Drug Therapy Guidelines

Applicable

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective: 9/20/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
</tr>
<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
</tr>
<tr>
<td>Pharmacy- Formulary 4/AON</td>
<td>x</td>
</tr>
</tbody>
</table>

I. Medication Description

Serotonin receptor agonists are used to treat (not prevent) acute attacks of migraine headaches. These medications work by binding to specific serotonin receptors in the brain which in turn decreases the release of chemicals responsible for the vasodilation of cerebral blood vessels, decreases the activity of pain signaling neurons, and reduces inflammation.

II. Position Statement

• For all lines of business, coverage is provided immediately, without requiring prior authorization, for preferred/formulary medications with associated quantity limit restrictions.
• Coverage is determined through a prior authorization process with supporting clinical evidence for all other requests for members aged 18 and older.

III. Policy

Formulary 1: See Sections B and C
Formulary 2: See Sections A and C
Formulary 3/Exclusive: See Sections A and C
Formulary 4/AON: See Sections A and C

A. Non-preferred medications: Amerge, Axert, Frova, Imitrex, Maxalt, Onzeta, Relpax, Treximet, Zembrace, Zomig
Plan-preferred medications: eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan

B. Non-preferred medications: Amerge, Axert, Frova, Imitrex, Maxalt, Onzeta, Relpax, Zembrace, Zomig
Plan-preferred medications: eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan

C. Coverage of any non-preferred medication will be provided when the patient has experienced intolerance or therapeutic failure with at least one plan-preferred medication first OR when the following criteria are met:
  • When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
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Triptans

Last Review Date: 3/2017

• At least one of the following must be met:
  o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  o The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  o The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  o The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
  o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

<table>
<thead>
<tr>
<th>Medication</th>
<th>Covered per 30 days</th>
<th>Covered per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imitrex/sumatriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 25mg, 50mg tablets</td>
<td>18</td>
<td>36</td>
</tr>
<tr>
<td>• 100mg tablets</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>• 4mg injection doses</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>• 6mg injection doses</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>• Nasal spray 5mg or 20mg</td>
<td>12</td>
<td>24</td>
</tr>
<tr>
<td>• Sumavel 4mg and 6mg injection</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>• Alsuma 6mg injection</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Treximet</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>Axert/almotriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 6.25mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>• 12.5mg tablets</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Relpax/eletriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 20mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>• 40mg tablets</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Frova 2.5mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>Amerge/naratriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>• 2.5mg tablets</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>Maxalt/Maxalt MLT/rizatriptan 5mg, 10mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>Zomig/Zomig ZMT/zolmitriptan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2.5mg tablets</td>
<td>12</td>
<td>36</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Triptans</th>
<th>Last Review Date: 3/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>5mg tablets</td>
<td>8</td>
</tr>
<tr>
<td>Nasal spray</td>
<td>12</td>
</tr>
<tr>
<td>Zembrace Symtouch (per dose)</td>
<td>8</td>
</tr>
<tr>
<td>Onzetra Xsail (per dose)</td>
<td>8</td>
</tr>
</tbody>
</table>

- Coverage for a greater quantity of a triptan is also determined through a prior authorization process.
  - Member must be experiencing a greater number of headaches per month than what the general covered quantity can treat AND
  - One of the following is true:
    - Member must be followed by a neurologist OR
    - Member must be receiving preventative therapy for migraine headaches

VI. Coverage Duration

- Coverage is approved indefinitely for the life of this policy once coverage criteria are met for non-preferred medications.
- Duration of coverage for increased quantities will be limited to 12 months.

VII. Coverage Renewal Criteria

n/a

X. Billing/Coding Information

Please see individual prescribing information for products.

XII. Summary of Policy Changes

- 6/1/11: Addition of naratriptan (generic Amerge) to the preferred medications in this class; Removal of Maxalt/Maxalt MLT from preferred products; Clarification of coverage of Axert in treatment of migraine in adolescent members (12 to 17 years); Change in quantity limit for naratriptan to 9 tablets/30 days, 27 tablets/90 days to reflect packaging in units of 9 tablets.
- 11/2011: Sumavel no longer targeted medication, quantity limits remain in place
- 6/15/12: addition of Alsuma to policy, extended authorization duration
- 6/15/13: rizatriptan/rizatriptan ODT and Zecuity added to policy; Typo re: quantity of Sumavel covered per month fixed; Brands with available generics are now non-preferred
- 6/2013: added zolmitriptan/ODT to policy
- 5/14/14: zolmitriptan and rizatriptan considered preferred for both Exchange and Commercial
- 6/15/14: simplified increased quantity coverage criteria; clarified quantity limits via mail order
- 6/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 5/16/16: Zembrace quantity limits added
- 5/26/16: Onzetra quantity limits added
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- 6/10/16: Onzetra considered non-preferred
- 6/15/16: no policy changes
- 6/16/16: Zembrace considered non-preferred
- 4/5/17: removed Zecuity due to no availability
- 5/1/17: step therapy criteria added
- 8/21/17: addition of eletriptan to preferred medications; removal of Relpax from preferred medications
- 9/20/17: updated duration of coverage for increased quantities

XIII. References

26. Consultation with Dr. Richard Lipton, Migraine Specialist, Department of Neurology, Montefiore Medical Center, Bronx, New York, Nov. 1996.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.