BlueCross BlueShield of Alabama

Topiramate ER Prior Authorization with Quantity Limit Program Summary

This prior authorization program applies to Commercial, GenPlus, NetResults A series, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the prior authorization with quantity limit program is to encourage appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines. The program will not be approved for those who have any FDA labeled contraindications to the requested agent. Patients with a prior claim for an anti-seizure drug which is not topiramate will not be subject to the prior authorization. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET AGENT(S)

Qudexy XR (topiramate ER)
Topiramate ER
Trokendi XR (topiramate ER)

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity Limit (Daily Limit)
Qudexy XR, Topiramate ER			
25 mg capsule	7260007500F310	M, N, O, Y	1 capsule
50 mg capsule	7260007500F320	M, N, O, Y	1 capsule
100 mg capsule	7260007500F330	M, N, O, Y	1 capsule
150 mg capsule	7260007500F340	M, N, O, Y	1 capsule
200 mg capsule	7260007500F350	M, N, O, Y	2 capsules
Trokendi XR (topiramate ER)			
25 mg capsule	72600075007020	M, N, O, Y	1 capsule
50 mg capsule	72600075007030	M, N, O, Y	1 capsule
100 mg capsule	72600075007040	M, N, O, Y	1 capsule
200 mg capsule	72600075007050	M, N, O, Y	2 capsules

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Target Agents will be approved when ALL of the following are met:

Initial Evaluation

1. ONE of the following:
    a. The patient's medication history includes an anti-seizure drug which is not topiramate
    OR
    b. BOTH of the following:
        i. The patient has ONE of the following:
            1. Diagnosis of partial onset seizures
            OR
            2. Diagnosis of primary generalized tonic-clonic seizures

OR

3. Diagnosis of Lennox-Gastaut Syndrome

OR

4. Diagnosis of Migraine

AND

c. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

2. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit

   OR

   b. ALL of the following:
      i. The requested quantity is greater than the program quantity limit

      AND

      ii. The requested quantity (dose) is less than or equal to the FDA labeled dose

      AND

      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

   OR

   c. ALL of the following:
      i. The requested quantity is greater than the program quantity limit

      AND

      ii. The requested quantity (dose) is greater than the FDA labeled dose

      AND

      iii. The prescriber has submitted documentation in support of therapy with a higher dose for an accepted diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

Renewal Evaluation

1. ONE of the following:
   a. The patient's medication history includes an anti-seizure drug which is not topiramate

   OR

   b. ALL of the following:
      i. The patient has been previously approved for the requested agent through Prime Therapeutics Prior Authorization Review process

      AND

      ii. The prescriber has indicated that the patient has received benefit from the requested agent

      AND

      iii. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

2. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit

   OR

   b. ALL of the following:
      i. The requested quantity is greater than the program quantity limit

      AND

      ii. The requested quantity (dose) is less than or equal to the FDA labeled dose

      AND

iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

OR

c. ALL of the following
   i. The requested quantity is greater than the program quantity limit
   AND
   ii. The requested quantity (dose) is greater than the FDA labeled dose
   AND
   iii. The prescriber has submitted documentation in support of therapy with a higher dose for an accepted diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1,2]

Agent	Indication	Dosage & Administration
Qudexy XR® (topiramate ER) Capsules	Partial Onset Seizures and Primary Generalized Tonic-Clonic Seizures; Initial monotherapy in patients 2 years and older with partial onset or primary generalized tonic-clonic seizures and adjunctive therapy in patients 2 years and older with partial onset or primary generalized tonic-clonic seizures Lennox-Gastaut Syndrome (LGS); Adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome Migraine: Prophylaxis of migraine headache in adults and adolescents 12 years of age and older	See Qudexy XR Dosing Tables 1 and 2 below

<table>
<tr>
<td>Trokendi XR®
(topiramate ER)

Capsules</td>
<td>Epilepsy: initial monotherapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures; adjunctive therapy in patients 6 years of age and older with partial onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox Gastaut syndrome (LGS)

Prophylaxis of migraine in patients 12 years of age and older</td>
<td>Dosing in Monotherapy Eplilepsy:
Adults and Pediatric Patients 10 Years of Age and Older with Partial Onset or Primary Generalized Tonic-Clonic Seizures:
Recommended dose for monotherapy is 400 mg orally once daily with the following titration schedule:
Week 1: 50 mg once daily
Week 2: 100 mg once daily
Week 3: 150 mg once daily
Week 4: 200 mg once daily
Week 5: 300 mg once daily
Week 6: 400 mg once daily

Pediatric Patients Ages 6-9 years of age:
Initial dose is 25mg/day nightly for the first week. Dosage can be increased to 50 mg/day in the second week. Dosage can be increased by 25-50 mg/day each subsequent week to first achieve the minimum daily dose and then further increased by 25-50 mg/day weekly to the maximum maintenance dose by body weight:
<table>
<tr><th>Weight (kg)</th><th>Total Daily Dose (mg/day) Minimum Maintenance Dose</th><th>Total Daily Dose (mg/day) Maximum maintenance Dose</th></tr>
<tr><td>Up to 11</td><td>150</td><td>250</td></tr>
<tr><td>12-22</td><td>200</td><td>300</td></tr>
<tr><td>23-31</td><td>200</td><td>350</td></tr>
</table>
Dosing in Adjunctive Therapy Epilepsy:
Adults (17 years of age and over):
The recommended total daily dose in partial onset seizures or LGS is 200-400 mg once daily.
The recommended total daily dose in primary generalized tonic-clonic seizures is 400 mg orally once daily.
Initiate therapy at 25-50 mg once daily followed by titration to an effective dose in increments of 25 mg to 50 mg every week. Doses above 400 mg/day have not been shown to improve responses in adults with partial onset seizures.

Pediatric patients 6-16 years of age:
The recommended total daily dose in partial onset seizures, primary generalized tonic-clonic seizures, or seizures associated with LGS is 5mg/kg to 9 mg/kg once daily.</td>
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</table>

Agent	Indication	Dosage & Administration
		Begin titration at 25 mg once daily (or less based on range of 1 mg/kg/day to 3 mg/kg/day) given nightly for the first week. Subsequently, increase the dosage at 1 or 2 week intervals by increments of 1 mg/kg to 3 mg/kg to achieve optimal clinical response. Total daily dose should not exceed 400 mg/day. **Dosing in Migraine Prophylaxis** The recommended total daily dose for patients 12 years of age and older is 100 mg once daily with the following titration schedule: Week 1: 25mg once daily Week 2: 50mg once daily Week 3: 75mg once daily Week 4: 100mg once daily

Qudexy XR Dosing Table 1[1]

	Initial	Titration	Recommended
Monotherapy: Partial Onset or Primary Generalized Tonic-Clonic Seizures			
Adults and pediatric patients 10 years and older	50 mg once daily	Increase dose weekly by increments of 50 mg for the first 4 weeks then 100 mg for weeks 5 to 6	400 mg once daily
Pediatric patients 2 to less than 10 years	25 mg once daily at nighttime for the first week	Titrate the dosage over 5 to 7 weeks	Once daily doses based on weight (Table 2)
Adjunctive Therapy			
Adults with partial onset seizures or LGS	25 mg to 50 mg once daily	Increase dose weekly by increments of 25 mg to 50 mg to achieve an effective dose	200 mg to 400 mg once daily
Adults with primary generalized tonic-clonic seizures	25 mg to 50 mg once daily	Increase dose weekly to an effective dose by increments of 25 mg to 50 mg	400 mg once daily
Pediatric patients 2 years and older with partial onset seizures, primary generalized tonic-clonic seizures or LGS	25 mg once daily at nighttime for the first week	Increase dosage at 1 or 2 week intervals by increments of 1 mg/kg to 3 mg/kg; dose titration should be guided by clinical outcome	5 mg/kg to 9 mg/kg once daily
Migraine	25 mg once daily at nighttime for the first week	Increase dose weekly by increments of 25 mg. Dosage and titration should be guided by clinical outcome.	100 mg once daily

Qudexy XR Dosing Table 2[1]

Weight (kg)	Once Daily Dose (mg per day) Minimum Maintenance Dose	Once Daily Dose (mg per day) Maximum Maintenance Dose
Up to 11	150	250
12 to 22	200	300
23 to 31	200	350
32 to 38	250	350
Greater than 38	250	400

CLINICAL RATIONALE

Safety

Qudexy XR is contraindicated in patients with metabolic acidosis taking concomitant metformin.

Trokendi XR is contraindicated in patients with recent alcohol use (i.e., within 6 hours prior to and 6 hours after Trokendi XR use).

REFERENCES

1. Qudexy XR prescribing information. Upsher-Smith Laboratories, Inc. March 2017.
2. Trokendi XR prescribing information. Supernus Pharmaceuticals. January 2018.