Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Title: Progressive Medication Program for Serotonin-Receptor Agonists (Axert, Frova, Relpax)

<table>
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<tr>
<th>Approval: Robert Bonnell, M.D., Med. Dir.</th>
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<td>Responsible Party: CPM Director</td>
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<td>Distribution: Medical Department</td>
<td>P&amp;T Review: 11/16/16</td>
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived:

3.2 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
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Background Information, continued:

Medication Summary

- Serotonin-receptor agonists ("triptans") are antimigraine medications structurally similar to serotonin. Triptans stimulate presynaptic 5-HT1D receptors, inhibiting dural vasodilation and inflammation. Triptans directly inhibit trigeminal nuclei nociceptive neurotransmission via 5-HT1B/D receptor agonism within the trigeminocervical complex of the brainstem and upper spinal cord. Vascular 5-HT1B receptor agonism also results in vasoconstriction of painfully dilated intracranial extracerebral vessels.
- Triptans are indicated for the acute treatment of migraine attacks with or without aura. Sumatriptan also has an added indication for the treatment of acute cluster headache.
- There are currently nine (9) different triptans available on the market. Four (4) generics include naratriptan, rizatriptan, sumatriptan and zolmitriptan. Single source brand name medications include Alsuma™ Auto-Injector (not covered), Axert®, Frova®, Relpax® and Sumavel® DosePro (not covered).

Eligibility Criteria

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members less than 18 years of age.
- Members with any of the following conditions: acute myocardial infarction, angina, arteriosclerosis, basilar/hemilegic migraine, cardiac disease, cerebrovascular disease (stroke or transient ischemic attack), coronary artery disease, severe hepatic disease, uncontrolled hypertension, concurrent MAOI therapy, peripheral vascular disease, or vasospastic angina.
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Background Information, continued:

Additional Information

• AvMed’s Clinical Pharmacists are licensed by the State of Florida.
• AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.1 Request for initial therapy with Axert®, Frova®, Relpax for migraine with or without aura requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying the following:

1.2 Member must be 18 years of age or older; AND

1.3 Member must have diagnosis of migraine with aura; AND

1.4 Member must have contraindication to or failure to an adequate trial (2 to 3 months) of naratriptan, rizatriptan, sumatriptan, or zolmitriptan;

1.5 If criteria are met, approve for one (1) year within quantity limits specified on formulary.

Reference: