Drug Therapy Guidelines

<table>
<thead>
<tr>
<th>Medical</th>
<th>Date of Origin: 8/29/06</th>
<th>Effective Date: 6/15/14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Rx</td>
<td>√</td>
<td>Next Review Date: 3/15</td>
</tr>
<tr>
<td>Medicaid/Family Health Plus Rx</td>
<td>√</td>
<td>Review Dates: 8/06, 11/07, 12/08, 12/09, 6/10, 3/11, 3/12, 3/13, 3/14</td>
</tr>
</tbody>
</table>
| Exclusive/Exchange Rx        | √                       |                         |}

I. Medication Description

Serotonin receptor agonists are used to treat (not prevent) acute attacks of migraine headaches. These agents 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 agents with associated quantity limit restrictions.
- Coverage is determined through a prior authorization process with supporting clinical evidence for all other requests for patients aged 18 and older.

III. Policy

Commercial Rx: See Sections A and B
Medicaid/Family Health Plus Rx: Section III does not apply
Exclusive/Exchange Rx: See Sections B and C

A. Coverage of a non-preferred medication (Amerge, Axert, Frova, Imitrex, Maxalt, Treximet, Zecuity, Zomig) will be provided when the patient has experienced intolerance or therapeutic failure with at least one preferred medication (naratriptan, rizatriptan, sumatriptan, zolmitriptan, Relpax) first.

B. Sumavel and Alsuma do not require prior authorization for usage; however, quantity limits apply, as outlined below.

C. Coverage of a non-preferred medication (Amerge, Axert, Frova, Imitrex, Maxalt, Relpax, Treximet, Zecuity, Zomig) will be provided when the patient has experienced intolerance or therapeutic failure with at least two preferred medications (naratriptan, rizatriptan, sumatriptan, zolmitriptan) first.
IV. Quantity Limitations

<table>
<thead>
<tr>
<th>Agent</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 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>• Zecuity transdermal</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Treximet</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>Axert</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</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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 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>
<tr>
<td>• 5mg tablets</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>• Nasal spray</td>
<td>12</td>
<td>24</td>
</tr>
</tbody>
</table>

- Coverage for a greater quantity of a triptan is also determined through a prior authorization process.
  - Patient 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:
    - Patient must be followed by a neurologist OR
    - Patient must be receiving preventative therapy

VI. Coverage Duration

- Coverage is approved indefinitely for the life of this policy once coverage criteria are met.
- Duration of coverage for increased quantities may be limited to 3 or 6 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 agents in this class
  - Removal of Maxalt/Maxalt MLT from preferred products.
  - Clarification of coverage of Axert in treatment of migraine in adolescent patients (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 agent, 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.

XIII. References

22. 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.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

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 agent 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.