

Louisiana Medicaid Antipsychotics

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

- Clinical authorization for pimavanserin (Nuplazid®); **OR**
- Behavioral Health clinical authorization for *all* preferred and non-preferred agents *for recipients younger than 76 years of age*; **OR**
- Prior authorization for non-preferred agents for recipients 76 years of age and older; **OR**
- Authorization to override the maximum daily dose/quantity limit for all ages

Additional Point-of-Sale edits may apply.

*Some agents 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.*

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**
 - 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 there is evidence of a positive response to therapy.

*****Duration of Initial and Reauthorization Approval: 12 months*****

Approval Criteria for ALL Agents (Preferred and Non-Preferred) for Recipients Under 76 Years of Age

- 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.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- 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 **7th6th** birthday, whichever is less.

Approval Criteria for Non-Preferred Agents for Recipients **76** years of Age and Older:

- The requested medication has been prescribed for an approved diagnosis (see POS Edits); **AND**
- 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**
- 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.

Reauthorization Criteria

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

*****Duration of Initial and Reauthorization Approval: 12 months*****

References

Abilify (aripiprazole) [package insert]. Rockville, MD: Otsuka Pharmaceutical Co., Ltd and Bristol-Myers Squibb Company; August 2019. https://www.otsuka-us.com/media/static/Abilify-PI.pdf?_ga=2.250692870.1489347898.1567693061-1492983432.1567693061

Abilify Maintena (aripiprazole) [package insert]. Rockville, MD: Otsuka Pharmaceutical Co., Ltd; February 2019. https://www.otsuka-us.com/media/static/Abilify-M-PI.pdf?_ga=2.146596848.532770352.1533929386-492455817.1533929386

Abilify MyCite (aripiprazole) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2017. https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.88803995.1605522370.1559672786-1890746611.1559672786

Adasuve (loxapine) [package insert]. Souderton, PA: Galen US Inc; August 2017. <https://www.adasuve.com/PDF/AdasuvePI.pdf>

Amitriptyline/perphenazine [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2016. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e2937445-c015-c9a5-52f8-a2959da97290&type=display>

Aristada (aripiprazole) [package insert]. Waltham, MA: Alkermes, Inc; August 2019. <https://www.aristadahcp.com/downloadables/ARISTADA-PI.pdf>

Aristada Initio (aripiprazole) [package insert]. Waltham, MA: Alkermes, Inc; August 2019. <https://www.aristadahcp.com/downloadables/ARISTADA-INITIO-PI.pdf>

Caplyta (lumateperone) [package insert]. New York, NY: Intra-Cellular Therapies, Inc; December 2019. https://www.intracellulartherapies.com/docs/caplyta_pi.pdf

Chlorpromazine [package insert]. Rockford, IL: Upsher-Smith Laboratories, Inc; January 2019. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=112393f8-b374-4ee0-8fcc-f229fadbe637&type=display>

Clozaril (clozapine) [package insert]. Rosemont, PA: Novartis Pharmaceuticals Corporation; February 2017. http://clozaril.com/wp-content/themes/eyesite/pi/Clozaril_PI.pdf

Fanapt (iloperidone) [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc; February 2017. <http://www.fanaptpro.com/wp-content/uploads/2016/02/Fanapt-Prescribing-Information.pdf>

FazaClo (clozapine) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals; February 2017. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=B7B7541A-1FE4-4B11-B6B7-68FB5510FAA4&type=display>

Fluphenazine Elixir/Solution [package insert]. Greenville, SC: Pharmaceutical Associates, Inc.; December 2017. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=0860b3f3-3116-40f8-bcb0-e5c47731bdc8&type=display>

Fluphenazine Decanoate [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; November 2016. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f8ba014e-aea0-49bc-8345-4e0a384b484e&type=display>

Fluphenazine Tablet [package insert]. Philadelphia, PA: Lannett Company, Inc; August 2017.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6cd6ba35-3481-48c1-87db-dc74ce9d7d75&type=display>

Geodon (ziprasidone) [package insert]. New York, NY: Roerig; November 2018.
<http://labeling.pfizer.com/ShowLabeling.aspx?id=584>

Haldol (haloperidol) injection [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2019.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=27cfe684-7d11-4f37-9c8b-b2bdd6b5348e&type=display>

Haloperidol tablet [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2016.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c559b0b0-4087-d12a-e718-c18ccb6811e6&type=display>

Haloperidol lactate oral concentrate [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2017. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2d848e8c-de42-4a09-96f1-a2d250af059d&type=display>

Haldol (haloperidol) decanoate injection [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2019. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/HALDOL+Decanoate-pi.pdf>

Invega (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.
<https://www.invega.com/prescribing-information.html>

Invega Sustenna (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.
<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+SUSTENNA-pi.pdf>

Invega Trinza (paliperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.
<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+TRINZA-pi.pdf>

Latuda (lurasidone) Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2018.
<https://www.latuda.com/LatudaPrescribingInformation.pdf>

Vraylar (cariprazine) [package insert]. Irvine, CA: Allergan; May 2019.
https://www.allergan.com/assets/pdf/vraylar_pi?guid=sem_goo_43700033903155483

Loxapine capsules [package insert]. Parsippany, NJ: Actavis Pharma, Inc; December 2016.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a6107bb1-3e23-4c5d-bbf4-5e29deff6728&type=display>

Moban (molindone. [package insert]. Chadds Ford, PA: Endo Pharmaceuticals; June 2009. (Discontinued 2017)
https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017111s066lbl.pdf

Nuplazid (pimavanserin) [package insert]. San Diego, CA: Acadia Pharmaceuticals Inc; May 2019.
https://www.nuplazidhcp.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-2efed69cfd4d&type=display>

Perphenazine tablet [package insert]. Atlanta, GA: Wilshire Pharmaceuticals, Inc; February 2018.

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5e455842-4892-4795-8c9b-4109a8f30783&type=display>

Perseris (risperidone) [package insert]. North Chesterfield, VA: Indivior Inc; July 2018.

<https://www.perserishcp.com/prescribing-information.pdf>

Risperdal (risperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.

https://www.janssenmd.com/pdf/risperdal/risperdal_pi.pdf

Risperdal Consta (risperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2019.

<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RISPERDAL+CONSTA-pi.pdf>

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

<https://www.otsuka-us.com/media/static/Rexulti-PI.pdf>

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

http://www.allergan.com/assets/pdf/saphris_pi

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

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=685eaf44-5944-4f38-afba0a4fc0b3462b&type=display>

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

<http://www.azpicentral.com/seroquel/seroquel.pdf>

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

<https://www.azpicentral.com/seroquel-xr/seroquelxr.pdf>

Symbyax (olanzapine/fluoxetine) [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2018.

<http://pi.lilly.com/us/symbyax-pi.pdf>

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

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=56b3f4c2-52af-4947-b225-6808ae9f26f5&type=display>

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

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b067b400-66cd-422d-a631-9ce0c935d2b2&type=display>

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

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c2575a86-19e5-44df-8603-ff066bb9c9c5&type=display>

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

<http://www.versacloz.com/docs/VERSACLOZ-Full-Prescribing-Information.pdf>

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

https://www.allergan.com/assets/pdf/vraylar_pi?guid=sem_goo_43700033903155483

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

http://pi.lilly.com/us/zyprexa_reprevv.pdf

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

<https://pi.lilly.com/us/zyprexa-pi.pdf>

CJ, P. (2019). *Atypical antipsychotics in the treatment of children and adolescents with pervasive developmental disorders*. - PubMed - NCBI. [online] Ncbi.nlm.nih.gov. Available at:

<https://www.ncbi.nlm.nih.gov/pubmed/23552907> [Accessed 18 Oct. 2019].

Gleason, M., Egger, H., Emslie, G., Greenhill, L., Kowatch, R., Lieberman, A., Luby, J., Owens, J., Scahill, L., Scheeringa, M., Stafford, B., Wise, B. and Zeanah, C. (2007). Psychopharmacological Treatment for Very Young Children: Contexts and Guidelines. *Journal of the American Academy of Child & Adolescent Psychiatry*, 46(12), pp.1532-1572.

Revision	Date
Single PDL Implementation	May 2019
Added POS wording, added Abilify MyCite to diagnosis and maximum daily dose charts, updated quantity limit chart	June 2019
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.	November 2019
Removed Fee-for-Service, modified format, removed footer, added revision table, combined antipsychotics criteria and pimavanserin criteria into one document	January 2020
Removed POS edits, added Secuado® reference, formatting changes	July 2020
Added Caplyta™ reference	July 2020
<u>Modified to apply new age requirement for behavioral health clinical authorization</u>	<u>September 2020</u>