**Louisiana Medicaid**
**Stimulants and Related Agents**

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

- Clinical authorization for **all** preferred and non-preferred agents for recipients younger than ~~6~~ 7 years of age; **OR**
- Prior authorization for non-preferred agents for recipients ~~6~~ 7 years of age and older.

Additional Point-of-Sale edits may apply.

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

---

**Approval Criteria for ALL Stimulants and Related Agents (both preferred and non-preferred) for Children under ~~6~~ 7 years of Age [except armodafinil (Nuvigil®), modafinil (Provigil®) or pitolisant (Wakix®)]:**

- For Dexmethylphenidate ER Capsules (generic for Focalin XR®) - there has been a treatment failure or intolerable side effect with or contraindication to brand Focalin XR®; **AND**
- For Dextroamphetamine Solution (generic for ProCentra®) - there has been treatment failure or intolerable side effect with or contraindication to brand ProCentra®; **AND**
- For all non-preferred agents, the following conditions apply:
  - There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
  - The child has had treatment failure with at least one preferred product; **OR**
  - The child has had an intolerable side effect to at least one preferred product; **OR**
  - The child has documented contraindication(s) to the preferred products that are appropriate for the condition being treated; **OR**
  - There is no preferred product appropriate to use for the condition being treated; **AND**
- The child has a diagnosis approved for the medication requested (see POS Edits); **AND**
- **ONE**~~nc~~ of the following (due to this diagnosis) is true and is **stated on the request**:
  - Child has had a trial of behavioral therapy and has ongoing impairing and/or dangerous symptoms; **OR**
  - Child has started behavioral therapy but has extremely impairing and/or potentially dangerous symptoms; **OR**
  - Child has been referred to behavioral treatment but has extremely impairing and/or potentially dangerous symptoms that warrant treatment before therapy has had a chance to have an effect (with plan to follow up); **OR**
  - There are no known behavioral therapy resources available to this child, who has extremely impairing and/or potentially dangerous symptoms; **OR**
  - **ALL** of the following:
    - The child is 6 years of age; **AND**
    - The diagnosis for the requested medication is Attention Deficit Hyperactivity Disorder (ADHD); **AND**

        - By submitting this request, the provider attests that behavioral treatment has been prescribed in addition to the requested medication; **AND**~~AND~~
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **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 receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling;

**OR**

- For Dexmethylphenidate ER Capsules (generic for Focalin XR®) - there has been treatment failure or intolerable side effect with or contraindication to brand Focalin XR®; **AND**
- For Dextroamphetamine Solution (generic for ProCentra®) - there has been treatment failure or intolerable side effect with or contraindication to brand ProCentra®; **AND**
- The child has a diagnosis approved for the medication requested (see POS Edits); **AND**
- The prescriber states that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **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 receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling.

---

**Approval Criteria for Non-Preferred Stimulants and Related Agents [except armodafinil (Nuvigil®), modafinil (Provigil®) or pitolisant (Wakix®)] for Recipients 7 years of Age and Older:**

- For Dexmethylphenidate ER Capsules (generic for Focalin XR®) - there has been treatment failure or intolerable side effect with or contraindication to brand Focalin XR®; **AND**
- For Dextroamphetamine Solution (generic for ProCentra®) - there has been treatment failure or intolerable side effect with or contraindication to brand ProCentra®; **AND**
- For all non-preferred agents, the following conditions apply:

    - 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 the preferred products that are appropriate for the condition being treated; **OR**
    - There is no preferred product appropriate to use for the condition being treated; **OR**
    - The prescriber states that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- The recipient has a diagnosis approved for the medication requested (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **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 receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling.

**Renewal Criteria for both Preferred and Non-Preferred Stimulants and Related Agents for All Ages [except armodafinil (Nuvigil®), modafinil (Provigil®) or pitolisant (Wakix®)]**

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

**Duration of Authorization Approval for all Stimulants and Related Agents for All Ages [except armodafinil (Nuvigil®), modafinil (Provigil®) or pitolisant (Wakix®)]**

- **Initial Approval: 12 months**
- **Reauthorization Approval: 12 months**

---

**Approval Criteria for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®) and Pitolisant (Wakix®)**

- On the date of the request, the recipient age is:
    - 17 years of age or older for armodafinil or modafinil; **OR**
    - 18 years of age or older for pitolisant; **AND**
- The following conditions apply:
    - 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 the preferred products that are appropriate for the condition being treated; **OR**
    - There is no preferred product appropriate to use for the condition being treated; **OR**
    - The prescriber states that the recipient is established on the requested medication with positive clinical outcomes; **AND**
- The recipient has a diagnosis approved for the medication requested (see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; **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 inappropriate concomitant drug therapies or disease states.

**Renewal Criteria for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®) and Pitolisant (Wakix®)**

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

**Duration of Authorization Approval for Non-Preferred Armodafinil (Nuvigil®), Modafinil (Provigil®) and Pitolisant (Wakix®)**

- **Initial Approval: 3 months**
- **Reauthorization Approval: 3 months**

**References**


Adderall (amphetamine/dextroamphetamine) [package insert]. Horsham, PA: Teva Select Brands, Division of Teva Pharmaceuticals USA, Inc; ~~December 2016~~January 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/011522s043lbl.pdf

Adderall XR (amphetamine/dextroamphetamine) [package insert]. Lexington, MA: Shire US Inc.; July 2019. http://pi.shirecontent.com/PI/PDFs/AdderallXR_USA_ENG.PDF

Adzenys ER (amphetamine) [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; September 2017. http://www.neostxcontent.com/Labeling/AdzenysER/AdzenysER_PI.pdf

Adzenys XR-ODT (amphetamine) [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; December 2017. http://www.neostxcontent.com/Labeling/Adzenys/Adzenys_PI.pdf

Aptensio XR (methylphenidate) [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; June 2019. ~~http://www.aptensioxr.com/resources/full-prescribing-information.pdf~~https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5adedc01-ebf0-11e3-ac10-0800200c9a66&type=display

Concerta (methylphenidate) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2017. https://www.janssenmd.com/pdf/concerta/concerta_pi.pdf

Cotempla XR ODT (methylphenidate) [package insert]. Grand Prairie, TX: Neos Therapeutics Brand, LLC; June 2017. http://www.neostxcontent.com/Labeling/Cotempla/Cotempla_PI.pdf

Daytrana (methylphenidate) [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2019. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2c312c31-3198-4775-91ab-294e0b4b9e7f&type=display

Desoxyn (methamphetamine) [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc; ~~March~~ April 2019. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f03a68d5-ed00-8a2d-af68-28be909ea85f&type=display

Dexedrine (dextroamphetamine) [package insert]. Horsham, PA: Amedra Pharmaceuticals LLC; ~~March 2017~~December 2018. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a37b6ef9-78b4-4b18-8797-ecb583502500&type=display

Dyanavel XR (amphetamine) [package insert]. Monmouth Junction, NJ: Tris Pharma; February 2019. http://dyanavelxr.com/pdfs/pi.pdf

Evekeo (amphetamine) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; September 2016. https://www.evekeo.com/pdfs/evekeo-pi.pdf

Focalin (dexmethylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; ~~January~~ November 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/focalin.pdf

Focalin XR (dexmethylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/focalinXR.pdf

Intuniv (guanfacine) [package insert]. Lexington, MA: Shire US Inc; ~~April~~ December 2019. http://pi.shirecontent.com/PI/PDFs/Intuniv_USA_ENG.pdf

Kapvay (clonidine) [package insert]. Dublin 9, Ireland: Amdipharm Limited; February 2020. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=aa7700e2-ae5d-44c4-a609-76de19c705a7&type=display

Metadate CD (methylphenidate) [package insert]. Smyrna, GA: UCB, Inc; ~~November 2016~~December 2017. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a6aedc40-5725-4bd3-9037-033746e8599e&type=display

Methylphenidate Chewable Tablet [package insert]. Somerset, NJ: Novel Laboratories, Inc; December 2019. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=16508cc6-13c7-4088-927a-b7206eb7c633&type=display

Methylin (methylphenidate) Solution [package insert]. Florham Park, NJ: Shionogi Inc; February 2020. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9e3c22d9-71d9-46a7-b315-8021c94c4bec&type=display

Mydayis (amphetamine) [package insert]. Lexington, MA: Shire US Inc; September 2019. http://pi.shirecontent.com/PI/PDFs/Mydayis_USA_ENG.pdf

Nuvigil (armodafinil) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2018. https://www.nuvigil.com/PDF/Full_Prescribing_Information.pdf

ProCentra (dextroamphetamine) [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; February 2017. http://independencepharma.com/wp-content/uploads/2017/07/ProCentra-PI-MedGuide-revised-feb2017.pdf

Provigil (modafinil) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2018. http://www.provigil.com/PDFs/prescribing_info.pdf

Quillivant XR (methylphenidate) [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; June 2017. http://labeling.pfizer.com/ShowLabeling.aspx?id=965

QuilliChew ER (methylphenidate) [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; March 2018. http://labeling.pfizer.com/ShowLabeling.aspx?id=2577

Ritalin & Ritalin SR (methylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November~~January~~ 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_ritalin-sr.pdf

Ritalin LA (methylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019.
https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_la.pdf

Strattera (atomoxetine) [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2020.
https://pi.lilly.com/us/strattera-pi.pdf

Wakix (pitolisant) [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; November 2019.
https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8daa5562-824e-476c-9652-26ceef3d4b0e&type=display

Vyvanse (lisdexamfetamine) [package insert]. Lexington, MA: Shire US Inc; January 2018.
http://pi.shirecontent.com/PI/PDFs/Vyvanse_USA_ENG.pdf

Zenzedi (dextroamphetamine sulfate) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; February 2017. http://zenzedi.com/docs/PIandMedicationGuide.pdf

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 Implemented | May 2019 |
| Added specific wording for use of Focalin XR® and ProCentra® | November 2019 |
| Removed POS information, added Wakix®, formatting changes, updated references | July 2020 |
| Modified to apply new age requirement for behavioral health clinical authorization, updated references | September 2020 |