1. **Background:**

**Multisource Brand Anticonvulsants**
This program requires a member to try the A-rated generic prior to receiving coverage for brand Depakote, Depakote ER, Felbatol, Keppra, Keppra XR, Lamictal, Lamictal XR (brand and generic), Lamictal ODT (brand and generic), Mysoline, Neurontin, Oxtellar XR*, Qudexy XR* (brand and authorized generic), Stavzor, Topamax, Trokendi XR*, Trileptal, Zonegran unless patient has a history of drug-resistant epilepsy or is at high risk of seizure recurrence.

**Modified Release Products**
This program requires a member to try divalproex sodium delayed release, Depakote delayed release, generic valproic acid, Depakene formulations, Depakote sprinkles, divalproex sodium sprinkles, lamotrigine, lamotrigine chewable tablet, oxcarbazepine, topiramate, Topamax or Trileptal prior to coverage of their respective modified release formulations: lamotrigine extended-release, lamotrigine orally disintegrating tablet, Oxtellar XR*, Qudexy XR*, Stavzor, and Trokendi XR* unless patient has a history of drug-resistant epilepsy or is at high risk of seizure recurrence.

2. **Coverage Criteria:**

**A. Epilepsy, Seizures and Status Epilepticus**

1. The multisource brand anticonvulsants **Depakote, Depakote ER, Felbatol, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, Mysoline, Neurontin, Trileptal, Topamax, or Zonegran** will be approved based on one of the following criteria:

   a. **All** of the following:

      (1) History of greater than or equal to 4 week trial of the therapeutically equivalent generic
(2) Documented history of an inadequate response to the therapeutically equivalent generic as evidenced by **one** of the following:

(a) Change in seizure frequency from baseline  
(b) Breakthrough seizures not explained by medication nonadherence or significant provoking factor  
(c) Status epilepticus

(3) **One** of the following:

(a) The FDA has been notified of the lack of effectiveness of the therapeutically equivalent generic through the FDA Adverse Event Reporting System (FAERS)

-OR-

(b) Submission of medical records documenting the inadequate response to the therapeutically equivalent generic

-OR-

b. **Both** of the following:

(1) Documented history of intolerance to the therapeutically equivalent generic which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. change timing of dosing, divide daily dose out for more frequent but smaller doses)

(2) **One** of the following:

(a) The FDA has been notified of the adverse effect of the therapeutically equivalent generic through the FDA Adverse Event Reporting System (FAERS)

-OR-

(b) Submission of medical records documenting the adverse effect of the therapeutically equivalent generic
-OR-

c. Documented history of drug-resistant epilepsy (defined as the failure of two tolerated and appropriately chosen and used anti-epileptic drug schedules [as either mono-therapy or combination therapy] to achieve sustained seizure freedom)

-OR-

d. Documented history of a high risk for seizure recurrence defined as one or more of the following:

(1) Identifiable brain disease
(2) Mental retardation
(3) Abnormal neurologic examination
(4) Seizure onset after the first decade
(5) Multiple seizure types
(6) Poor initial response to treatment
(7) Juvenile myoclonic epilepsy
(8) Epileptiform discharges on electroencephalogram (EEG)
(9) Family history of epilepsy
(10) Hippocampal atrophy or abnormal hippocampal signal on magnetic resonance imaging (MRI)

Authorization will be issued for 12 months.

2. The modified release products lamotrigine orally disintegrating tablet, Oxtellar XR*, Qudexy XR* (brand and authorized generic), Stavzor, and Trokendi XR* will be approved based on one of the following criteria:

a. Both of the following:

(1) History of greater than or equal to 4 week trial of the corresponding release products:

(a) For lamotrigine orally disintegrating tablet: a trial of lamotrigine immediate release or lamotrigine chewable tablet
(b) For Oxtellar XR: a trial of either oxcarbazepine or Trileptal
(c) For Stavzor: a trial of any of divalproex sodium delayed release, Depakote delayed release, valproex acid, Depakene, Depakote Sprinkles, divalproex sodium sprinkles
(d) For Qudexy XR (brand and authorized generic) or Trokendi XR: a trial of either topiramate or Topamax

-AND-
(2) **One** of the following:

(a) Documented history of an inadequate response to the corresponding release product as evidenced by **one** of the following:

i. Change in seizure frequency from baseline
ii. Breakthrough seizures not explained by medication nonadherence or significant provoking factor
iii. Status epilepticus

-OR-

(b) Documented history of intolerance to the corresponding release product which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. change timing of dosing, divide daily dose out for more frequent but smaller doses)

-OR-

b. Documented history of drug-resistant epilepsy (defined as the failure of two tolerated and appropriately chosen and used anti-epileptic drug schedules [as either mono-therapy or combination therapy] to achieve sustained seizure freedom)

-OR-

c. Documented history of a high risk for seizure recurrence defined as **one** or more of the following:

(1) Identifiable brain disease
(2) Mental retardation
(3) Abnormal neurologic examination
(4) Seizure onset after the first decade
(5) Multiple seizure types
(6) Poor initial response to treatment
(7) Juvenile myoclonic epilepsy
(8) Epileptiform discharges on electroencephalogram (EEG)
(9) Family history of epilepsy
(10) Hippocampal atrophy or abnormal hippocampal signal on magnetic resonance imaging (MRI)

Authorization will be issued for 12 months.

**B. Other Indications** (e.g. mania, bipolar disorder, migraine prophylaxis, neuropathy, postherpetic neuralgia)
1. The multisource brand anticonvulsants **Depakote, Depakote ER, Felbatol, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, Mysoline, Neurontin, Trileptal, Topamax, or Zonegran** will be approved based on one of the following criteria:

   a. **All** of the following:

      (1) History of greater than or equal to 4 week trial of the therapeutically equivalent generic

      -AND-

      (2) Documented history of an inadequate response to the therapeutically equivalent generic

      -AND-

      (3) **One** of the following:

         (a) The FDA has been notified of the lack of effectiveness of the therapeutically equivalent generic through the FDA Adverse Event Reporting System (FAERS)

         -OR-

         (b) Submission of medical records documenting the inadequate response to the therapeutically equivalent generic

         -OR-

   b. **Both** of the following:

      (1) Documented history of intolerance to the therapeutically equivalent generic which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. change timing of dosing, divide daily dose out for more frequent but smaller doses)

      -AND-

      (2) **One** of the following:

         (a) The FDA has been notified of the adverse effect of the therapeutically equivalent generic through the FDA Adverse Event Reporting System (FAERS)
(b) Submission of medical records documenting the adverse effect of the therapeutically equivalent generic

**Authorization will be issued for 12 months.**

2. The modified release products lamotrigine extended-release, lamotrigine orally disintegrating tablet, Oxtellar XR*, Qudexy XR* (brand and authorized generic), Stavzor, and Trokendi XR* will be approved based on one of the following criteria:

   a. **Both** of the following:

      (1) History of greater than or equal to 4 week trial of the corresponding release products:

         (a) For lamotrigine extended-release or orally disintegrating tablet: a trial of lamotrigine immediate release or lamotrigine chewable tablet
         (b) For Oxtellar XR: a trial of either oxcarbazepine or Trileptal
         (c) For Stavzor: a trial of any of divalproex sodium delayed release, Depakote delayed release, valproic acid, Depakene, Depakote Sprinkles, divalproex sodium sprinkles
         (d) For Qudexy XR (brand and authorized generic) or Trokendi XR: a trial of either topiramate or Topamax

         -AND-

         (2) Documented history of an inadequate response to the corresponding release product

   -OR-

   b. Documented history of intolerance to the corresponding release product which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. change timing of dosing, divide daily dose out for more frequent but smaller doses)

   **Authorization will be issued for 12 months.**

3. **Additional Clinical Programs:**

   *Oxtellar XR, Qudexy XR (brand and authorized generic) and Trokendi XR are typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

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4. **References:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2013</td>
<td>New program</td>
</tr>
<tr>
<td>2/2014</td>
<td>Added modified release products Oxtellar XR, Stavzor and Trokendi XR to program.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Moved Lamictal ODT from Multisource Brand section to Modified release section, as generic launch has been delayed.</td>
</tr>
<tr>
<td>8/2014</td>
<td>Updates to FAERS requirement to allow for submission of medical records documenting failure or intolerance to generic rather than submission of FAERS report.</td>
</tr>
<tr>
<td>4/2015</td>
<td>Added Qudexy XR to criteria. Moved brand Lamictal ODT to Multisource Brand section as the generic has launched.</td>
</tr>
<tr>
<td>2/2016</td>
<td>Added lamotrigine extended-release, Felbatol and Mysoline to criteria. Reduced authorization period from 5 years to 12 months.</td>
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