### FDA APPROVED INDICATIONS AND DOSAGE

<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 Scheduleb</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amerge®</strong>&lt;br&gt;(naratriptan)&lt;br&gt;1 mg, 2.5 mg tablets</td>
<td>✔</td>
<td></td>
<td>Initial dose: 1 mg or 2.5 mg&lt;br&gt;Min time before repeat dose: 4 hours&lt;br&gt;Max dose/24 hours: 5 mg</td>
<td></td>
</tr>
<tr>
<td><strong>Axert®</strong>&lt;br&gt;(almotriptan)&lt;br&gt;6.25 mg, 12.5 mg tablets</td>
<td>✔</td>
<td>✔</td>
<td>Initial dose: 6.25 mg or 12.5 mg&lt;br&gt;Min time before repeat dose: 2 hours&lt;br&gt;Max dose/24 hours: 25 mg</td>
<td></td>
</tr>
<tr>
<td><strong>Frova®</strong>&lt;br&gt;(frovatriptan)&lt;br&gt;2.5 mg tablet</td>
<td>✔</td>
<td></td>
<td>Initial dose: 2.5 mg&lt;br&gt;Min time before repeat dose: 2 hours&lt;br&gt;Max dose/24 hours: 7.5 mg</td>
<td></td>
</tr>
<tr>
<td><strong>Imitrex®, Sumatriptan</strong>&lt;br&gt;25 mg, 50 mg, 100 mg tablets</td>
<td>✔</td>
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<td>Initial dose: 25 mg to 100 mg&lt;br&gt;Min time before repeat dose: 2 hours&lt;br&gt;Max dose/24 hours: 200 mg</td>
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</tr>
<tr>
<td><strong>Imitrex®</strong>&lt;br&gt;(sumatriptan) nasal spray&lt;br&gt;5 mg, or 20 mg/spray</td>
<td>✔</td>
<td></td>
<td>Initial dose: 5 mg or 10 mg (1-2 sprays) or 20 mg (1 spray)&lt;br&gt;Min time before repeat dose: 2 hours&lt;br&gt;Max dose/24 hours: 40 mg</td>
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<tr>
<td><strong>Imitrex®, Sumavel™, Sumatriptan</strong>&lt;br&gt;(sumatriptan) injectable&lt;br&gt;4 mg or 6 mg subcutaneous</td>
<td>✔</td>
<td></td>
<td>Initial dose: 4 mg or 6 mg SC&lt;br&gt;Min time before repeat dose: 1 hour&lt;br&gt;Max dose/24 hours: 12 mg</td>
<td></td>
</tr>
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</table>

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.
<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>
</table>
| Maxalt®, Maxalt MLT® (rizatriptan) 5 mg or 10 mg tablets | ✓ | | | Initial dose: 5 mg or 10 mg  
Min time before repeat dose: 2 hours  
Max dose/24 hours: 30 mg |
| Onzeta Xsail™ (sumatriptan nasal powder) 11 mg nosepiece | ✓ | | | Initial dose: 22 mg  
Min time before repeat dose: 2 hours  
Max dose/24 hours: 44 mg |
| Relpax® (eletriptan) 20 mg, 40 mg tablets | ✓ | | | Initial dose: 20 mg or 40 mg  
Min time before repeat dose: 2 hours  
Max dose/24 hours: 80 mg |
| Tosymra™ (sumatriptan) 10 mg nasal spray | ✓ | | | Initial dose: 10 mg  
Minimum time before repeat dose: 1 hour  
Maximum dose/24 hours: 30 mg |
| Treximet™ (sumatriptan/naproxen) 85/500 mg tablets 10/60 mg tablets | ✓ | ✓ | | 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 |
| Zembrace SymTouch™ (sumatriptan injection) 3 mg/0.5 mL | ✓ | | | 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. |
| Zomig®, Zomig ZMT® (zolmitriptan) | ✓ | | | Initial dose: 1.25 mg or 5 mg  
Min time before repeat dose: 2 hours |
<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&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mg or 5 mg tablets</td>
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<td></td>
<td>Max dose/24 hours: 10 mg</td>
<td></td>
</tr>
<tr>
<td>Zomig&lt;sup&gt;®&lt;/sup&gt; (zolmitriptan nasal spray) 2.5 mg/spray; 5 mg/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>

<sup>b</sup> - Min=minimum; Max=maximum

All products in the above chart are indicated for the acute treatment of migraine attacks with or without aura in adults.<sup>1-13,14,19,20</sup>

- 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 methysergide.<sup>1-13,14,19,20</sup>  

**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 (Onzetra 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.<sup>17</sup>

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 menstrually associated migraine (MAMs) prevention (Strong Evidence). Naratriptan and zolmitriptan are probably effective and should be considered for short-term MAMs prevention (Moderate Evidence).<sup>15</sup>
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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{21}

The American Headache Society (AHS) and the American Academy of Neurology (AAN) suggest the following agents for the prevention of migraine:\textsuperscript{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.
REFERENCES – Clinical Rationale

18. The acute treatment of migraine in adults: the American Headache Society evidence 
assessments of migraine pharmacotherapies. 2015. Available at 
22. The American Headache Society Position Statement On Integrating New Migraine 

ADDITIONAL INFORMATION - Migraine Frequency and Prophylactic Therapy

Following appropriate management of acute migraine, patients should be evaluated for initiation 
of preventive therapy. Factors that should prompt consideration of preventive therapy include 
the occurrence of two or more migraines per month with disability lasting three or more days 
per month; failure of, contraindication for, or adverse events from acute treatments; use of 
abortive medication more than twice per week; and uncommon migraine conditions (e.g., 
hemiplegic migraine, migraine with prolonged aura, migrainous infarction). Risk of medication 
overuse headache is also a factor that should be considered.\textsuperscript{15} Patient preference and cost also 
should be considered.\textsuperscript{1}

For continuous prophylaxis, beta-blockers are commonly used; propranolol and timolol are FDA 
approved, but metoprolol, nadolol, and atenolol also have been effective. Antiepileptic drugs 
such as valproate and topiramate have been effective in decreasing migraine frequency in 50% 
of patients; gabapentin has been used with varying degrees of success. Calcium channel 
blockers are also used but the evidence for their effectiveness is weak. Tricyclic antidepressants 
can prevent migraine in some patients but often cause sedation, dry mouth and weight gain. In 
small double-blind studies, lisinopril and candesartan have reduced migraine frequency.\textsuperscript{2} A 
Cochrane review (2004)\textsuperscript{3} of anticonvulsants for migraine prophylaxis states that valproic
acid/sodium valproate has proven efficacy for this use. This review suggested that gabapentin needed further evaluation and that topiramate had reasonable evidence to support its use.3

In 2012, the American Academy of Neurology (AAN) updated its guidelines for migraine prevention.13,14 Strongly recommended agents include divalproex sodium/sodium valproate, topiramate, metoprolol, propranolol, and timolol; medications listed as probably effective include amitriptyline, venlafaxine, atenolol, and nadolol; and those possibly effective are lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol and pindolol. Certain NSAIDs are also listed as probably effective (fenoprofen, ibuprofen, ketoprofen, naproxen) or possibly effective (flurbiprofen, mefenamic acid).13,14

Based on published data from a 1989 survey4 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.4 Additional surveys from the mid to late 1990’s have confirmed these data.5-8 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.5-8 Evidence-based guidelines and published practice parameters from the American Academy of Neurology (AAN) for the pharmacologic management of migraine headaches suggest that acute therapy should be limited to no more than two headache days per week to guard against medication-overuse headache.9 AAN guidelines recommend preventive treatment where the frequency of attacks has increased the use of acute medications to a level that would increase the potential for medication overuse headaches.5,10 Medication overuse headache is now included in the International Classification of Headache Disorders.11,12 According to this classification, medication overuse headache can be diagnosed when headaches occur on 15 or more days per month, the pain is characterized as bilateral, dull, and of light to moderate intensity, drug intake includes ergots, triptans and opioids for ten or more days per month or analgesics are used for 15 or more days per month for at least three months, and the headache disappears after withdrawal.11,12

REFERENCES – Additional Information section


### Acute Migraine 5HT Quantity 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><strong>Amerge® (naratriptan) Tablets</strong></td>
<td>67406050100310</td>
<td>18 tablets (2 packages of 9)</td>
</tr>
<tr>
<td>1 mg&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>18 tablets (2 packages of 9)</td>
</tr>
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<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406010100320</td>
<td>12 tablets (2 packages of 6)</td>
</tr>
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<td>12.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67406010100330</td>
<td>12 tablets (1 package of 12)</td>
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<td><strong>Axert® (almotriptan) Tablets</strong></td>
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<td>12 tablets (2 packages of 6)</td>
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<tr>
<td><strong>Frova® (frovatriptan) Tablets</strong></td>
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<td>18 tablets (2 packages of 9)</td>
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<td>2.5 mg&lt;sup&gt;a&lt;/sup&gt;</td>
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<td><strong>Imitrex® (sumatriptan) Injection</strong></td>
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<td>4 mg STATdose® system&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>6740607010E210</td>
<td>12 doses (6 packages)</td>
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<tr>
<td>6 mg STATdose® system&lt;sup&gt;a&lt;/sup&gt;</td>
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</tr>
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<td>6740607010E220</td>
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<td><strong>Sumatriptan Injection</strong></td>
<td><strong>Sumatriptan Injection</strong></td>
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<td>6740607010E520</td>
<td>12 doses (12 syringes)</td>
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<td><strong>Imitrex®, Sumatriptan (sumatriptan) Nasal Spray</strong></td>
<td><strong>Imitrex®, Sumatriptan (sumatriptan) Nasal Spray</strong></td>
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<td><strong>Onzetra Xsail™ (sumatriptan) nasal powder</strong></td>
<td><strong>Onzetra Xsail™ (sumatriptan) nasal powder</strong></td>
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<td><strong>Sumatriptan Injection</strong></td>
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<td><strong>Treximet™ (sumatriptan/naproxen) Tablets</strong></td>
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</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
<sup>c</sup> – agent discontinued

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**
Quantities above the program set 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])
      OR
      ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an anticonvulsant, a beta blocker, AND an antidepressant listed above
   AND
   c. The patient has been evaluated for and does not have medication overuse headache
   AND
   d. ONE of the following:
      i. The patient is not currently taking another acute migraine 5HT agent or an ergotamine agent
      OR
      ii. The patient’s current acute migraine 5HT agent or ergotamine agent will be discontinued prior to starting the requested agent
   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.]
This program applies to Medicaid.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT
OBJECTIVE
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL
The requested agent will be approved when ONE of the following are met:

1. 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

2. BOTH of the following
   a. The patient’s medication history includes the required prerequisite/preferred agent(s) or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following:
      i. Evidence of a paid claim(s) within the past 999 days
      OR
      ii. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days
   AND
   b. ONE of the following:
      i. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event
      OR
      ii. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s)

OR

3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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: As per program specific criteria