SmartPA Criteria Proposal

Drug/Drug Class:	Fibromyalgia Agents PDL Edit
First Implementation Date:	June 2, 2010
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

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

Why 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™, 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
• Duloxetine 20, 30, 60 mg • Pregabalin Caps	• Cymbalta® • Drizalma Sprinkle™ • Duloxetine 40 mg • Lyrica® • Lyrica® CR • Prebagalin CR • Pregabalin Soln • Savella®

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **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

Approval Criteria

- Participants aged 18 years of age or older, except claim for a preferred duloxetine product **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
- For Lyrica: Documented diagnosis of fibromyalgia, neuropathy post spinal cord injury, postherpetic neuralgia, partial onset seizures, or peripheral neuropathy associated with diabetes

Denial Criteria

- Lack of adequate trial on required preferred agents
- For pregabalin:
  - Participant has documented history of gabapentin therapy in the past 30 days
  - **Cumulative daily doses > 660 mg**
- Therapy will be denied if all approval criteria are not met
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for pregabalin and:
  - Participant has history of > 7 days of opioid therapy (excluding buprenorphine tablets and buprenorphine/naloxone combinations) in the past 60 days **AND**
  - Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years
- Claim exceeds maximum dosing limitations on the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitations
CYMBALTA 20 MG CAPSULE	DULOXETINE	2 capsules per day
CYMBALTA 30 MG CAPSULE	DULOXETINE	2 capsules per day
CYMBALTA 60 MG CAPSULE	DULOXETINE	2 capsules per day
DRIZALMA SPRINKLE DR 20 MG CAP	DULOXETINE	1 capsule per day
DRIZALMA SPRINKLE DR 30 MG CAP	DULOXETINE	1 capsule per day
DRIZALMA SPRINKLE DR 40 MG CAP	DULOXETINE	2 capsules per day
DRIZALMA SPRINKLE DR 60 MG CAP	DULOXETINE	2 capsules per day
DULOXETINE HCL DR 40 MG CAP	DULOXETINE	2 capsules per day
LYRICA 25 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 50 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 75 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 100 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 150 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 200 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 225 MG CAPSULE	PREGABALIN	3 capsules per day
LYRICA 300 MG CAPSULE	PREGABALIN	2 capsules per day
LYRICA 20 MG/ML ORAL SOLUTION	PREGABALIN	30 mL per day
LYRICA CR 82.5 MG TABLET	PREGABALIN	1 tablet per day
LYRICA CR 165 MG TABLET	PREGABALIN	1 tablet per day
LYRICA CR 330 MG TABLET	PREGABALIN	1 tablet per day
SAVELLA 12.5 MG TABLET	MILNACIPRAN	2 tablets per day
SAVELLA 25 MG TABLET	MILNACIPRAN	2 tablets per day
SAVELLA 50 MG TABLET	MILNACIPRAN	2 tablets per day
SAVELLA 100 MG TABLET	MILNACIPRAN	2 tablets per day

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

- Evidence-Based Medicine and Fiscal Analysis: "Fibromyalgia – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: "Fibromyalgia Agents", UMKC-DIC; August 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.