

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2020 P 3001-13 |
| Program | Step Therapy - Anticonvulsants |
| Medication/Therapeutic Class | Anticonvulsants – Depakote [®] , Depakote ER [®] , Felbatol, Keppra [®] , Keppra [®] XR [®] , Lamictal [®] , Lamictal XR [®] , Lamictal ODT [®] , lamotrigine extended-release, lamotrigine orally disintegrating tablet, Lyrica, Mysoline, Neurontin [®] , Onfi, Oxtellar [™] XR*, Qudexy XR* (brand and authorized generic), Spritam*, Topamax [®] , Trileptal [®] , Trokendi [®] XR*, Zonegran [®] |
| P&T Approval Date | 8/2010, 11/2010, 11/2011, 2/2013, 11/2013, 4/2014, 7/2014, 11/2014, 4/2015, 1/2016, 6/2016, 6/2017, 9/2018, 9/2019, 10/2020 |
| Effective Date | 2/1/2021; Oxford only: N/A |

1. Background

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes.

a. Multi-Source Brand Products

This program requires a member to try the A-rated generic prior to receiving coverage for Depakote, Depakote ER, Felbatol, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, Lyrica, Mysoline, Neurontin, Onfi, Topamax, Trileptal and Zonegran. There will be exceptions for members with a documented diagnosis of a seizure disorder. For members with a claim for at least a 14 day supply of the A-rated generic in the previous 6 months, the prescription will process automatically.

b. Modified Release Products

This program requires a member to try levetiracetam immediate release, levetiracetam extended-release, levetiracetam solution, lamotrigine immediate release, divalproex sodium delayed release, Depakote delayed release, generic valproic acid, Depakene formulations, Depakote sprinkles, divalproex sodium sprinkles, oxcarbazepine or Trileptal prior to coverage of their respective modified release formulations: lamotrigine extended-release, lamotrigine orally disintegrating tablet, Oxtellar XR*, Qudexy XR*, Spritam and Trokendi XR*. There will be exceptions for members with a documented diagnosis of a seizure disorder. For members with a claim for at least a 14 day supply of the step 1 medication in the previous 6 months, the prescription will process automatically. The brand version of each generic step 1 medication will also qualify. Members currently on therapy will be grandfathered.

2. Coverage Criteria^a:

A. Depakote will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of divalproex sodium delayed release

-AND-

b. History of an inadequate response to divalproex sodium delayed-release

-OR-

2. History of intolerance to generic divalproex sodium delayed-release formulations

-OR-

3. Patient is receiving Depakote for the treatment of a seizure disorder

B. Depakote ER will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of divalproex sodium ER

-AND-

b. History of an inadequate response to divalproex sodium ER

-OR-

2. History of intolerance to generic divalproex sodium extended release formulations

-OR-

3. Patient is receiving Depakote ER for the treatment of a seizure disorder

C. Felbatol will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of felbamate

-AND-

- b. History of an inadequate response to felbamate

-OR-

2. History of intolerance to generic felbamate formulations

-OR-

3. Patient is receiving Felbatol for the treatment of a seizure disorder

D. Keppra will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of levetiracetam

-AND-

- b. History of an inadequate response to levetiracetam

-OR-

2. History of intolerance to generic levetiracetam formulations

-OR-

3. Patient is receiving Keppra for the treatment of a seizure disorder

E. Keppra XR will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of **one** of the following:

- (1) generic levetiracetam
- (2) generic levetiracetam extended release

-AND-

- b. History of an inadequate response to **one** of the following:

- (1) generic levetiracetam
- (2) generic levetiracetam extended release

-OR-

2. History of intolerance to **one** of the following:

- (1) generic levetiracetam
- (2) generic levetiracetam extended release

-OR-

3. Patient is receiving Keppra XR for the treatment of a seizure disorder

F. Lamictal will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of lamotrigine

-AND-

- b. History of an inadequate response to lamotrigine

-OR-

2. History of intolerance to generic lamotrigine formulations

-OR-

3. Patient is receiving Lamictal for the treatment of a seizure disorder

G. Lamictal ODT will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of lamotrigine orally disintegrating tablet

-AND-

- b. History of an inadequate response to lamotrigine orally disintegrating tablet

-OR-

2. History of intolerance to lamotrigine orally disintegrating tablet

-OR-

3. Patient is receiving Lamictal ODT for the treatment of a seizure disorder

H. Lamictal XR will be approved based on **one** of the following criteria:

1. Both of the following:
 - a. History of ≥ 2 week trial of lamotrigine extended-release

-AND-

- b. History of an inadequate response to lamotrigine extended-release

-OR-

2. History of intolerance to generic lamotrigine extended-release formulations

-OR-

3. Patient is receiving Lamictal XR for the treatment of a seizure disorder

I. Lamotrigine extended-release will be approved based on **one** of the following criteria:

1. **Both** of the following:
 - a. History of ≥ 2 week trial of **one** of the following:
 - (1) generic lamotrigine
 - (2) Lamictal immediate release

-AND-

- b. History of an inadequate response to **one** of the following:
 - (1) generic lamotrigine
 - (2) Lamictal immediate release

-OR-

2. History of intolerance to **one** of the following:
 - a. generic lamotrigine

b. Lamictal immediate release

-OR-

3. Patient is receiving lamotrigine extended-release for the treatment of a seizure disorder

J. Lamotrigine Orally Disintegrating Tablet will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of one of the following:

- (1) generic lamotrigine
- (2) Lamictal immediate release

-AND-

b. History of an inadequate response to one of the following:

- (1) generic lamotrigine
- (2) Lamictal immediate release

-OR-

2. History of intolerance to one of the following:

- a. generic lamotrigine
- b. Lamictal immediate release

-OR-

3. Patient is receiving lamotrigine orally disintegrating tablet for the treatment of a seizure disorder

K. Lyrica will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of generic pregabalin

-AND-

b. History of an inadequate response to generic pregabalin

-OR-

2. History of intolerance to generic pregabalin formulations

-OR-

3. Patient is receiving Lyrica for the treatment of a seizure disorder

L. Mysoline will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of primidone

-AND-

- b. History of an inadequate response to primidone

-OR-

2. History of intolerance to generic primidone formulations

-OR-

3. Patient is receiving Mysoline for the treatment of a seizure disorder

M. Neurontin will be approved based on **one** of the following criteria:

1. **Both** of the following:

- a. History of ≥ 2 week trial of gabapentin

-AND-

- b. History of an inadequate response to gabapentin

-OR-

2. History of intolerance to generic gabapentin formulations

-OR-

3. Patient is receiving Neurontin for the treatment of a seizure disorder

N. Onfi will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of clobazam

-AND-

b. History of an inadequate response to clobazam

-OR-

2. History of intolerance to generic clobazam formulations

-OR-

3. Patient is receiving Onfi for the treatment of a seizure disorder

O. Oxtellar XR* will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of **one** of the following:

(1) generic oxcarbazepine

(2) Trileptal

-AND-

b. History of an inadequate response to **one** of the following:

(1) generic oxcarbazepine

(2) Trileptal

-OR-

2. History of intolerance to **one** of the following:

a. generic oxcarbazepine

b. Trileptal

-OR-

3. Patient is receiving Oxtellar XR for the treatment of a seizure disorder

P. Spritam* will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of **one** of the following:

- (1) generic levetiracetam tablet
- (2) generic levetiracetam solution

-AND-

b. History of an inadequate response to **one** of the following:

- (1) generic levetiracetam tablet
- (2) generic levetiracetam solution

-OR-

2. History of intolerance to **one** of the following:

- (1) generic levetiracetam tablet
- (2) generic levetiracetam solution

-OR-

3. Patient is receiving Spritam for the treatment of a seizure disorder

Q. Trileptal will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of oxcarbazepine

-AND-

b. History of an inadequate response to oxcarbazepine

-OR-

2. History of intolerance to generic oxcarbazepine formulations

-OR-

3. Patient is receiving Trileptal for the treatment of a seizure disorder

R. Topamax will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of topiramate

-AND-

b. History of an inadequate response to topiramate

-OR-

2. History of intolerance to generic topiramate formulations

-OR-

3. Patient is receiving Topamax for the treatment of a seizure disorder

S. Trokendi XR* or Qudexy XR* (brand and authorized generic) will be approved based on one of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of **one** of the following:

- (1) generic topiramate
- (2) Topamax

-AND-

b. History of an inadequate response to **one** of the following:

- (1) generic topiramate
- (2) Topamax

-OR-

2. History of intolerance to **one** of the following:

- (1) generic topiramate
- (2) Topamax

-OR-

3. Patient is receiving Trokendi XR or Qudexy XR (brand and authorized generic) for the treatment of a seizure disorder

T. Zonegran will be approved based on **one** of the following criteria:

1. **Both** of the following:

a. History of ≥ 2 week trial of zonisamide

-AND-

b. History of an inadequate response to zonisamide

-OR-

2. History of intolerance to generic zonisamide formulations

-OR-

3. Patient is receiving Zonegran for the treatment of a seizure disorder

Authorization of therapy will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- * Oxtellar XR, Qudexy XR (brand and authorized generic), Spritam and Trokendi XR are typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

4. References:

1. Depakote [package insert]. North Chicago, IL: AbbVie; May 2020.
2. Depakote ER [package insert]. North Chicago, IL: AbbVie; May 2020.
3. Keppra [package insert]. Smyrna, GA: UCB, Inc; October 2019.
4. Keppra XR [package insert]. Smyrna, GA: UCB, Inc; November 2019.
5. Lamictal/Lamictal ODT [package insert]. Research Triangle Park, NC: GSK LLC; February 2020.
6. Lamictal XR [package insert]. Research Triangle Park, NC: GSK LLC; September 2019.
7. Neurontin [package insert]. New York, NY: Pfizer Inc; April 2020.

8. Oxtellar XR [package insert]. Rockville, MD: Supernus Pharmaceuticals Inc; December 2018.
9. Qudexy XR [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc; February 2020.
10. Trileptal [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020.
11. Trokendi XR [package insert]. Rockville, MD: Supernus Pharmaceutical Inc; February 2019.
12. Topamax [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; May 2019.
13. Zonegran [package insert]. Dublin, Ireland: Concordia Pharmaceuticals Inc; April 2020.
14. Felbatol [package insert]. Sommerset, NJ: Meda Pharmaceuticals Inc; February 2018.
15. Mysoline [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2019.
16. Spritam [package insert]. East Windsor, NJ: Aprelia Pharmaceuticals Company; September 2018.
17. Onfi [package insert]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; June 2018.
18. Lyrica [package insert]. New York, NY: Pfizer Inc; April 2020.

| Program | Step Therapy - Anticonvulsants |
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| Change Control | |
| Date | Change |
| 10/2013 | Added lamotrigine orally disintegrating-tablet, and Trokendi XR as step 2 agents. Updated lamotrigine extended-release to include Lamictal XR as a step 1 agent. |
| 11/2013 | Added Depakote, Neurontin, Trileptal and Zonegran as step 2 agents. Updated Lamictal ODT and Lamictal XR to require the use of the corresponding generic before the brand is covered. |
| 4/2014 | Added lamotrigine as step one agent for Lamictal ODT tablets. Administrative changes. |
| 7/2014 | Added lamotrigine chewable tablet as step one agent for Lamictal ODT. |
| 11/2014 | Added levetiracetam as a step one agent for Keppra XR. |
| 4/2015 | Added Qudexy XR to criteria. Updated step one criteria for Lamictal ODT to the generic product only. |
| 1/2016 | Added Felbatol and Mysoline to criteria. Added Maryland coverage information. |
| 6/2016 | Removed Stavzor from criteria as it has been discontinued. Added Spritam to criteria. Added Indiana and West Virginia coverage information. |
| 11/2016 | Administrative change. Added California coverage information. |
| 6/2017 | Annual review. Updated references. State mandate reference language updated. |
| 9/2018 | Annual review. Updated references. |

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| 12/2018 | Administrative change to add statement regarding use of automated processes. |
| 9/2019 | Lyrica and Onfi added to criteria. Updated references. |
| 102020 | Annual review. Updated references. |