



## Uniform Formulary Medical Necessity Criteria for Lyrica (Pregabalin)

**Drug Class** - GABA analogs. Medications in this class are used for the adjunctive treatment of partial seizures (added to other seizure medications) and neuropathic pain. This drug class includes the following medications: gabapentin, pregabalin (Lyrica), and tiagabine (Gabitril).

**Background** - After evaluating the relative clinical and cost effectiveness of medications in this class, the DoD P&T Committee recommended that the following medications be designated as non-formulary: pregabalin (Lyrica). This recommendation has been approved by the Director, TMA.

**Effective Date:** 28 Jun 2006

Patients currently using Lyrica may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for GABA Analogs <sup>\*,\*\*</sup>

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) cost share for up to a 90 day supply	Mail Order cost share for up to a 90 day supply	Retail Network cost share for up to a 30 day supply
Non-Formulary (Tier 3)	Lyrica (pregabalin)	Not available**	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	Gabitril (tiagabine) ***	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic (Tier 1)	gabapentin	\$0	Generic cost share applies	Generic cost share applies

\* Active duty cost share always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.

\*\* MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

\*\*\* Tiagabine is not approved by the FDA for the treatment of neuropathic pain and clinical evidence supporting its use for this indication is limited. For this reason, tiagabine is not considered to be a therapeutic alternative to pregabalin for the treatment of neuropathic pain. All three medications are approved by the FDA for use as adjunctive therapy (added to other seizure medications) in the treatment of partial seizures.

### Medical Necessity Criteria for Lyrica

Medical Necessity Criteria for Lyrica The non-formulary cost share for Lyrica may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. The patient is being treated for seizure disorder AND the patient meets one of the following criteria:
  - Use of at least one of the two formulary medications (gabapentin or tiagabine) is contraindicated (e.g., hypersensitivity), and use of other formulary anticonvulsants is not clinically appropriate.
  - The patient has previously responded to Lyrica, and changing to a formulary anticonvulsant would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Lyrica and changing to a formulary anticonvulsant would present an increased risk of seizure).
  - The patient has failed an adequate trial of at least one of the two formulary medications (gabapentin or tiagabine), is expected to respond to Lyrica, and use of other formulary anticonvulsants is not clinically appropriate.
  - The patient has tried and been unable to tolerate at least one of the two formulary medications (gabapentin or tiagabine), is expected to tolerate Lyrica, and use of other formulary anticonvulsants is not clinically appropriate.
2. The patient is being treated for neuropathic pain AND the patient meets one of the following criteria:
  - The patient has failed adequate trials of gabapentin AND at least one medication from one of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants, anticonvulsants (other than gabapentin), or opioids (e.g., tramadol). Note: an adequate trial is, in general, considered to be at least 6 weeks in duration.
  - The patient has tried and been unable to tolerate gabapentin AND at least one medication from one of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants, anticonvulsants (other than gabapentin), or opioids (e.g., tramadol).
  - It is clinically inappropriate (e.g., due to contraindications) for the patient to receive treatment with gabapentin AND at least one medication from one of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants, anticonvulsants (other than gabapentin), or opioids (e.g., tramadol).
3. The patient has been diagnosed with fibromyalgia AND the patient meets one of the following criteria:
  - Has failed an adequate trial of at least one medication from the following category: tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.
  - Has tried and been unable to tolerate at least one medication from the following category: tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.
  - It is clinically inappropriate (e.g., due to contraindications) for the patient to receive treatment with tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.

Medical necessity recommended by the DoD Pharmacy & Therapeutics Committee at the February 2006 meeting, approved by the Director, TMA on 26 April 2006, and modified in October 2007 due to the FDA approval of pregabalin (Lyrica) for fibromyalgia. For more information, please see the Feb 2006 and August 2007 [DoD P&T Committee minutes](#).

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