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 years of age; **OR**
- ~~prior~~ Prior authorization for non-preferred agents for recipients 6 years of age and older. ~~**AND** to request clinical authorization for **all** preferred and non-preferred agents for recipients younger than 6 years of age.~~

Additional Point-of-Sale edits may apply.

~~*Stimulants and Strattera®~~ *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.* ~~*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 years of Age [except ~~modafinil (Provigil®) or**~~ 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~~ see ~~Table~~POS Edits); **AND**
- One 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; **AND**

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- 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~~See Table~~); **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®)~~except modafinil (Provigil®) or armodafinil (Nuvigil®)~~] for Recipients 6 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**

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- 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~~See Table~~); **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®)~~except modafinil (Provigil®) or armodafinil (Nuvigil®)~~]

- 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®)~~except modafinil (Provigil®) or armodafinil (Nuvigil®)~~]

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

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

- On the date of the request, the recipient age is:
  - ~~The recipient is~~ 17 years of age or older for armodafinil or modafinil ~~[additional edits apply; refer to http://www.lamedicaid.com/provweb1/Pharmacy/Provider_notice_Provigil-Nuvigil_11-20-14.pdf for more information.]~~; **OR**
  - 18 years of age or older for pitolisant; **AND**
- The following conditions apply:

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- 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~~See Table~~); **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®)~~Modafinil (Provigil®) and Armodafinil (Nuvigil®) Agents~~

- 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®)~~Modafinil (Provigil®) and Armodafinil (Nuvigil®) Agents~~

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

Acceptable ICD-10-CM Diagnosis Codes for Stimulants and Related Agents

Generic (Brand Example)	ADHD	Narcolepsy	Tics and Tourette's Disorder	Cancer-Related Fatigue	Circadian Rhythm Sleep Disorder, Shift Work Type; Obstructive Sleep Apnea	Hypertension or Hypertension in Congenital Heart Disease
	F90.*	G47.4*	F95.*, G25.6*	R53.0	G47.26; G47.33	I10, I11.*, I12.*, I13.*, I15.*, Q20.*-Q28.*
Amphetamine ER (Adzenys ER®, Adzenys XR-ODT®, Dyanavel® XR)	X					
Amphetamine IR (Evekeo®)	X	X				
Amphetamine Salt Combo IR/ER (Adderall®, Adderall XR®, Mydayis®)	X	X				
Armodafinil (Nuvigil®)		X			X	
Atomoxetine (Strattera®)	X					
Clonidine ER (Kapvay™)	X		X			
Clonidine IR (Catapres®); Clonidine Patch (Catapres-TTS®)†	X		X			X
Dexmethylphenidate IR/ER (Focalin®, Focalin XR®)	X			X		
Dextroamphetamine IR/ER (Dexedrine®, ProCentra®, Zenzedi®)	X	X				
Guanfacine ER (Intuniv®)	X		X			
Guanfacine IR† (Tenex®)	X		X			X
Lisdexamfetamine (Vyvanse®)	X					
Methamphetamine (Desoxyn®)	X					
Methylphenidate IR/ER/Patch (Ritalin®, Methylin™ Solution / Aptensio XR™, Concerta®, Metadate® ER, QuilliChew ER™, Quillivant XR®, Ritalin LA®, Cotempla XR-ODT™ / Daytrana®)	X	X		X		
Modafinil (Provigil®)		X			X	

*Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

†Clonidine IR, Clonidine Transdermal Patch and Guanfacine IR are not listed in the 'Stimulant and Related Agents' therapeutic class but can be used to treat not only hypertension or hypertension in congenital heart disease, but also ADHD and tics or Tourette's disorder. In order to identify use of these agents for a behavioral health diagnosis in children, a diagnosis code is required on pharmacy claims for Clonidine IR, Clonidine Transdermal Patch and Guanfacine IR for recipients younger than 21 years old. A diagnosis of Hypertension or Hypertension in Congenital Heart Disease on the pharmacy claim will bypass the authorization requirement for children younger than 6 years old.

References

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

1.

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

2.

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

3.

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

4.

Aptensio XR (methylphenidate) [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; January 2017. http://www.aptensioxr.com/resources/full-prescribing-information.pdf

5.

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

6.

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

7.

Daytrana (methylphenidate) [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; November 2017. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2c312c31-3198-4775-91ab-294e0b4b9e7f&type=display

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

~~9.~~

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

~~10.~~

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

~~11.~~

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

~~12.~~

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

~~13.~~

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

~~14.~~

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

~~15.~~

Kapvay (clonidine) [package insert]. Dublin 9, Ireland: Amdipharm Limited; September 2019. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=aa7700e2-ae5d-44c4-a609-76de19c705a7&type=display

~~16.~~

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

~~17.~~

Methylphenidate Chewable Tablet [package insert]. Somerset, NJ: Novel Laboratories, Inc; November 2015. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=16508cc6-13c7-4088-927a-b7206eb7c633&type=display

~~18.~~

Methylin (methylphenidate) Solution [package insert]. Florham Park, NJ: Shionogi Inc; August 2017. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9e3c22d9-71d9-46a7-b315-8021c94c4bec&type=display

~~19.~~

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

~~20.~~

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

~~21.~~

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

~~22.~~ Provigil (modafinil) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2018. http://www.provigil.com/PDFs/prescribing_info.pdf

~~23.~~ Quillivant XR (methylphenidate) [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; June 2017. http://labeling.pfizer.com/ShowLabeling.aspx?id=965

~~24.~~ QuilliChew ER (methylphenidate) [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; March 2018. http://labeling.pfizer.com/ShowLabeling.aspx?id=2577

~~25.~~ Ritalin & Ritalin SR (methylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_ritalin-sr.pdf

~~26.~~ Ritalin LA (methylphenidate) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_la.pdf

~~27.~~ Strattera (atomoxetine) [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2017. https://pi.lilly.com/us/strattera-pi.pdf

~~28.~~ 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

~~29.~~ Zenzedi (dextroamphetamine sulfate) [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; January 2017. http://zenzedi.com/docs/PIandMedicationGuide.pdf

~~30.~~

~~31.~~ 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®	July 2020

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