Clinical Policy: Fibromyalgia Agents
Reference Number: OH.PHAR.PPA.39
Effective Date: 01.01.2020
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

CNS AGENTS: FIBROMYALGIA AGENTS

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREGABALIN (generic for Lyrica®)</td>
<td>SAVELLA® (milnacipran)</td>
</tr>
</tbody>
</table>

FDA Approved Indication(s)
- Savella is indicated for the management of fibromyalgia
- Lyrica is indicated for:
  - Neuropathic pain associated with diabetic peripheral neuropathy
  - Postherpetic neuralgia (PHN)
  - Patients 1 month of age and older with partial onset seizures as adjunctive therapy
  - Fibromyalgia
  - Neuropathic pain associated with spinal cord injury

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Savella® is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Fibromyalgia (must meet all):
      1. Diagnosis of fibromyalgia;
      2. Age ≥ 18 years;
      3. Member has had a trial of medications from no less than 2 of the following drug classes for at least 14 days each in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):
         a) Gabapentin
         b) Pregabalin
         c) Short and/or long acting opioids
         d) Skeletal muscle relaxants
e) SNRI’s
f) SSRI’s
g) Trazodone
g) Tricyclic antidepressants

4. Trial of medications from no less than two of the above drug classes unless any of the following:
   a. Allergy to at least two medications in different classes (see above) not requiring prior approval;
   b. Contraindication to all medications not requiring prior approval
   c. History of unacceptable/toxic side effects to at least two medications in different classes (see above) not requiring prior approval

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy– CP.CPA.09 CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration
   SNRI: selective serotonin and norepinephrine reuptake inhibitor
   SSRI: selective serotonin reuptake inhibitor

   Appendix B: Therapeutic Alternatives*
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregabalin (Lyrica®)</td>
<td>Fibromyalgia 75mg PO BID titrated to 225mg BID</td>
<td>450mg/day</td>
</tr>
</tbody>
</table>

   Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

   Appendix C: Contraindications/Boxed Warnings
   • Contraindication(s): known hypersensitivity to pregabalin or any of its components
   • Milnacipran is contraindicated with concurrent use of MAOI therapy.
   • Boxed warning(s): none reported
IV. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Savella® (milnacipran)</td>
<td>Fibromyalgia 12.5mg PO QD titrated to 100mg BID</td>
<td>200 mg/day</td>
</tr>
</tbody>
</table>

V. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Savella® (milnacipran)</td>
<td>Tablets: 12.5mg, 25mg, 50mg, 100mg</td>
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<tr>
<td></td>
<td>Titration pack: 12.5mg tablets (5)</td>
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<tr>
<td></td>
<td>25mg tablets (8)</td>
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<td>50mg tablets (42)</td>
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</tbody>
</table>

VI. References

Refer to package insert

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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</thead>
<tbody>
<tr>
<td>Policy created</td>
<td></td>
<td>11.2019</td>
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</table>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering
benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage
decisions and the administration of benefits are subject to all terms, conditions, exclusions and
limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,
contract of insurance, etc.), as well as to state and federal requirements and applicable Health
Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting
may not be the effective date of this clinical policy. This clinical policy may be subject to
applicable legal and regulatory requirements relating to provider notification. If there is a
discrepancy between the effective date of this clinical policy and any applicable legal or
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policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is
not intended to dictate to providers how to practice medicine. Providers are expected to exercise
professional medical judgment in providing the most appropriate care, and are solely responsible
for the medical advice and treatment of members. This clinical policy is not intended to
recommend treatment for members. Members should consult with their treating physician in
connection with diagnosis and treatment decisions.

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herein through the terms of their contracts. Where no such contract exists, providers, members
and their representatives agree to be bound by such terms and conditions by providing services to
members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage
provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please
refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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