



SmartPA Criteria Proposal

Drug/Drug Class:	Fibromyalgia Agents PDL Edit
First Implementation Date:	June 2, 2010
Revised Date:	September 10, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why was this Issue Selected: Fibromyalgia is characterized by chronic widespread pain and heightened painful response to pressure. The underlying cause of fibromyalgia is unknown. Diagnosis is based on expert opinions. It affects 0.5% to 5% of the general population and up to 15.7% in a clinic setting. Clinical guidelines recommend a multidisciplinary approach with short-term use of medication for relief. There are three FDA approved medications for management of fibromyalgia: pregabalin, duloxetine and milnacipran. Current evidence supports the safety and efficacy of the approved agents as monotherapy for up to 6 months for Cymbalta®, Drizalma Sprinkle™, Irenka™ and Lyrica® and up to 3 months for Savella®. Many other agents are used off-label for management of fibromyalgia. Combination therapy of approved or off-label medications can potentially cause severe adverse events, drug interactions and interfere with disease management. Studies also show the efficacy of these agents in managing fibromyalgia decreases over time.

Total program savings for the PDL classes will be regularly reviewed.

Program-specific information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> Duloxetine 20, 30, 60mg Pregabalin Caps 	<ul style="list-style-type: none"> Cymbalta® Drizalma Sprinkle™ Duloxetine 40mg Irenka™ Lyrica® Lyrica® CR Pregabalin Soln Savella®

Type of Criteria:
 Increased risk of ADE
 Preferred Drug List
 Appropriate Indications
 Clinical Edit

Data Sources:
 Only Administrative Databases
 Databases + Prescriber-Supplied

Setting & Population

- Drugs class for review: Fibromyalgia Agents
- Age Range: All appropriate MO HealthNet participants 13 years of age or older

Approval Criteria

- **For Cymbalta: participants aged 18 years of age or older OR**
- Participants aged 18 years of age or older **AND**
- Failure to achieve desired therapeutic outcomes with a trial on 2 preferred agents
 - Documented trial period for preferred agents **OR**
 - Documented ADE/ADR to preferred agents
- For Savella: Documented diagnosis of fibromyalgia in the last 2 years
- For Irenka or Drizalma Sprinkle: Documented diagnosis of depression, anxiety, chronic musculoskeletal pain, or peripheral neuropathy associated with diabetes in the last 2 years
- For Lyrica: Documented diagnosis of fibromyalgia, neuropathy post spinal cord injury, postherpetic neuralgia, partial onset seizures, or peripheral neuropathy associated with diabetes in the last 2 years

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- After 90 days of fibromyalgia therapy, participants receiving any combination of > 3 of the following drug classes in the last 120 days:
 - Tricyclic Antidepressants (TCA)
 - Selective Serotonin Re-uptake Inhibitors (SSRI)
 - Opioids
 - Skeletal Muscle Relaxants

Required Documentation

Laboratory results:

Progress notes:

X

MedWatch form:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List Edit)

Rule Type: PDL

Default Approval Period

1 year

References

1. Drug Effectiveness Review Project – Drug Class Review: "Drugs for Fibromyalgia", Center for Evidence-Based Policy, Oregon Health & Science University; April 2011; Evidence Scan Update, June 2018.
2. Evidence-Based Medicine and Fiscal Analysis: "Fibromyalgia – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2019.
3. Evidence-Based Medicine Analysis: "Fibromyalgia Agents", UMKC-DIC; August 2019.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
5. USPDI, Micromedex; 2019.
6. Drug Facts and Comparisons On-line; 2019.

SmartPA PDL Proposal Form

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