

Louisiana Medicaid
Antipsychotic Oral/Transdermal Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Behavioral Health clinical authorization for *all* preferred and non-preferred agents *for recipients younger than 7 years of age*; **OR**
- Prior authorization for non-preferred agents for recipients 7 years of age and older; **OR**
- Clinical authorization for pimavanserin (Nuplazid®); **OR**
- Authorization to override the maximum daily dose/quantity limit for all ages

Additional Point-of-Sale edits may apply.

*These Some agents may have **Black Box Warnings**, and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for ALL Agents (Preferred and Non-Preferred) for Recipients Under 7 Years of Age

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; AND
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
 - ~~There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; AND~~
 - The recipient has had *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the medication with positive clinical outcomes; **AND**
- The requested medication has been prescribed for an approved diagnosis (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the fact that a systematic evaluation and assessment have been performed which includes but is not limited to, the following:
 - Detailed history of symptoms (including symptoms from non-custodial caregivers); **AND**
 - Medical, substance use, developmental, and social factors that may influence clinical presentation have been addressed; **AND**
 - Documentation of in-office observations (including appointment dates) which support recorded behavior / symptoms; **AND**
 - Documentation of impairing, extreme symptoms of aggression towards self and/or others; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS),

- contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed (as of the date of the request) at baseline, every six months, and with dosage changes, and will be repeated as recommended in the prescribing information; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that the recipient is established on the medication with evidence of a positive response to therapy.
- The prescriber states on the request that there is evidence of a positive response to therapy.

*****Duration of Initial and Reauthorization Approval: 12 months or up to the recipients 7th birthday, whichever is less.*****

Approval Criteria for Non-Preferred Agents for Recipients 7 years of Age and Older:

- For asenapine sublingual tablet (generic for Saphris®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Saphris®; OR
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The recipient is established on the medication with positive clinical outcomes; **AND**
- The requested medication has been prescribed for an approved diagnosis (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed (as of the date of the request) at baseline, every six months, and with dosage changes, and will be repeated as recommended in the prescribing information; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that the recipient is established on the medication with evidence of a positive response to therapy.

The prescriber states on the request that there is evidence of a positive response to therapy.

Duration of initial and reauthorization approval for Abilify MyCite®: 3 months

Duration of initial and reauthorization approval for all other non-preferred antipsychotic agents: 12 months

Pimavanserin (Nuplazid®)

Approval Criteria

- The recipient is 18 years of age or older on date of request; **AND**
- The recipient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis (Nuplazid® is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis); **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - There has been a treatment failure or intolerable side effect with or contraindication to a preferred product; **OR**
 - There is no preferred product appropriate to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The recipient has been assessed for risk factors for prolonged QT interval; **AND**
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**
 - The prescriber is aware that this medication should be used with caution in severe renal impairment (CrCl less than 30ml/minute) and end stage renal disease.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Approval Criteria for All Ages to Override Maximum Daily Dose and/or Quantity Limits⁺

- The requested medication has been prescribed for an approved diagnosis (see POS Edits); **AND**
- **ONE** of the following conditions apply:
 - The recipient has been treated in the past or is currently receiving treatment with the requested dosage and quantity of the requested medication with a lack of objective adverse effects (such as weight) and subjective adverse effects (by patient report); **OR**
 - The recipient had a partial but inadequate response to the requested medication at a lower dosage/quantity available under the plan **AND ALL** of the following:
 - Medication non-adherence was ruled out as a reason for the inadequate response; **AND**
 - The recipient tolerated the medication at the lower dosage; **AND**
 - There was a lack of objective adverse effects (such as weight) and subjective adverse effects (by patient report); **AND**
 - The requested dose is considered medically necessary; **OR**
 - The recipient has not previously used this medication; however, the prescriber is submitting evidence supporting quantity limit exception with this request (for example, a peer-reviewed journal article demonstrating the safety and efficacy of the requested dose for the indication); **AND ALL** of the following:
 - The requested quantity and dosing are supported in the accepted medical compendia; **AND**
 - The requested dose is considered medically necessary.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- **The prescriber states on the request that the recipient is established on the medication with evidence of a positive response to therapy.**
- **The prescriber states on the request that there is evidence of a positive response to therapy.**

Duration of ~~i~~Initial and ~~r~~Reauthorization ~~a~~Approval: 12 months

References

~~Abilify MyCite (aripiprazole) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2017.~~

~~Adasuve (loxapine) [package insert]. Souderton, PA: Galen US Inc; August 2017.~~

~~Amitriptyline/perphenazine [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2016.~~

~~Aristada (aripiprazole) [package insert]. Waltham, MA: Alkermes, Inc; August 2019. Aristada Initio (aripiprazole) [package insert]. Waltham, MA: Alkermes, Inc; August 2019. Caplyta (lumateperone) [package insert]. New York, NY: Intra Cellular Therapies, Inc; December 2019.~~

~~Chlorpromazine [package insert]. Rockford, IL: Upsher Smith Laboratories, Inc; January 2019.~~

~~Clozaril (clozapine) [package insert]. Rosemont, PA: Novartis Pharmaceuticals Corporation; February 2017.~~

~~Fanapt (iloperidone) [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; February 2017.~~

~~FazaClo (clozapine) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals; February 2017.~~

~~Fluphenazine Elixir/Solution [package insert]. Greenville, SC: Pharmaceutical Associates, Inc.; December 2017.~~

~~Fluphenazine Decanoate [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; November 2016.~~

~~Fluphenazine Tablet [package insert]. Philadelphia, PA: Lannett Company, Inc; August 2017.~~

~~Geodon (ziprasidone) [package insert]. New York, NY: Roerig; November 2018.~~

~~Haldol (haloperidol) injection [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2019.~~

~~Haloperidol tablet [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2016.~~

~~Haloperidol lactate oral concentrate [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2017.~~

~~Haldol (haloperidol) decanoate injection [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2019.~~

~~Invega (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.~~

~~Invega Sustenna (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.~~

~~Invega Trinza (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.~~

~~Latuda (lurasidone) Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2018.~~

Vanlyra (cariprazine) [package insert]. Irvine, CA: Allergan; May 2019.

Loxapine capsules [package insert]. Parsippany, NJ: Actavis Pharma, Inc; December 2016.

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Nuplazid (pimavanserin) [package insert]. San Diego, CA: Acadia Pharmaceuticals Inc; November 2020May 2019. https://www.nuplazidhep.com/pdf/NUPLAZID_Prescribing_Information.pdf

Orap (pimozide) [package insert]. Horsham, PA; Teva Select Brands; April 2018. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=90c0086a-b62c-4cdd-a6af-2efed69cf4d&type=display>
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Risperdal Consta (risperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.

Rexulti (brexpiprazole) [package insert]. Deerfield, IL: Otsuka Pharmaceutical Co., Ltd; February 2018.

Saphris (asenapine) [package insert]. Irvine, CA: Allergan; February 2017.

Secuado (asenapine) [package insert]. Miami, FL: Noven Therapeutics, LLC; October 2019.

Seroquel XR (quetiapine) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2019.

~~Thioridazine [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2016.~~

~~Thiothixene [package insert]. East Windsor, NJ: Novitium Pharma LLC; April 2019.~~

~~Trifluoperazine [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; August 2019.~~

~~VersaLoz (clozapine) [package insert]. Tampa, FL: Tasman Pharma; January 2018.~~

~~Vyvlar (cariprazine) [package insert]. Irvine, CA: Allergan; May 2019.~~

~~Zyprexa Relprevv (olanzapine) [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2018.~~

~~Zyprexa (olanzapine) [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2018.~~

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<u>Revision / Date</u>	<u>Date</u> <u>Implementation Date</u>
Single PDL Implementation	May 2019
Added POS wording, added Abilify MyCite to diagnosis and maximum daily dose charts, updated quantity limit chart <u>/ June 2019</u>	<u>June 2019</u> <u>November 2019</u>
Removed medication tables, modified remaining table numbers and references to tables, removed POS wording, added override wording under maximum daily dose chart, added peer-reviewed literature reference <u>/ November 2019</u> :-	<u>November 2019</u> <u>January 2020</u>
Removed Fee-for-Service, modified format, removed footer, added revision table, combined antipsychotics criteria and pimavanserin criteria into one document <u>/ January 2020</u>	<u>January 2020</u> <u>January 2020</u>
Removed POS edits, added Secuado® reference, formatting changes <u>/ July 2020</u>	<u>July 2020</u> <u>July 2020</u>
Added Caplyta™ reference <u>/ July 2020</u>	<u>July 2020</u> <u>July 2020</u>

Modified to apply new age requirement <u>/ September 2020</u>	<u>September 2020</u> <u>January 2021</u>
<u>Modified duration of authorization for Abilify MyCite®, formatting changes, updated references / June 2021</u>	<u>January 2022</u>
<u>Added specific wording for use of Saphris® / October 2021</u>	<u>January 2022</u>