

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Selective Serotonin Reuptake Inhibitors (SSRI) Step Therapy Edit |
| First Implementation Date: | October 26, 2005 |
| Proposed Date: | October 17, 2023 |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria |

Executive Summary

Purpose: Ensure appropriate use of selective serotonin reuptake inhibitor (SSRI) agents

Why Issue Selected: MO HealthNet will assess the usage of SSRI agents in the pharmacy program with a primary goal of patient safety. Participants may have multiple prescribers and/or multiple pharmacies caring for them and without a clinical edit it is almost impossible to prevent duplication within a drug class, dangerous drug interactions, or overmedication. By using medical evidence guidelines, this clinical edit can flag potentially dangerous duplicate and high dose therapy for SSRI agents. The edit helps to provide an "early warning alert" to the pharmacist filling the prescription and the prescribing physician. As always, if a provider wishes to override a denial for medically necessary reasons, a claim can be approved with further medical input through direct communication with the MHD Hotline.

Program-Specific Information:

| Date Range FFS 7-1-2022 to 6-30-2023 | | | | |
|--------------------------------------|-------------------------|--------|----------------|---------------------|
| Generic Equivalent | Drug Description | Claims | Spend | Avg Spend per Claim |
| CITALOPRAM HBR | CELEXA 10 MG TAB | 18710 | \$191,525.08 | \$10.24 |
| | CELEXA 10 MG/5 ML SOL | 414 | \$25,020.58 | \$60.44 |
| | CELEXA 20 MG TAB | 43324 | \$444,865.45 | \$10.27 |
| | CELEXA 20 MG/10 ML SOL | 0 | - | - |
| | CELEXA 40 MG TAB | 37136 | \$387,210.87 | \$10.43 |
| | CITALOPRAM 30 MG CAP | 0 | - | - |
| ESCITALOPRAM OXALATE | LEXAPRO 5 MG TAB | 18641 | \$244,910.63 | \$13.14 |
| | LEXAPRO 5 MG/5 ML SOL | 401 | \$36,259.95 | \$90.42 |
| | LEXAPRO 10 MG TAB | 79362 | \$1,045,176.30 | \$13.17 |
| | LEXAPRO 10 MG/10 ML SOL | 0 | - | - |
| | LEXAPRO 20 MG TAB | 74815 | \$1,023,966.30 | \$13.69 |
| FLUOXETINE HCL | FLUOXETINE 60 MG TAB | 5846 | \$176,157.17 | \$30.13 |
| | PROZAC 10 MG CAP | 31492 | \$395,727.89 | \$12.57 |
| | PROZAC 20 MG CAP | 76281 | \$814,617.33 | \$10.68 |
| | PROZAC 20 MG/5 ML SOL | 3112 | \$153,462.96 | \$49.31 |
| | PROZAC 40 MG CAP | 56864 | \$677,349.66 | \$11.91 |
| | PROZAC WEEKLY 90 MG | 294 | \$35,985.00 | \$122.40 |
| | SARAFEM 10 MG TAB | 9134 | \$125,493.23 | \$13.74 |
| | SARAFEM 20 MG TAB | 12090 | \$225,339.37 | \$18.64 |

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|------------------------|------------------------|----------------|------------------------|----------------|
| FLUVOXAMINE MALEATE | LUVOX 25 MG TAB | 816 | \$16,070.63 | \$19.69 |
| | LUVOX 50 MG TAB | 2543 | \$54,975.45 | \$21.62 |
| | LUVOX 100 MG TAB | 3377 | \$84,272.21 | \$24.95 |
| | LUVOX CR 100 MG CAP | 319 | \$78,843.00 | \$247.16 |
| | LUVOX CR 150 MG CAP | 415 | \$112,031.24 | \$269.95 |
| PAROXETINE HCL | PAXIL 10 MG TAB | 7571 | \$101,384.15 | \$13.39 |
| | PAXIL 10 MG/5 ML SUSP | 88 | \$37,937.63 | \$431.11 |
| | PAXIL 20 MG TAB | 14936 | \$170,572.37 | \$11.42 |
| | PAXIL 30 MG TAB | 5434 | \$73,333.62 | \$13.50 |
| | PAXIL 40 MG TAB | 10360 | \$146,000.76 | \$14.09 |
| | PAXIL CR 12.5 MG TAB | 157 | \$5,977.78 | \$38.08 |
| | PAXIL CR 25 MG TAB | 431 | \$18,396.60 | \$42.68 |
| | PAXIL CR 37.5 MG TAB | 233 | \$10,363.47 | \$44.48 |
| PAROXETINE MESYLATE | BRISDELLE 7.5 MG CAP | 59 | \$6,728.64 | \$114.04 |
| | PEXEVA 10 MG TAB | 0 | - | - |
| | PEXEVA 20 MG TAB | 7 | \$3,135.35 | \$447.91 |
| | PEXEVA 30 MG TAB | 3 | \$1,355.73 | \$451.91 |
| | PEXEVA 40 MG TAB | 0 | - | - |
| SERTRALINE HCL | SERTRALINE 150 MG CAP | 6 | \$486.01 | \$81.00 |
| | SERTRALINE 200 MG CAP | 10 | \$441.07 | \$44.11 |
| | ZOLOFT 20 MG/ML CONC | 1509 | \$83,041.28 | \$55.03 |
| | ZOLOFT 25 MG TAB | 45254 | \$542,821.11 | \$11.99 |
| | ZOLOFT 50 MG TAB | 103453 | \$1,337,820.12 | \$12.93 |
| | ZOLOFT 100 MG TAB | 111913 | \$1,449,976.72 | \$12.95 |
| VILAZODONE HCL | VIIBRYD 10 MG-20 MG PK | 31 | \$9,929.98 | \$320.32 |
| | VIIBRYD 10 MG TAB | 1095 | \$336,856.46 | \$307.63 |
| | VIIBRYD 20 MG TAB | 2744 | \$845,406.97 | \$308.09 |
| | VIIBRYD 40 MG TAB | 4192 | \$1,280,947.32 | \$305.57 |
| VORTIOXETINE HBR | TRINTELLIX 5 MG TAB | 1413 | \$585,143.13 | \$414.11 |
| | TRINTELLIX 10 MG TAB | 4910 | \$2,100,254.96 | \$427.75 |
| | TRINTELLIX 20 MG TAB | 6998 | \$2,914,530.15 | \$416.48 |
| Total | | 798,193 | \$18,412,101.68 | \$23.07 |

Type of Criteria: ☐ Increased risk of ADE
☒ Appropriate Indications

☐ Preferred Drug List
☒ Clinical Edit

Data Sources: ☐ Only Administrative Databases

☒ Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Selective serotonin reuptake inhibitor (SSRI) agents
- Age range: All appropriate MO HealthNet participants aged 5 years and older

Approval Criteria

- Participant aged 5 years or older **AND**
- Documented compliance to current SSRI therapy regimen (90 days in the past 120 days) **OR**
- Documented adequate initial therapeutic intervention with 1 or more reference products (see Appendix A) **OR**
- Documented ADE/ADR to reference products
- Documented appropriate diagnosis required for:
 - Participants < 18 years of age **OR**
 - Participants < 26 years of age who are also enrolled in foster care
- Claim for Citalopram HBR 30 mg capsule, Sertraline 150 mg capsule, or Sertraline 200 mg capsule: Clinical Consultant review required for why generic tablet alternatives cannot be utilized

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Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosage limits (see Appendix B)
- Participants < 18 years of age: history of > 2 SSRI agents for more than 30 days in the past 90 days
- Participants ≥ 18 years of age: history of > 2 SSRI agents for more than 60 days in the past 90 days
- Participant is on more than one SSRI agent and one SNRI agent concurrently for more than 30 days

Required Documentation

Laboratory Results: ☐
MedWatch Form: ☐

Progress Notes: ☐
Other: ☒

Disposition of Edit

Denial: Exception code "0681" (Step Therapy)
Rule Type: CE

Appendix A – SSRI reference products

- CITALOPRAM HBR SOLN/TAB
- ESCITALOPRAM TAB
- FLUOXETINE HCL CAP/SOLN
- FLUOXETINE HCL TAB 10 MG AND 20 MG
- FLUVOXAMINE MALEATE TAB
- PAROXETINE HCL TAB
- SERTRALINE HCL SOLN/TAB

Appendix B – Maximum Daily Dosage Limits

| Generic Equivalent | Max Daily Dose |
|----------------------|----------------|
| CITALOPRAM HBR | 60 mg |
| ESCITALOPRAM OXALATE | 20 mg |
| FLUOXETINE HCL | 80 mg |
| FLUVOXAMINE MALEATE | 300 mg |
| PAROXETINE HCL | 80 mg |
| PAROXETINE MESYLATE | 80 mg |
| SERTRALINE HCL | 200 mg |
| VILAZODONE HCL | 40 mg |
| VORTIOXETINE HBR | 20 mg |

| Drug Description | Generic Equivalent | Dose Optimization Limit |
|----------------------|----------------------|--|
| BRISDELLE 7.5 MG CAP | PAROXETINE MESYLATE | Deny dosing more frequently than 1 per day |
| CELEXA 10 MG TAB | CITALOPRAM HBR | Deny dosing more frequently than 2 per day |
| CELEXA 20 MG TAB | CITALOPRAM HBR | Deny dosing more frequently than 1.5 per day |
| CELEXA 40 MG TAB | CITALOPRAM HBR | Deny dosing more frequently than 2 per day |
| LEXAPRO 5 MG TAB | ESCITALOPRAM OXALATE | Deny dosing more frequently than 2 per day |
| LEXAPRO 10 MG TAB | ESCITALOPRAM OXALATE | Deny dosing more frequently than 1.5 per day |
| LEXAPRO 20 MG TAB | ESCITALOPRAM OXALATE | Deny dosing more frequently than 1.5 per day |

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| LUVOX 25 MG TAB | FLUVOXAMINE MALEATE | Deny dosing more frequently than 3 per day |
| LUVOX 50 MG TAB | FLUVOXAMINE MALEATE | Deny dosing more frequently than 3 per day |
| LUVOX 100 MG TAB | FLUVOXAMINE MALEATE | Deny dosing more frequently than 3 per day |
| LUVOX CR 100 MG CAP | FLUVOXAMINE MALEATE | Deny dosing more frequently than 2 per day |
| LUVOX CR 150 MG CAP | FLUVOXAMINE MALEATE | Deny dosing more frequently than 2 per day |
| PAXIL 10 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 1 per day |
| PAXIL 10 MG/5 ML SUSP | PAROXETINE HCL | Deny dosing more frequently than 30 ml per day |
| PAXIL 20 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 2 per day |
| PAXIL 30 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 2 per day |
| PAXIL 40 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 1.5 per day |
| PAXIL CR 12.5 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 1 per day |
| PAXIL CR 25 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 2 per day |
| PAXIL CR 37.5 MG TAB | PAROXETINE HCL | Deny dosing more frequently than 2 per day |
| PEXEVA 10 MG TAB | PAROXETINE MESYLATE | Deny dosing more frequently than 1 per day |
| PEXEVA 20 MG TAB | PAROXETINE MESYLATE | Deny dosing more frequently than 1 per day |
| PEXEVA 30 MG TAB | PAROXETINE MESYLATE | Deny dosing more frequently than 2 per day |
| PEXEVA 40 MG TAB | PAROXETINE MESYLATE | Deny dosing more frequently than 1 per day |
| PROZAC WEEKLY 90 MG | FLUOXETINE HCL | Deny dosing more frequently than 1 per week |
| ZOLOFT 20 MG/ML CONC | SERTRALINE HCL | Deny dosing more frequently than 10 ml per day |
| ZOLOFT 25 MG TAB | SERTRALINE HCL | Deny dosing more frequently than 3 per day |
| ZOLOFT 50 MG TAB | SERTRALINE HCL | Deny dosing more frequently than 3 per day |
| ZOLOFT 100 MG TAB | SERTRALINE HCL | Deny dosing more frequently than 2 per day |

References

- Facts & Comparisons. Selective Serotonin Reuptake Inhibitors. Accessed August 31, 2023.