   b. **ONE** of the following:
      i. The patient is currently using a migraine prophylactic medication (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [i.e. atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e. amitriptyline, venlafaxine], candesartan, CGRP [i.e. Aimovig, Ajovy, Emgality], onabotulinum toxin A [Botox])
      **OR**
      ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, CGRP, AND onabotulinum toxin A listed above
   **AND**
   c. The patient has been evaluated for and does not have medication overuse headache
   **AND**
   d. The patient will **NOT** be using the requested agent in combination with another acute migraine 5HT agent (i.e. triptan, 5HT-1F, ergotamine, acute CGRP)
   **AND**
   e. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication
   **OR**

2. **BOTH** of the following:
   a. The patient has a diagnosis of cluster headache
   **AND**
   b. The requested agent is an injection or nasal spray

**Length of Approval**: 12 months
[For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]
Triptan Step Therapy

TARGET AGENTS
- Amerge® (naratriptan)a
- Axert® (almotriptan)a
- Frova® (frovatriptan)a
- Imitrex® (sumatriptan)a
- Maxalt®, Maxalt® MLT (rizatriptan)a
- Onztra Xsal™ (sumatriptan)
- Relpax® (eletriptan)a
- Sumatriptan
- Sumavel DosePro® (sumatriptan)
- Tosymra™ (sumatriptan)
- Treximet™ (sumatriptan/naproxen)a
- Zembrace SymTouch (sumatriptan injection)
- Zomig®, Zomig® ZMT (zolmitriptan)³

¹ available as a generic; used as prerequisite not target in step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand Agents will be approved when ONE of the following is met:

1. The patient’s medication history includes use of a generic triptan agent within the past 999 days

OR

2. BOTH of the following:
   a. The prescriber has stated that the patient has tried a generic triptan agent
   AND
   b. The generic triptan agent was discontinued due to lack of effectiveness or an adverse event

OR

3. Information has been provided that the patient is currently being treated with the requested agent within the past 90 days

OR

4. The prescriber states the patient is currently being treated with the requested agent AND is at risk if therapy is changed

OR

5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   a. A statement by the prescriber that the patient is currently taking the requested agent
   AND
   b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   AND
   c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

6. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL generic triptan agents

OR

7. The prescriber has provided documentation that ALL generic triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm
Length of approval: 12 months
# Triptan Step Therapy with Quantity Limit

## TARGET AGENTS
- Amerge® (naratriptan)
- Axert® (almotriptan)
- Frova® (frovatriptan)
- Imitrex® (sumatriptan)
- Maxalt®, Maxalt® MLT (rizatriptan)
- Onzetra Xsail™ (sumatriptan)
- Relpax® (eletriptan)
- Sumatriptan
- Sumavel DosePro® (sumatriptan)
- Tosymra™ (sumatriptan)
- Treximet™ (sumatriptan/naproxen)
- Zembrace SymTouch™ (sumatriptan injection)
- Zomig®, Zomig® ZMT (zolmitriptan)

*a – available as a generic; used as prerequisite not target in step therapy program*

## QUANTITY LIMIT TARGET AGENTS - RECOMMENDED LIMITS

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Quantity Limit per Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amerge® (naratriptan) Tablets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406050100310</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406050100320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td><strong>Axert® (almotriptan) Tablets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.25 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406010100320</td>
<td>12 tablets (2 packages of 6)</td>
</tr>
<tr>
<td>12.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406010100330</td>
<td>12 tablets (1 package of 12)</td>
</tr>
<tr>
<td><strong>Frova® (frovatriptan) Tablets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406030100320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td><strong>Imitrex® (sumatriptan) Injection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 mg STATdose&lt;sup&gt;a&lt;/sup&gt; system</td>
<td>6740607010D510</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>4 mg STATdose&lt;sup&gt;a&lt;/sup&gt; refill</td>
<td>6740607010E210</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6 mg STATdose&lt;sup&gt;a&lt;/sup&gt; system</td>
<td>6740607010D520</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6 mg STATdose&lt;sup&gt;a&lt;/sup&gt; refill</td>
<td>6740607010E220</td>
<td>12 doses (6 packages)</td>
</tr>
<tr>
<td>6 mg/0.5 mL single dose vial (5 x 0.5 mL/package)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406070102010</td>
<td>5 mL (2 packages)</td>
</tr>
<tr>
<td><strong>Sumatriptan injection</strong></td>
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</tr>
<tr>
<td>6 mg/0.5 mL syringe&lt;sup&gt;b&lt;/sup&gt;</td>
<td>6740607010E520</td>
<td>12 doses (12 syringes)</td>
</tr>
<tr>
<td><strong>Imitrex®, Sumatriptan (sumatriptan) Nasal Spray</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406070002010</td>
<td>12 units (2 packages of 6)</td>
</tr>
<tr>
<td>20 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406070002040</td>
<td>12 units (2 packages of 6)</td>
</tr>
<tr>
<td><strong>Imitrex® (sumatriptan) Tablets</strong></td>
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<td></td>
</tr>
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<td>25 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406070100305</td>
<td>18 tablets (2 packages of 9)</td>
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<td>50 mg&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>100 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406070100320</td>
<td>18 tablets (2 packages of 9)</td>
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<tr>
<td><strong>Maxalt® (rizatriptan) MLT Tablets</strong></td>
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<td></td>
</tr>
<tr>
<td>5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406060107220</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td>10 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406060107230</td>
<td>18 tablets (1 package of 18)</td>
</tr>
<tr>
<td><strong>Maxalt® (rizatriptan) Tablets</strong></td>
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<td></td>
</tr>
<tr>
<td>5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406060100310</td>
<td>18 tablets (1 package of 18)</td>
</tr>
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<td>10 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406060100320</td>
<td>18 tablets (1 package of 18)</td>
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<tr>
<td><strong>Onzetra Xsail™ (sumatriptan) nasal powder</strong></td>
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<tr>
<td>11 mg nosepiece</td>
<td>6740607010G420</td>
<td>32 nosepieces (2 kits of 16)</td>
</tr>
<tr>
<td><strong>Relpax® (eletriptan) Tablets</strong></td>
<td></td>
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</tr>
<tr>
<td>20 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406025100320</td>
<td>12 tablets (2 packages of 6)</td>
</tr>
<tr>
<td>Brand (generic)</td>
<td>GPI</td>
<td>Quantity Limit per Month</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>40 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406025100340</td>
<td>12 tablets (2 packages of 6)</td>
</tr>
<tr>
<td><strong>Sumatriptan Injection</strong></td>
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</tr>
<tr>
<td>6 mg/0.5 mL single dose injection device</td>
<td>6740607010D520</td>
<td>12 doses (6 packages of 2)</td>
</tr>
<tr>
<td><strong>Sumavel</strong>&lt;sup&gt;™&lt;/sup&gt; <strong>DosePro</strong>&lt;sup&gt;™&lt;/sup&gt; (sumatriptan) Injection</td>
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<tr>
<td>6 mg/0.5 mL single dose injection device</td>
<td>6740607010D820</td>
<td>12 doses (2 packages of 6)</td>
</tr>
<tr>
<td><strong>Tosymra</strong>&lt;sup&gt;™&lt;/sup&gt; (sumatriptan) Nasal Spray</td>
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<td></td>
</tr>
<tr>
<td>10 mg</td>
<td>67406070002020</td>
<td>18 sprays</td>
</tr>
<tr>
<td><strong>Treximet</strong>&lt;sup&gt;™&lt;/sup&gt; (sumatriptan/naproxen) Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/60 mg</td>
<td>67992002600305</td>
<td>9 tablets (1 package of 9)</td>
</tr>
<tr>
<td>85/500 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67992002600320</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td><strong>Zembrace SymTouch</strong>&lt;sup&gt;™&lt;/sup&gt; (sumatriptan injection)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 mg/0.5 ml pens</td>
<td>6740607010D505</td>
<td>24 pens (12 ml)</td>
</tr>
<tr>
<td><strong>Zomig</strong>&lt;sup&gt;®&lt;/sup&gt; (zolmitriptan) Nasal Spray</td>
<td></td>
<td></td>
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<tr>
<td>2.5 mg/100 microliters</td>
<td>67406080002010</td>
<td>12 units (2 packages of 6)</td>
</tr>
<tr>
<td>5 mg/100 microliters</td>
<td>67406080002020</td>
<td>12 units (2 packages of 6)</td>
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<tr>
<td><strong>Zomig</strong>&lt;sup&gt;®&lt;/sup&gt; (zolmitriptan) Tablets</td>
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<tr>
<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406080000320</td>
<td>12 tablets (2 packages of 6)</td>
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<tr>
<td>5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406080000330</td>
<td>12 tablets (4 packages of 3)</td>
</tr>
<tr>
<td><strong>Zomig</strong>&lt;sup&gt;®&lt;/sup&gt; (zolmitriptan) ZMT Tablets</td>
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<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406080007220</td>
<td>12 tablets (2 packages of 6)</td>
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<td>5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406080007230</td>
<td>12 tablets (4 packages of 3)</td>
</tr>
</tbody>
</table>

<sup>a</sup> - available as a generic, included in quantity limit program
<sup>b</sup> – available as generic only, included in quantity limit program

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

Quantities above the program quantity limit for **Generic Triptan Agents** will be approved when ONE of the following is met:

1. **ALL** of the following:
   a. The patient has a diagnosis of migraine headache
   **AND**
   b. **ONE** of the following:
      i. The patient is currently using migraine prophylactic medication
         (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers
         [i.e. atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants
         [i.e. amitriptyline, venlafaxine], candesartan, CGRP [i.e. Aimovig, Ajovy,
         Emgality], onabotulinum toxin A [Botox])
      **OR**
      ii. The patient has an intolerance, FDA labeled contraindication, or
         hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant,
         candesartan, CGRP, AND onabotulinum toxin A listed above
      **AND**
   c. The patient has been evaluated for and does not have medication overuse
         headache
   **AND**
   d. The patient will NOT be using the requested agent in combination with another
      acute migraine 5HT agent (i.e. triptan, 5HT-1F, ergotamine, acute CGRP)
      **AND**
   e. The requested quantity (dose) does not exceed the maximum FDA labeled dose
      for the requested indication
   **OR**
2. **BOTH** of the following:
   a. The patient has a diagnosis of cluster headache
b. The requested agent is an injection or nasal spray

Length of Approval: 12 months
[For a diagnosis of migraine, the quantity requested up to the FDA-labeled maximum dose allowed per 24 hours will be approved.]

Brand Triptan Agents will be approved when BOTH of the following are met:
1. ONE of the following:
   a. The patient’s medication history includes use of a generic triptan agent within the past 999 days
   OR
   b. BOTH of the following:
      i. The prescriber has stated that the patient has tried a generic triptan agent
      AND
      ii. The generic triptan agent was discontinued due to lack of effectiveness or an adverse event
   OR
   c. Information has been provided that the patient is currently being treated with the requested agent within the past 90 days
   OR
   d. The prescriber states the patient is currently being treated with the requested agent AND is at risk if therapy is changed
   OR
   e. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      i. A statement by the prescriber that the patient is currently taking the requested agent
      AND
      ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
      iii. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   f. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL generic triptan agents
   OR
   g. The prescriber has provided documentation that ALL generic triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND
2. ONE of the following:
   a. The quantity is within the program quantity limit
   OR
   b. ALL of the following:
      i. The patient has a diagnosis of migraine headache
      AND
      ii. ONE of the following:
         a. The patient is currently using migraine prophylactic medication (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [i.e. atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e. amitriptyline, venlafaxine], candesartan, CGRP [i.e. Aimovig, Ajovy, Emgality], onabotulinum toxin A [Botox])
         OR
b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to an anticonvulsant, a beta blocker, an antidepressant, candesartan, CGRP, AND onabotulinum toxin A listed above

AND

iii. The patient has been evaluated for and does not have medication overuse headache

AND

iv. The patient will NOT be using the requested agent in combination with another acute migraine 5HT agent (i.e. triptan, 5HT-1F, ergotamine, acute CGRP)

AND

v. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication

OR

c. BOTH of the following:

i. The patient has a diagnosis of cluster headache

AND

ii. The requested agent is an injection or nasal spray

Length of Approval: 12 months

[For a diagnosis of migraine, the quantity requested up to the FDA labeled maximum dose allowed per 24 hours will be approved.]